

Patient-Specific Anatomical Models Made from Photopolymers: Imaging, Segmentation, Fidelity and Clinical Use Validation

Translational medical manufacturing

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Abstract

Patient-specific anatomical models convert clinical image data into physical surrogates used for planning, communication, training and verification. Their apparent simplicity conceals a chain of transformations in which image acquisition, segmentation, digital editing, meshing, print preparation, fabrication and post-processing can each introduce error. Photopolymer routes are prominent within medical 3D printing, but the evidence base remains process-mixed. This review therefore treats a photopolymer model as a controlled measurement product rather than as a visually convincing object. It separates segmentation error, digital-editing error and printing error; distinguishes geometric fidelity from imaging-modality equivalence and mechanical realism; and proposes a minimum validation architecture tied to the intended clinical use. Claims that derive from mixed 3D-printing evidence are explicitly identified as such. A proposed stage-specific error budget illustrates cancellation and links dimensional assessment to the intended clinical task.

Keywords: patient-specific anatomical models · photopolymers · imaging · segmentation · fidelity · clinical validation

1. Scope and ownership

ER-461 owns the qualification chain from patient imaging to a patient-specific anatomical model when the engineering question is whether the physical model remains an adequate representation for its declared clinical use. It does not own surgical-guide procedural accuracy, which is treated in ER-462, or ultrasound and tactile phantom equivalence, which is reserved to ER-469. The evidence used here includes multiple additive-manufacturing routes; whenever a mechanism is not photopolymer-specific, that limitation is stated in the same claim.

2. The model is a transformed measurement object

A patient-specific model is not a direct copy of anatomy. Clinical image acquisition creates a sampled representation; segmentation converts that representation into labelled geometry; digital editing repairs, smooths or simplifies the mesh; slicing and support generation prepare a manufacturable file; printing and post-processing convert the digital object into a physical one. Schulze et al. classify major error contributions as segmentation error, digital-editing error and printing error, and caution that partial errors may compensate rather than accumulate monotonically [1]. The practical consequence is that a low total deviation does not prove every upstream stage was accurate.

3. Imaging and segmentation

The starting modality sets the spatial information available for segmentation. Slice thickness, reconstruction kernel, contrast, motion and artefacts constrain the boundary that can be inferred. Segmentation then adds algorithmic and operator dependence. A threshold or automated tool can be repeatable while still being systematically biased. Validation should therefore distinguish repeatability from truth against an appropriate reference.

4. Digital editing and mesh preparation

Smoothing, hole filling, Boolean operations and polygon reduction can improve printability but can also erase clinically relevant detail. Editing should be logged as a transformation step, not treated as clerical cleanup. The acceptance question is not whether an STL is watertight; it is whether the altered geometry still preserves the structures necessary for the declared use.

5. Printing and photopolymer state

Vat photopolymerisation and related photopolymer processes introduce optical, mechanical and post-processing variables. Exposure, support placement, cleaning and post-cure can influence dimensions and surface condition. The broader medical-3D-printing literature reviewed by Leng et al. includes several technologies, so generic workflow recommendations cannot be promoted automatically to a universal photopolymer process window [2]. For photopolymer models, the qualified state must name the material, printer route, build orientation, support strategy, cleaning and post-cure condition.

6. Fidelity must be tied to use

A model used for surgical orientation may require faithful external landmarks and spatial relationships. A model used for device deployment may additionally require lumen geometry and compliance. An imaging phantom may require modality-specific attenuation or signal response. Therefore geometric accuracy alone is necessary in many workflows but is not a universal surrogate for clinical validity.

7. Verification architecture

A defensible verification plan contains: a traceable imaging dataset; a frozen segmentation version; a record of mesh edits; a print-state definition; dimensional comparison at clinically relevant landmarks; a declared uncertainty or tolerance model; and a statement of what the model is and is not validated to represent. Where possible, independent partial-error checks should be retained rather than collapsing the whole chain into one final deviation.

8. Clinical-use validation

Clinical validation should be task-specific. Planning, communication, education, device rehearsal and imaging-system evaluation do not require identical endpoints. Evidence that a model is geometrically accurate does not by itself demonstrate improved patient outcome.

Conversely, a model can be clinically useful without reproducing every tissue property. The intended-use claim determines the validation burden.

9. Minimum reporting set

Report image modality and acquisition parameters relevant to resolution; segmentation method and operator control; mesh-editing operations; file format; printing technology; material identity; orientation; post-processing; measurement method; reference geometry; uncertainty; and the clinical task for which adequacy is claimed. When data arise from non-photopolymer routes, label the transfer explicitly.

10. A direct comparison that separates digital preparation and manufacture

Nguyen and colleagues compared vascular models produced by four routes, including SLA, with CTA data and corresponding digital models [3]. Eleven imaging datasets supported separate assessments of digital preparation and manufacture. For SLA, the reported overall relative dimensional error against CTA was $0.53 \pm 3.16\%$. This is a study-specific observation, not a universal tolerance. The methods describe landmark measurements and a surface comparison involving rescanning and registration. Agreement with a processed digital object therefore examines a different stage from agreement with the imaging representation. This primary case illustrates the measurement architecture; it does not establish improved patient outcomes or performance of untested material-printer combinations.

11. An error budget tied to the anatomical question

The following measurement design is proposed for an anatomical-model study. It distinguishes the source image, the segmented surface, the manufacturing file and the finished object. Comparing the print only with the manufacturing file measures a different quantity from comparing it with a physical anatomical reference. The former can identify manufacturing deviation while leaving an earlier segmentation error invisible. Where no independent anatomical reference is available, the conclusion should be restricted to agreement with the imaging-derived representation.

For a declared landmark distance, let the image-derived, segmented and printed measurements be x_I , x_S and x_P . The signed differences $x_S - x_I$ and $x_P - x_S$ describe consecutive transformations; their sum is $x_P - x_I$. This identity is useful for checking a measurement record, but it does not make the individual stages statistically independent. A shared landmark-placement error can affect more than one comparison. An uncertainty calculation that adds variances must therefore retain covariance where the measurements share a reference or registration.

An illustrative calculation shows why reporting only the final difference is inadequate. Suppose a reference distance is 20.00 mm, the segmented distance is 19.70 mm and the printed distance is 19.95 mm. The final difference is -0.05 mm, but segmentation contributed -0.30 mm and manufacture contributed $+0.25$ mm. These invented values demonstrate cancellation, not the performance of any printer. A different anatomy could expose either contribution without cancellation.

12. Testing decision relevance

A proposed validation would nominate the features relevant to the intended task before viewing the results. Whole-surface agreement can be reported alongside a local assessment of a narrow lumen, branching point or planned contact surface. Distances, angles and surface deviations should not be collapsed into one score unless the combination has a declared decision meaning. Repeated measurements by different observers would help distinguish manufacture from landmark-placement variation.

The next layer is task performance. A model could reproduce selected dimensions yet provide no demonstrated improvement in planning. Conversely, a visualisation task might tolerate a deviation that is unacceptable for selecting a size-dependent component. A study should therefore specify whether its endpoint is geometric agreement, a planning decision, procedural performance or a patient outcome. Advancing from one endpoint to another requires additional observations, rather than a broader adjective attached to the same geometry result. This design makes the review operational while leaving acceptance limits with the intended use.

13. Critical appraisal of available accuracy evidence

Schulze and colleagues reviewed 139 publications addressing the geometric quality assurance of patient-specific anatomical models, with a literature-search cutoff of 4 December 2022 [1]. Their study classified measurements by the stage of the transformation, the type of reference, and the measurement technique. The distinction is consequential: a discrepancy between a segmented mesh and an imaging-derived reference is not the same measurand as a discrepancy between a cured print and its manufacturing mesh. Combining these results under the general label “accuracy” obscures both causes and opportunities for control.

The review reported median maximum average mean deviation values of 0.8 mm for segmentation error, 0.26 mm for printing error, and 0.825 mm for combined error [1]. These figures must not be read as normative tolerances or as a single comparative ranking. The metric is a paper-level summary of the largest reported average deviation, not a shared landmark with an identical protocol across all included studies. Anatomy, imaging reference, device class, registration, sampling and printing technology differ. Moreover, the literature did not yield average values for the digital-editing contribution. Hence a manufacturer cannot subtract 0.26 mm from 0.825 mm to estimate its own segmentation performance.

The review also documents a concentration of evidence in teeth or jaws, skull structures, and cardiac or coronary anatomy [1]. Evidence density for these domains cannot be assumed to transfer to a thin-walled vessel, highly trabecular bone, calcified feature or deformable soft-tissue interface. Vat photopolymerisation was represented frequently, but the pooled conclusions span different photopolymer machines, materials and workflows. Any use of published values should record both the anatomical and manufacturing boundary conditions. The evidence supports a structured error taxonomy and a need for stage-resolved testing; it does not supply a universal pass/fail number.

14. Metrology, registration and the meaning of surface deviations

A dimensional comparison must define a measurand before selecting an instrument. Examples include the distance between two predefined anatomical landmarks, a lumen minimum diameter, a curvature radius, a branching angle, and a signed surface displacement measured within a task-relevant region of interest. Each captures different failure modes. Global mean absolute surface distance can

remain small while a narrow lumen is substantially obstructed. Conversely, an isolated surface outlier may be irrelevant to a planning task. The report should preserve a distribution, not only its central tendency, and should identify the denominator and sampling density.

Registration is itself an analytical choice. A best-fit alignment that minimises whole-surface deviations can hide systematic shifts of a clinically relevant feature. Registration to stable fiducials or a specified anatomical region answers a different question from free iterative closest-point alignment. An engineering report should name the coordinate system, registration algorithm, inclusion mask, excluded artefacts, mesh resolution and outlier policy. Where the printed object is rescanned, the verification scanner adds its own calibration, resolution and segmentation contributions. A difference map between two triangulated surfaces is therefore not a direct observation of manufacturing error unless the verification chain is independently characterised.

Stage-resolved measurements should carry uncertainty statements. For an illustrative scalar difference $d = xP - xS$, the combined variance is $u^2(d) = u^2(xP) + u^2(xS) - 2 \text{cov}(xP, xS)$. This expression is a measurement-model identity, not a claim that either input uncertainty is known. Shared observers, fiducials and registration can make the covariance relevant. For spatial features, vector or matrix treatments may be needed rather than treating x , y and z as independent. Precision can be assessed from repeated segmentation, multiple builds and repeated metrology; trueness requires a defensible external reference. A tight repeatability band around a biased mesh does not establish anatomical correctness.

15. From photopolymer process capability to anatomical risk

For a vat-photopolymerised anatomical model, the accepted physical state should be defined by the complete process rather than by the resin label alone. Build orientation, support contacts, local feature thickness, exposure pattern, vat-interface separation, washing, drying, post-curing, ageing and storage may affect the final geometry. Their relevance is feature- and process-dependent, and must be established experimentally for the chosen system. The observation that a printed specimen matches a CAD surface immediately after manufacture does not establish that the object remains dimensionally stable at the time of its intended use.

A useful factorial or blocked qualification design would investigate a deliberately limited set of risk-bearing variables. For example, print anatomies with thin walls and narrow channels in more than one orientation; distribute replicate specimens across independently prepared batches; inspect immediately after cure and at the relevant use interval; and distinguish systematic offsets from between-build variability. The design should not assume all factors interact or assign mechanisms without supporting measurements. A manufacturing change, such as a new printer, resin revision or post-cure cycle, should trigger a documented assessment of whether the earlier process validation still covers the intended feature and endpoint.

The release decision can be constructed from a feature-criticality matrix: list the claimed use, the feature needed for the task, the relevant failure mode, the observable quantity, the independent reference, and the predeclared acceptance basis. For a communication model, feature recognisability and spatial relationships may dominate. For a dimensional rehearsal model, aperture width or fit to a tool may be critical. For an imaging phantom, radiological or signal properties require their own evidence and fall outside geometric qualification alone. This arrangement does not predetermine tolerances; it forces a traceable rationale for choosing and testing them.

16. Clinical endpoint hierarchy and prospective validation

The quality-assurance report by AAPM Task Group 336 addresses medical-imaging and radiotherapy-related 3D-printing quality systems, including governance and application-specific tests [2]. Such quality management informs reproducibility but is not interchangeable with proof of clinical benefit. The evidence hierarchy should distinguish successful file conversion, geometric correspondence, repeatable use in a simulated task, changes in clinical decision-making, procedural accuracy, and patient-level outcomes. A result at one level does not automatically verify the next.

A prospective task study should specify the clinical decision or manoeuvre before model production. It should document who interprets the model, the baseline comparator, operator training, any blinding feasible, and the clinically meaningful endpoint. If the endpoint is a planning decision, capture that decision prospectively; do not substitute a retrospective assertion that the model “looked realistic.” If evaluating user performance, account for learning effects and operator experience. If the model influences a patient intervention, distinguish feasibility and process outcomes from improvements in morbidity or long-term health. These design choices are proposals for future validation, not findings demonstrated by the three cited publications.

The vascular-model comparison of Nguyen and colleagues [3] offers a useful caution about interpreting fit-for-purpose evidence. Its comparison of image-derived and manufactured measurements is informative for a defined vascular workflow, but includes multiple manufacturing technologies and a limited collection of datasets. Its reported study-specific SLA error therefore cannot be extrapolated to different organs, geometries, photopolymer formulations or hospitals. The appropriate output of this Engineering Review is consequently a reproducible validation and reporting architecture, supported by a critically bounded reading of published results, rather than an unqualified claim that printed anatomical models are clinically accurate.

17. Evidence integration: imaging-to-model traceability

The reported accuracy of an anatomical model is conditional on the definition of its reference. A physical surface-to-surface comparison with a segmented image cannot quantify the error already embedded in segmentation; conversely, a comparison with a clinical reference specimen cannot isolate which stage introduced an observed deviation. A rigorous review therefore separates imaging acquisition, segmentation, digital repair, physical manufacture and measurement into different traceability links. This prevents a low printed-model deviation from being mistaken for proof of anatomical truth.

The appropriate uncertainty model also depends on the anatomy. A whole-surface mean distance can conceal a local defect at an osteotomy margin, vessel bifurcation or narrow channel. Reviews should distinguish global registration sensitivity from signed local deviations, topology changes and small-feature completeness. Validation plans require prespecified anatomical regions of interest, a reference with documented uncertainty and blinded repeat assessment when interpretation is subjective.

Finally, clinical utility is a separate outcome from geometric agreement. A model that reproduces a segmentation faithfully may not change a surgical decision, reduce an error or improve communication. Such effects require a defined clinical comparator and patient- or

task-relevant endpoints. The available evidence must therefore be organised by endpoint rather than pooled as one undifferentiated accuracy claim.

Critical synthesis: metrology across the imaging-to-object chain

Geometric fidelity cannot be assigned to the printer alone. Image acquisition, reconstruction kernel, voxel sampling, segmentation, mesh conditioning, support removal and post-cure can each move the final surface. A model-to-STL comparison is therefore not a substitute for comparing the manufactured model against a defensible imaging reference. A review should report which reference was used, whether its uncertainty was estimated, and whether the region of interest was preselected or chosen after the result was observed.

Comparative evidence should be separated by anatomical site, imaging modality, material, intended use and endpoint. Global mean surface distance may conceal local errors at a surgical margin, thin cortical wall or interlocking feature. A stronger evaluation combines signed deviations, percentile or worst-region analysis, repeatability across builds and blinded landmark measurement. These are proposed qualification measures, not established clinical acceptance thresholds.

Clinical relevance depends on the intended decision. Models used for communication, implant pre-bending and patient-specific cutting plans face different loss functions when geometry is wrong. A review must map the error budget to that decision, identify the action taken when a model fails inspection and report whether patient outcomes were actually measured. Improved geometric agreement alone does not establish improved clinical outcomes.

18. Limitations

The two framework sources [1,2] address broad medical 3D printing. The added primary case [3] includes SLA within a four-route comparison; it does not establish class-wide photopolymer performance. This review therefore does not claim universal photopolymer tolerances or clinical benefit. It provides a qualification architecture that requires photopolymer-specific validation where process-specific behaviour can affect the use claim.

Source access limitation: the cited publications were not systematically verified against their complete primary texts. The evidence appraisal is therefore restricted to the accessible records and reported findings; bibliographic identification does not constitute full-text verification.

19. Conclusions

Patient-specific anatomical models should be qualified as traceable transformations from image data to a physical state. Segmentation, editing and printing errors are separable and can compensate. The clinically relevant question is not whether the print looks anatomically plausible, but whether the complete chain preserves the features and material responses required for the stated task under a controlled photopolymer manufacturing state.

Competing interests

The author is Founder, CEO and CTO of 3Dresyns by Resynr Technologies S.L. The company develops and supplies photoresins and related process materials. No proprietary formulation, manufacturing sequence, process window or comparative product recommendation is disclosed.

Data availability

No new experimental dataset was generated.

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