

Patient-Specific Surgical Guides Made from Photopolymers: Design Transfer, Fit, Sterilisation and Procedural Accuracy

Translational medical manufacturing

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Abstract

Patient-specific surgical guides translate an operative plan into a physical interface between anatomy, instruments and procedural intent. Their qualification therefore spans more than printing accuracy: design transfer, registration surfaces, guide-to-bone fit, instrument clearance, manufacturing state and procedural deviation all interact. The present evidence base used for this review is deliberately narrow: its fit-and-accuracy claims rest on one systematic review and meta-analysis of 3D-printed guides [1], and the underlying literature is process-mixed rather than photopolymer-specific. Sterilisation is treated only as a condition that may affect post-sterilisation dimensional fit and procedural accuracy; high-dose radiation chemistry and material-state requalification remain owned by ER-388. A proposed paired treatment design separates guide geometry, seating, trajectory and microbiological endpoints; a geometric illustration shows the dependence of endpoint displacement on trajectory length.

Keywords: patient-specific surgical guides · photopolymers · design transfer · fit · sterilisation · procedural accuracy

1. Scope and evidence boundary

ER-462 owns transfer of a patient-specific guide from digital plan to procedural positioning and execution. It does not claim ownership of high-dose sterilisation chemistry. Its evidence base is one systematic review and meta-analysis, so this article is a qualification framework rather than a deep multi-source meta-analysis.

2. From plan to guide geometry

The digital plan contains target axes, planes, trajectories or resection boundaries. A guide must preserve those relationships after segmentation, guide design, manufacturing and use. A geometrically accurate guide can still fail if the intended registration surface is unstable, if soft tissue prevents seating, or if the instrument-guide interface introduces clearance and angular play.

3. Fit as an interface problem

Guide fit should be evaluated at the actual registration interface. Global surface deviation is not equivalent to local seating quality. Contact distribution, access, rocking, undercuts, support removal and contamination of the mating surface can all influence the achieved pose. Photopolymer-specific qualification should therefore include the final cleaned and post-cured state rather than only the digital model.

4. Procedural accuracy

Hess et al. found that reported accuracy varies by anatomical site and procedure, and that deviations of a few degrees are common in the reviewed orthopaedic applications [1]. Those pooled values are not universal acceptance limits. They demonstrate that procedural accuracy must be evaluated as the deviation between planned and achieved result, with axes and planes defined explicitly.

5. Printer and process transfer

The evidence reviewed by Hess et al. spans multiple printing routes, including DLP, SLA, PolyJet, FDM and SLS [1]. Any inference about patient-specific photopolymer guides must therefore identify whether the supporting evidence is process-mixed. A guide transferred from one printer/material/post-cure system to another requires renewed fit evidence because the manufacturing state has changed.

6. Sterilisation boundary

For this review, sterilisation enters only as a pre-use state transition that can change dimensions, seating or procedural accuracy. The material chemistry, radiation-dose response and requalification science of gamma or electron-beam sterilisation are deferred to ER-388. ER-462 asks whether the guide still fits and performs after the validated sterilisation route; it does not establish why a polymer changes under high-dose radiation.

7. Verification sequence

The minimum sequence is: freeze the clinical plan; identify registration surfaces; verify the manufacturing file; print in a controlled state; clean and post-cure; inspect critical guide features; apply the validated sterilisation route when required; remeasure seating and critical dimensions; and compare the achieved procedural result with the plan.

8. Minimum reporting

Report anatomy, imaging source, guide design basis, registration surface, printer technology, material, build orientation, post-processing, sterilisation route if used, dimensional verification method, instrument clearance, planned target, achieved target and uncertainty. Process-mixed evidence should be labelled as such.

9. Separate the geometry of the guide from the geometry of the procedure

A useful experimental design would treat the guide as a chain of interfaces: anatomical support, guide body, sleeve or guiding feature, instrument and final trajectory. Each interface has its own measurement question. A guide can reproduce its design and still seat inconsistently; a seated guide can constrain an instrument differently from the nominal axis. The proposed comparison therefore preserves both unloaded geometric measurements and measurements made under a declared seating and loading procedure.

For a simple geometric illustration, consider a straight trajectory of length L whose axis differs from its target by angle θ . If the entry position is unchanged, the transverse displacement at the end is $L \sin(\theta)$. With hypothetical values $L = 20$ mm and $\theta = 2$ degrees, that displacement is approximately 0.70 mm. This is a geometric calculation, not a surgical tolerance or an estimate of clinical error. It shows why an angular difference cannot be interpreted independently of the trajectory length. An entry-position displacement would add another component whose direction must also be retained.

Combining all deviations into a single unsigned mean would lose this structure. Reporting the entry deviation, axis deviation, endpoint deviation and their coordinate conventions allows another investigator to determine which comparison has actually been made.

10. A paired sterilisation comparison

A proposed sterilisation study would measure the same guide before and after the declared treatment, with an untreated time-matched group to identify changes caused by storage or repeated measurement. Independent manufacture would remain necessary: repeatedly scanning one guide cannot estimate between-build variation. Material, build orientation, washing, post-cure and elapsed time would be retained alongside the sterilisation cycle and any packaging conditions.

The study would distinguish change in surface geometry from change in fit. A surface comparison could use an explicitly declared registration, while fit could be assessed on a controlled counterpart under a reproducible seating procedure. A registration that optimises the complete surface may conceal a local change at the supporting interface; the region used for alignment should therefore be reported.

The conclusion would state what remained within a prespecified, use-specific geometric or functional margin. A non-significant before-and-after difference would not, by itself, establish equivalence. Nor would dimensional stability establish that a sterilisation process achieved its microbiological objective. Keeping these endpoints separate prevents a single successful test from being used to qualify the complete procedural chain.

11. Critical reading of the evidence and external validity

The systematic review and meta-analysis by Hess and colleagues [1] provides a structured overview of orthopaedic and trauma surgical-guide applications, but its aggregation is not a qualification trial for any one photopolymer, printer or sterilisation route. An evidence table should distinguish anatomical site, indication, guide location, support tissue, manufacturing process, guide-to-instrument interface, reference imaging, operator experience and definition of accuracy. Without those qualifiers, the term “accurate guide” is underspecified. A pooled angular or positional deviation is not a guaranteed result for a new manufacturing workflow.

Several levels of external validity should be separated. An intraoperative guide that rests on exposed bone is not equivalent to a guide that must be placed through soft tissue. A drill sleeve is not equivalent to a cutting slot; the instrument constrains pose differently. A guide used for a single short trajectory is not necessarily comparable with a guide controlling several spatially related trajectories. Likewise, an in vitro seating experiment can identify reproducibility of placement on a rigid replica, but cannot by itself reproduce visibility, loading, irrigation, instrument deflection or operative access. The evidence can support hypotheses and endpoint selection across these applications; it cannot collapse them into a single universal acceptance envelope.

A review should report whether the cited study assesses guide design error, manufactured shape, applied guide pose, executed drilling or cutting, or clinical outcomes. These are successive but distinct outcomes. A low printed-part surface deviation does not show that the guide was fully seated; an apparently stable seat does not show that the tool followed its planned direction. The literature should be organised by the measurand actually observed rather than by a common label of manufacturing accuracy.

12. Registration, tolerance allocation and a geometric error budget

The functional chain begins in imaging and segmentation and continues through anatomical landmark definition, guide-base design, transfer to manufacturing geometry, fabrication, cleaning and curing, seating, instrument constraint, and final verification. Each stage can introduce translation, rotation or local deformation. Their magnitudes should not be added arithmetically unless they are defined in a compatible coordinate system and the assumptions for worst-case combination are explicit. Nor can a root-sum-of-squares model be used without information on correlations and distributions. This article therefore proposes an error-budget record rather than numeric universal tolerances.

A useful budget identifies a planned reference frame, a guide frame and an instrument frame. It records the planned entry point and trajectory and the achieved entry point and trajectory in the same anatomical coordinates. Angular deviation and positional deviation should be reported separately, with a signed convention wherever clinically meaningful. For a straight trajectory, a small angular error produces a progressively greater transverse offset with depth; the same angular deviation can therefore have very different implications near a vulnerable structure than near a broad target. A clinically justified margin must arise from the anatomy and intended action, not from whichever dimensional metric is easiest to measure.

Contact and kinematic redundancy deserve separate assessment. A guide may have several potential seating poses when anatomy provides nearly symmetric or shallow contact. Conversely, a geometrically overconstrained guide can fail to seat fully if one contact point is obstructed. Candidate assessments include repeated placement by independent operators, rocking or gap mapping under a documented seating force, and comparison of achieved guide poses before instrument introduction. These are proposed methods, not outcomes demonstrated by [1].

13. Manufacturing state, sterilisation and verification design

The reported manufacturing state should include the exact print orientation, support strategy, resin or material identification, cleaning and drying treatment, post-curing conditions, any conditioning interval, and the state at which critical dimensions were assessed. A guide printed within its nominal CAD tolerances immediately after post-cure may be altered by subsequent handling or sterilisation. The relevant qualified object is the guide in its final state immediately before the intervention. This distinction also prevents a manufacturer from attributing a change observed after sterilisation solely to sterilisation without measuring storage, handling and repeated-scanning effects.

A scientifically interpretable assessment should specify independent printed replicates and more than one production batch. The design can include baseline metrology, treatment allocation, a time-matched control, a predeclared post-treatment inspection interval and repeated seating tests. The same anatomical counterpart and the same pose-estimation method should be used under conditions that permit comparison. If treatment and untreated groups differ in baseline accuracy, the analysis must address baseline imbalance rather than reporting only their post-treatment means. Sample-size justification should relate to a predetermined equivalence or noninferiority margin and measurement variability.

Sterility-assurance evidence and mechanical-functional evidence are parallel requirements rather than substitutes. Dimensional invariance does not establish microbiological effectiveness, and evidence of effective sterilisation does not establish preservation of guide fit or dimensional accuracy. Where procedure-specific regulations require further evidence, such as biocompatibility or cleaning validation, those claims need separate supporting data. ER-462 confines its analysis to guide-function consequences and leaves underlying radiation chemistry to ER-388.

14. Endpoint hierarchy and failure-oriented reporting

Before collecting data, a study should define the primary endpoint corresponding to the guide's intended function. Candidate primary endpoints include planned-versus-achieved entry deviation, angular deviation, depth-dependent endpoint deviation, or deviation of a resection plane. Secondary endpoints might include print conformity, seating repeatability, instrument play, post-treatment drift and deviations observed in specific anatomical regions. Reporting all endpoints is useful, but their interpretation differs. An apparent improvement in a surrogate endpoint is not proof of an improved patient-level outcome.

Failure-oriented reporting should capture guides that could not be seated, required trimming, fractured, obstructed access, allowed ambiguous seating or were not used. Excluding these guides because no final trajectory was recorded creates a success-only dataset and may materially distort the practical reliability estimate. Report the number manufactured, rejected during production, rejected during pre-use inspection, attempted intraoperatively, successfully seated, and used for the planned action. Repeat-use experiments must identify whether placements are statistically dependent and whether the same guide or anatomical replica is reused.

The most defensible engineering conclusion is conditional: a particular planned procedure can be reproduced within a specified accuracy envelope only after the entire digital, material, manufacturing, preparation and use chain has been assessed against that envelope.

Reference [1] motivates the endpoint families and literature questions, but it should not be represented as validating the proposed testing framework or a photopolymer-specific numerical threshold.

15. Failure-mode synthesis across the guide workflow

Guide fit, guide manufacturing accuracy and placement accuracy are related but non-equivalent variables. A guide may match its design while failing to seat because supporting anatomy changed, the planned contact region was inadequately segmented or a sterilisation cycle affected its interface. Reviews must distinguish guide-to-plan deviation, guide-to-anatomy seating repeatability and the final instrument or implant deviation. Each requires its own datum, sampling protocol and measurement method.

A defensible comparison should stratify studies by support geometry, tooth- or bone-supported contact, registration method, print orientation and sterilisation history. The pooled outcome of heterogeneous guide systems is not a transferable printer tolerance. The technically useful result is a breakdown of the error pathway and identification of controls that can be observed before use, such as fit checks, support-surface inspection and post-process dimensional verification.

Evaluation should record adverse and unsuccessful outcomes, not only mean accuracy in successfully completed procedures. A failed seating, fractured guide or inaccessible instrument path is a process failure even when the surviving cases show small positional deviations. For a new photopolymer workflow, the case-specific acceptance rationale must connect tolerances to the clinical task and to an independently verified final-device state.

Critical synthesis: seating error and procedure-level validity

A surgical guide is a constrained locating system, not merely a printed shape. The operative error chain includes planning registration, anatomic reference stability, guide seating, manufacturing shrinkage, drilling or cutting-tool play and intraoperative handling. Studies reporting only the printed-guide surface deviation do not estimate the final placement error. A review should stratify endpoints into geometric fit, placement deviation and actual procedural outcome before comparing them.

For a reproducible validation experiment, seating should be challenged under realistic interference and access conditions, with independent placements by multiple operators and measurement of both translations and angular deviations. A close-fitting guide may remain rotationally ambiguous; conversely, a guide with acceptable dimensional error may fail when a contact feature is obscured. Such tests are proposed engineering controls, not a claim that existing trials used the same protocol.

Where sterilisation or disinfection is required, the comparison must use the finished guide after its specified processing cycle. Evidence about a resin coupon, an as-printed guide and a processed clinical guide should be tabulated separately. The review should highlight missing negative cases, aborted placements and corrections made at the point of use, because excluding these cases can bias apparent accuracy.

16. Limitations

The controlling evidence is one systematic review and meta-analysis and is not photopolymer-exclusive. The review therefore cannot justify universal guide tolerances, universal sterilisation allowances or a material-independent acceptance criterion.

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.

17. Conclusions

A patient-specific surgical guide is a chain of design transfer and interfaces. The relevant endpoint is the achieved procedure relative to the plan, not only the dimensional accuracy of the printed object. Photopolymer guides require validation in their final cleaned, post-cured and, where applicable, sterilised state.

Competing interests

The author is Founder, CEO and CTO of 3Dresyns by Resyner 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.

References

1. Hess S, Husarek J, Müller M, Eberlein SC, Klenke FM, Hecker A. Applications and accuracy of 3D-printed surgical guides in traumatology and orthopaedic surgery: a systematic review and meta-analysis. *Journal of Experimental Orthopaedics*. 2024;11(3):e12096. <https://doi.org/10.1002/jeo2.12096>

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