

Industrial Implementation of a Material–Process–Workflow Framework in Dental and Hearing-Device Photopolymer Additive Manufacturing

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Paper	Function	Main contribution
I	Framework	Material–Process–Workflow architecture for dental photopolymer biocompatibility
II	Industrial implementation	Production-scale case studies in hearing-device and dental photopolymer manufacturing
III	Audit methodology	Wavelength-matched post-cure audit for the post-TPO chemistry transition

Companion paper note

This article is the second paper in a three-part perspective trilogy on engineering-led photopolymer additive manufacturing biocompatibility. Paper I is “Biocompatibility in Dental Photopolymer Additive Manufacturing: A Material–Process–Workflow Perspective” (DOI 10.5281/zenodo.21969973). Paper III is “Wavelength-Matched Process Control as a Prerequisite for the Post-TPO Photopolymer Transition” (DOI 10.5281/zenodo.21973554).

Abstract

The Material–Process–Workflow framework developed in the first paper of this trilogy proposes that device-level biological performance in photopolymer additive manufacturing is determined by the coupled interaction of material chemistry, cure kinetics and post-processing workflow rather than by chemistry alone. The remaining engineering question is whether such a framework operates reproducibly under industrial production conditions.

This second perspective applies the framework to two production-scale implementation cases. The first case is the H3D custom hearing-device manufacturing pipeline, which integrates iPhone TrueDepth scanning, statistical 3D modelling, direct photopolymer additive manufacturing, validated post-processing and release under documented acceptance criteria within an ISO 13485 quality-management system. The workflow has been implemented at commercial production scale according to the cited company documentation. Independent process-window characterisation conducted at the Technical University of Denmark supports the cure-kinetics component of the implementation.

The second case applies the framework to a commercial monomer-free dental photopolymer architecture spanning continuous-contact (direct-printed aligners), intermittent-contact (denture bases and occlusal splints) and semi-permanent (interim crown and bridge) applications. Across both cases the framework supports sustained operational implementation at industrial scale, with the cure-kinetics and post-processing workflow components documented through manufacturer technical data and independent peer-reviewed process characterisation where available.

The cases are presented as industrial-academic implementation perspectives rather than as controlled clinical validation studies. Cross-vendor extractables benchmarking and longer-term clinical outcome studies remain necessary to establish generalised biological performance claims.

Keywords: dental photopolymer manufacturing · hearing aid 3D printing · industrial implementation · case study perspective · ISO 13485 · direct-printed aligners · denture bases · monomer-free photopolymer · production scale · H3D

Scope and methodology. *This article is an industrial-academic perspective that applies a framework developed conceptually elsewhere (Paper I of this trilogy) to two implementation cases. The framework is summarised in §2 with*

reference to the first paper. The hearing-device case (§3) and the dental case (§4) draw on production data and manufacturer documentation from 3Dresyns by Resyner Technologies S.L. (the author's affiliation) and H3D (Australia, an industrial customer operating the manufacturer's photopolymer systems at production scale); the relationship is supplier–customer and is disclosed in full in the Disclosure note. The H3D production-scale process characterisation drawn upon in §3.3 was conducted independently at the Technical University of Denmark (DTU) and published peer-reviewed. The dental portfolio characterisation draws on the manufacturer's product technical data sheets (M-data) supplemented by peer-reviewed independent evidence where available; internal production-environment characterisation (I-data) is identified explicitly. The two cases are presented as industrial implementation perspective and not as controlled clinical validation studies; this scope

limitation is restated in §7.

1. Introduction

1.1 Motivation and framing

The first paper of this trilogy [P1] develops a Material–Process–Workflow framework in which the biocompatibility of a dental photopolymer device is the integrated outcome of three engineering variables: material chemistry, cure kinetics governed by the Jacobs working curve, and the post-processing workflow (drain, clean, dry, post-cure). The framework is conceptually motivated by the 2023 European Union regulatory transition away from the photoinitiator TPO and by the published evidence on cure-kinetics × cytotoxicity coupling [P2,P3,P4]; it is methodologically related to Quality-by-Design frameworks established under ICH Q8/Q9/Q10 in pharmaceutical and medical device manufacturing.

The engineering question that follows is whether the framework operates at industrial production scale — not as a theoretical claim about how dental photopolymer devices ought to be made, but as a documented operational practice in production environments. This second perspective addresses the question through two implementation cases. The H3D custom hearing-device pipeline (§3) operates the framework end-to-end from patient scan through device release at production scale. The application of the framework to a commercial monomer-free Bio dental photopolymer portfolio (§4) extends the implementation across three biological contact regimes within the dental segment.

1.2 Scope of the present article

The two cases are industrial-academic perspective and not controlled clinical validation studies. Production volume and continuity document sustained operational implementation of the framework; they do not, on their own, constitute quantitative biocompatibility characterisation. Cross-vendor extractables benchmarking and longer-term clinical outcome data remain the necessary research directions for the field (§7); this scope limitation is restated throughout.

2. The Material × Process × Workflow framework — summary

The framework presented in detail in the first paper of this trilogy [P1] is summarised here to make the present article self-contained. The framework organises the three engineering variables that jointly determine device-level biocompatibility outcomes into a three-layer architecture — material chemistry, cure kinetics, and post-processing workflow validation — sketched in Figure 1 of the first paper and shared as the conceptual reference across the trilogy:

Material chemistry covers photoinitiator selection, monomer architecture and additive selection. In the post-TPO segment, monomer-free formulations (free of intentionally added low-molecular-weight reactive diluent monomers such as TEGDMA, HEMA or Bis-GMA) represent the chemistry-side mitigation of the residual extractables liability historically associated with conventional dental dimethacrylate systems. The monomer-free classification used throughout this trilogy refers to formulation architecture — the absence of intentionally added low-molecular-weight reactive diluent monomers — and does not, on its own, imply biological superiority over conventional dimethacrylate systems; biological performance requires independent characterisation under ISO 10993 for each specific chemistry-process-workflow combination.

Cure kinetics are governed by the Jacobs working curve $C_d = D_p \cdot \ln(E/E_c)$, determining the residual reactive species fraction at the end of post-cure and therefore the upstream extractables potential of the cured device.

Post-processing workflow is the four-step sequence drain → clean → dry → post-cure, linked by physical-chemistry dependencies that make the sequence order-dependent. A formal validation and release step (organised as a six-tier hierarchy from visual inspection through device-level biocompatibility evaluation) closes the workflow under ISO 13485:2016 quality management system traceability. ISO 13485 defines quality-management-system requirements. It does not itself define biological, mechanical or clinical acceptance criteria for the finished device; those criteria must be established through the applicable product, process, risk-management and regulatory requirements.

The two cases that follow apply this framework to industrial production environments.

3. Case A — H3D custom hearing-device production at scale

3.1 Industrial context

H3D (Perth, Western Australia) operates a custom hearing-device production pipeline that integrates iPhone TrueDepth ear-canal scanning, statistical 3D modelling of the device cavity geometry, direct photopolymer additive manufacturing, validated post-processing and release under documented acceptance criteria within an ISO 13485 quality-management system [M1]. The workflow has been implemented at commercial production scale according to the cited company documentation. The H3D production architecture is documented in the press and industry release record cited at [M1]; the present perspective applies the framework of [P1] to this operational case.

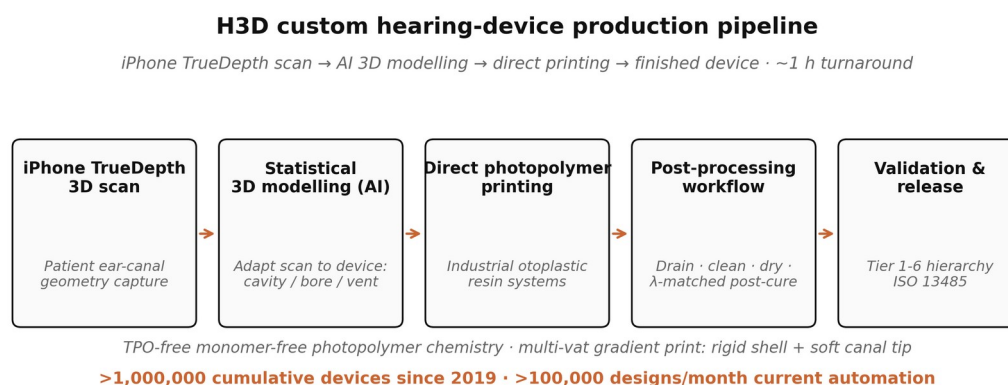


Figure 1. H3D custom hearing-device production pipeline. Five sequential stages from patient ear-canal capture (iPhone TrueDepth) through statistical 3D modelling of the cavity geometry, direct photopolymer printing of the rigid shell and soft canal tip in a multi-vat gradient configuration, post-processing workflow (drain, clean, dry, λ -matched post-cure) and ISO 13485 validation and release. The figure represents the company-documented commercial production workflow; production scale is not evidence of biological or clinical performance.

3.2 Material chemistry — OTO portfolio

The H3D pipeline operates on a portfolio of industrial otoplastic photopolymer resins covering Shore hardness from soft canal-tip elastomer (Shore A50) through rigid shell housing (Shore D90), with intermediate-hardness transition grades. The portfolio supports multi-vat gradient printing in a single operation: rigid shell printed in one vat, soft canal-tip elastomer printed in a contiguous vat with co-cured interface, eliminating the assembly step that conventionally joined rigid and soft components. The chemistry family is monomer-free and TPO-free, formulated for compatibility with 385 nm and 405 nm LED post-cure cabinets that constitute the current industrial installed base. The OTO portfolio is documented in the manufacturer technical data sheets and supplemented by independent peer-reviewed process characterisation discussed in §3.3.

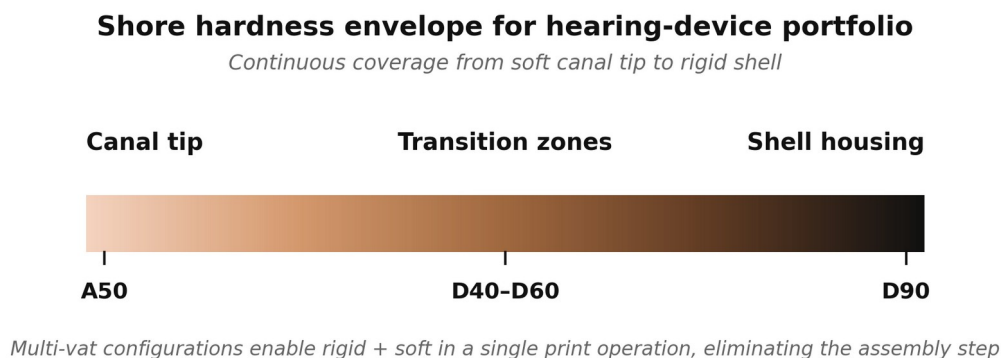


Figure 2. Shore hardness envelope of the industrial otoplastics photopolymer portfolio applied in the H3D pipeline. Continuous coverage from soft canal tip (Shore A50) through transition zones (Shore D40–D60) to rigid shell housing (Shore D90). Multi-vat gradient printing enables single-operation rigid + soft device fabrication, eliminating the assembly step that conventionally joined the two mechanical regimes.

3.3 Cure kinetics and process characterisation — third-party DTU study

Independent peer-reviewed process characterisation of OTO-UHF Bio, one of the resin grades operated in the H3D pipeline, was conducted at the Additive Manufacturing group of the Technical University of Denmark (DTU) and reported at the 2019 Joint Special Interest Group meeting between euspen and ASPE on Advancing Precision in Additive Manufacturing held at École Centrale de Nantes [12]. Danielak et al. (2019) characterise the OTO-UHF Bio formulation explicitly in the source publication as "a special acrylic-based resin for hearing-aids applications from 3Dresyns" with chemistry "a mixture of alkenyl, ethenyl, allyl, vinyl and methacrylate" and reported features of "durability, high hardness, sweat and water resistance and tensile strength above 40 MPa"; the explicit chemistry attribution in the peer-reviewed source allows direct citation here without manufacturer-side claims about formulation specifics.

The DTU study combined FTIR degree-of-cure measurement, weight-stability tracking and dimensional-stability assessment across a two-level full-factorial design of experiments varying layer thickness (1 versus 5 μm) and irradiance (0.91 versus 1.0 mW/cm^2). Stable process windows were identified at the matched parameter combinations — the low-low and high-high configurations in the DoE terminology — with the matched windows delivering release-grade FTIR degree of cure and dimensional stability within specification. The mismatched configurations (low-irradiance high-layer-thickness and high-irradiance low-layer-thickness) under-performed on degree of cure and on dimensional stability. The DTU finding is methodologically relevant to the present case study because the process-window structure observed in the third-party characterisation aligns with the cure-kinetics $\times$ post-processing coupling described by the framework: matched chemistry-process combinations deliver release-grade outcomes, mismatched combinations under-perform on the cure metric that subsequently propagates into extractables and biocompatibility risk. Cross-validation of the DTU finding under H3D production conditions, and characterisation of the wider OTO portfolio under similar DoE protocols, remain open research directions for the case study.

3.4 Post-processing workflow and validation

The H3D post-processing workflow follows the four-step sequence developed in [P1]: drain protocol calibrated to resin viscosity, two-bath cascade cleaning with periodic primary-bath replacement, controlled drying before post-cure entry, and wavelength-matched LED post-cure at 385–405 nm. Validation operates the six-tier hierarchy under ISO 13485:2016 quality management system traceability, with batch-level records linking each finished device to resin batch certificate, cleaning fluid lot, post-cure cabinet calibration record and validation test results.

3.5 Operational outcomes and scope of the evidence

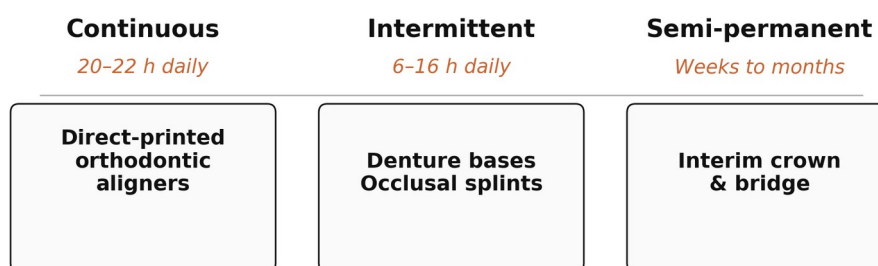
Sustained operational implementation of the framework at industrial scale is documented in the H3D case; the implementation supports continuous production at high volume with batch-level traceability under ISO 13485 quality management. Production volume and absence of public recall events do not, on their own, constitute

quantitative biological performance characterisation; cross-vendor extractables benchmarking against a defined standardised extractables protocol and longer-term clinical outcome data tracking patient retention, ear-canal mucosal response and hypersensitivity events are necessary to establish generalised biological performance claims. The H3D case is therefore presented as a documented industrial implementation of the framework; the formal biological performance characterisation is open research direction (§7).

4. Case B — Application of the framework to a commercial monomer-free Bio dental photopolymer portfolio

4.1 Portfolio architecture across biological contact regimes

The commercial monomer-free Bio dental photopolymer portfolio of the manufacturer of the present author's affiliation [I1] is organised to cover three biological contact regimes within the dental segment: continuous contact (direct-printed orthodontic aligners worn 20–22 hours per day), intermittent contact (denture bases, occlusal splints, night guards), and semi-permanent contact (interim crown and bridge, temporary restorations). The portfolio architecture — rather than the specific product names — is the subject of analysis here; product nomenclature is retained only where it serves the structural argument of the case.



All three regimes addressed within the monomer-free Bio chemistry family through distinct product variants

Figure 3. Three biological contact regimes addressed within the commercial monomer-free Bio dental photopolymer portfolio. Continuous regime (direct-printed orthodontic aligners worn 20–22 hours per day across 6–24 month treatments); intermittent regime (denture bases, occlusal splints, night guards worn 6–16 hours daily); semi-permanent regime (interim crown and bridge, temporary restorations worn weeks to months). Each regime is addressed through a dedicated product variant within the monomer-free Bio chemistry family.

4.2 Direct-printed orthodontic aligner — continuous regime

Evidence generated for other commercial formulations is included as field context only. It cannot establish the biological performance, regulatory suitability or final-device acceptance of a 3Dresyns formulation because composition, printing, cleaning, post-curing, specimen geometry and intended use can differ. For the continuous-regime application, the manufacturer's monomer-free Bio aligner photopolymer variant operates within the framework architecture: TPO-free monomer-free chemistry; cure kinetics characterised through manufacturer working-curve data; validated post-processing chain documented through the manufacturer's technical white paper series [I1]; six-tier validation hierarchy documented within the ISO 13485:2016 quality-management system, with application-specific acceptance criteria defined separately. The cytotoxicity behaviour of comparable monomer-free direct-printed aligner chemistries is consolidated in the Goracci et al. (2025) PRISMA systematic review [P13], which reports non-cytotoxic outcomes as a recurrent observation among the limited set of independently characterised monomer-free direct-printed aligner systems for which peer-reviewed cytotoxicity data were available at the time of the review (Graphy Tera Harz TC-85 DAC, with additional studies on TA-28 and Senertek Clear-A [P14,P15]). Independent peer-reviewed characterisation specific to the manufacturer's aligner variant is an open research direction; the Bleilöb et al. (2025) [P14] direct-printed aligner biocompatibility study provides chemistry-agnostic peer-reviewed evidence of the cytotoxicity-by-wall-thickness coupling relevant to the regime.

4.3 Denture base and occlusal splint — intermittent regime

For the intermittent-regime application, the relevant performance standard is ISO 20795-1:2013 (water sorption $\leq 32 \text{ } \mu\text{g/mm}^3$; water solubility $\leq 1.6 \text{ } \mu\text{g/mm}^3$; flexural strength $\geq 65 \text{ MPa}$). The Lee et al. (2023) [P16] characterisation of NextDent Denture 3D+ reported water solubility at $5.32 \pm 0.61 \text{ } \mu\text{g/mm}^3$, exceeding the 1.6 threshold by more than threefold, demonstrating that ISO 20795-1 compliance is not a universal property of 3D-printed denture base resins. The Greil et al. (2023) [P17] comprehensive evaluation across four commercial 3D-printed denture base resins reports water sorption in the 25.31–37.94 $\mu\text{g/mm}^3$ range and solubility in 0.08–8.27 $\mu\text{g/mm}^3$ range, with two of the four tested resins failing one or both ISO 20795-1 thresholds. Within this peer-reviewed reference set, the integrated chemistry–process–workflow combination is what determines ISO 20795-1 compliance — not chemistry alone. The manufacturer's denture base photopolymer variant operates the framework architecture; cross-vendor benchmarking against the Lee and Greil reference data remains an open external validation step.

4.4 Interim crown and bridge — semi-permanent regime

For the semi-permanent regime, ceramic-composite-reinforced monomer-free Bio formulations represent the chemistry-side mitigation of the mechanical performance constraint typical of interim restorations. The Sabatini et al. (2024) [P18] multicentre study across Bern, Biruni, São Paulo and Geneva of additive manufacturing trueness and internal fit of crowns in resin modified with a commercially available ceramic composite concentrate provides independent peer-reviewed evidence on this regime; the present perspective draws on this study to anchor the framework application without restating its specific quantitative outcomes.

4.5 Cross-application internal characterisation

The following observation is manufacturer-generated evidence obtained under the stated specimen preparation, extraction and analytical conditions. It is not an independent comparative study and does not, by itself, establish the biological safety or regulatory suitability of a finished medical device. Internal characterisation indicated a lower measured extractables response than the selected internal comparator under the specific test conditions. Cross-vendor and device-level conclusions require independently defined comparative testing. The absolute magnitude of the reduction is strongly dependent on extraction protocol and on the upstream chemistry–process–workflow chain, so cross-vendor and cross-study quantitative comparison remains limited; the standardised extractables protocol direction (§7) addresses this limitation. The internal characterisation is presented as indicative of framework support rather than as peer-reviewed quantitative measurement.

5. Operational outcomes consolidated across the two cases

Table 1 consolidates the operational outcomes of the two case studies against the three framework variables and the validation hierarchy. The cases document sustained operational implementation of the framework at industrial scale; formal cross-vendor extractables benchmarking and longer-term clinical outcome characterisation remain open research directions (§7).

Framework variable	Case A — H3D hearing devices	Case B — Monomer-free Bio dental portfolio
Material chemistry	Monomer-free TPO-free OTO portfolio; Shore A50–D90 envelope; multi-vat gradient print	Monomer-free TPO-free Bio chemistry; aligner, denture base and interim crown variants
Cure kinetics	385–405 nm LED matched; FTIR DC characterisation via DTU study [I2]; matched DoE process windows identified	Manufacturer working-curve characterisation [I1]; wavelength-matched 385–405 nm LED post-cure
Post-processing workflow	Validated four-step chain; two-bath cascade cleaning; λ -matched post-cure	Validated four-step chain documented in manufacturer technical white paper series [I1]
Validation hierarchy	Six-tier hierarchy under ISO 13485:2016; batch-level traceability	Six-tier hierarchy under ISO 13485:2016; cross-regime application
Independent peer-reviewed evidence	DTU process characterisation [I2]; H3D production-architecture	Goracci PRISMA review [P13]; Iodice [P10], Kim [P11], Hwangbo [P12] on cure

	documentation [M1]	kinetics × cytotoxicity; Lee [P16] and Greil [P17] on ISO 20795-1; Sabatini [P18] on interim crown trueness
Operational outcomes (production environment, not validation study)	Commercial production-scale implementation according to company documentation [M1]	Substantial reduction in total ISO 10993-12 extractables relative to conventional baseline (I-data) [I1]
Open external validation step	Cross-vendor extractables benchmarking; longer-term clinical outcome data (ear-canal mucosal response, retention, hypersensitivity events)	Independent head-to-head peer-reviewed characterisation across the three contact regimes against the reference comparators

Table 1. Operational outcomes of the two case studies consolidated against the framework variables and the validation hierarchy. Production volume and continuity are evidence of operational feasibility; they do not, on their own, constitute quantitative biological performance evidence.

6. Limitations of the case-study evidence

The case-study perspective is subject to four limitations made explicit here. First, the perspective is single-author and industrial-academic in origin; the relationship between the manufacturer (3Dresyns) and the hearing-device customer (H3D) is supplier–customer and is disclosed in full. Second, production volume and absence of public recall events indicate operational continuity rather than quantitative biocompatibility characterisation; the framework's biological performance contribution requires the cross-vendor extractables and longer-term clinical outcome data identified in §7. Third, the DTU process characterisation [I2] is the only independent peer-reviewed characterisation of the OTO portfolio at the time of this perspective; cross-validation under H3D production conditions and characterisation of the wider OTO portfolio remain open. Fourth, the dental portfolio characterisation in §4 anchors on peer-reviewed independent evidence for comparable monomer-free dental photopolymer chemistries (Goracci 2025, Iodice 2024, Kim 2024, Hwangbo 2021, Lee 2023, Greil 2023, Sabatini 2024, Bleilöb 2025) rather than on direct independent peer-reviewed characterisation

of the manufacturer's specific product variants; head-to-head peer-reviewed characterisation of these variants is an open research direction.

7. Conclusions and research directions

The Material–Process–Workflow framework supports sustained operational implementation at industrial production scale across two cases — the H3D custom hearing-device pipeline (Case A, §3) and the application of the framework to a commercial monomer-free Bio dental photopolymer portfolio across three biological contact regimes (Case B, §4). The cases are supported by independent peer-reviewed process characterisation conducted at the Technical University of Denmark for one component of the hearing-device case and by the consolidated peer-reviewed cytotoxicity evidence base on comparable monomer-free dental photopolymer chemistries for the dental case. Formal cross-vendor extractables benchmarking and longer-term clinical outcome benchmarking remain necessary to establish generalised biological performance claims; the cases are presented as industrial-academic perspective and not as controlled clinical validation studies.

Three external research directions emerge from the case studies. First, a standardised extractables benchmark conducted under a defined ISO 10993-12 protocol across the major commercial monomer-free dental photopolymer chemistries would enable the cross-vendor comparison that internal manufacturer characterisation cannot deliver. Second, longer-term in vivo clinical follow-up beyond two years across direct-printed aligner and denture-base applications — with primary outcomes including device retention, oral and ear-canal mucosal response, patient-reported quality of life and hypersensitivity events — is the research direction that would refine the framework's biological performance contribution. Third, cross-validation of the DTU process characterisation [I2] under H3D production conditions, and characterisation of the wider OTO portfolio under similar DoE protocols, would consolidate the independent peer-reviewed evidence base on the hearing-device case. Paper III, “Wavelength-Matched Process Control as a Prerequisite for the Post-TPO Photopolymer

Transition” (DOI 10.5281/zenodo.21973554), develops a wavelength-matched audit methodology that addresses one of the operational constraints identified across both cases — the matching of the post-cure cabinet emission to the photoinitiator absorption window after the TPO-to-TPO-free chemistry transition.

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Disclosure. The author is the founder and Scientific Director of 3Dresyns by Resyner Technologies S.L. The H3D case discussed in §3 is an industrial customer of 3Dresyns operating the manufacturer's photopolymer systems at production scale; H3D and 3Dresyns are independent legal entities in a supplier–customer relationship. The dental portfolio discussed in §4 is the manufacturer's commercial portfolio. This perspective is written from an industrial-academic perspective; the cases are presented as illustrative industrial implementation rather than as controlled clinical validation studies. All peer-reviewed citations are independently verifiable; internal production-environment characterisation data are coded explicitly with the I evidence designator. Device-level regulatory classification of any finished medical device remains with the legal manufacturer of that device under the applicable jurisdictional framework.

Source-use map for the shared trilogy bibliography. [P2–P3] provide dental-resin cytotoxicity, stability and residual-TPO context; [P4–P9] support the common polymer-network, working-curve and vat-photopolymerisation background; [P15] complements the direct-aligner post-process evidence; and [P19–P21] provide adjacent digital-workflow and orthodontic-application context. These contextual sources do not establish the performance of either industrial implementation case.

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