

Photopolymer Vascular Stents and Resorbable Vascular Scaffolds: What the Present Evidence Supports and the Qualification Evidence Still Required

Translational medical manufacturing

Juan Seguro

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Correspondence: info@3Dresyns.com · www.3Dresyns.com

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Abstract

Photopolymer routes are discussed within the broader literature on additively manufactured vascular stents, but the evidence includes a broad manufacturing review and primary studies of photocurable polyester systems and DLP-produced nitric-oxide-releasing vascular stent prototypes. The source touches radial mechanics, deployment, flow, endothelialisation, restenosis and degradation, but it does not establish a photopolymer-specific qualification envelope. This review therefore distinguishes an evidence signal from qualified performance and defines the minimum direct evidence needed before deployment, radial mechanics, flow or healing claims can be treated as established for photopolymer vascular devices. A proposed temporal assessment separates absolute support, retained fraction and material fate, with an illustrative calculation showing how normalisation can change a ranking.

Keywords: photopolymer vascular stents · resorbable vascular scaffolds · deployment · radial mechanics · flow · healing

1. Scope and evidence state

ER-465 addresses what can and cannot presently be claimed for photopolymer vascular stents and resorbable vascular scaffolds from the evidence available to this review. It does not convert a multi-process review into primary photopolymer evidence.

2. Controlling source

The cited single-author review by Faisal Khaled Aldawood surveys advanced materials and manufacturing strategies for 3D-printed bioengineered vascular stents [1]. The publisher full text was read in part; it carries a dedicated vat-photopolymerisation section naming SLA, DLP and CLIP. The same partial read touched radial strength, fatigue life, elastic recoil, self-deploying designs, flow optimisation, endothelialisation, in-stent restenosis and in vivo degradation. The source is therefore on scope, but it remains one secondary review rather than a primary photopolymer qualification study.

3. Manufacturing route must be explicit

A vascular device is not qualified by the generic label “3D printed”. Photopolymerisation introduces a distinct material and process state. Any engineering claim must identify the route, material, cure state, geometry and post-processing condition used to create the tested device.

4. Radial mechanics

Radial performance is a device-level property. The present source confirms that radial strength, fatigue and elastic recoil are relevant axes in the broader stent literature [1]. It does not establish a transferable target for a photopolymer device. Direct testing should therefore report device geometry, loading mode, environmental state and cyclic history rather than borrowing limits from another process family.

5. Deployment and recoil

Self-deploying and self-expanding concepts are discussed in the controlling review [1]. That is evidence that deployment architecture belongs in the qualification problem, not proof that a particular photocured material can deploy safely or reproducibly. A photopolymer-specific study must connect material state to deployment sequence and post-deployment geometry.

6. Flow and biological response

The source discusses blood-flow optimisation, endothelialisation, restenosis and in vivo degradation [1]. These remain coupled but distinct outcomes. A favourable geometry does not establish biological compatibility, and degradation is not automatically beneficial unless its timing matches mechanical and healing requirements.

7. Minimum direct evidence still required

The strongest next evidence would be independently reproduced photopolymer-device studies with qualified mechanical, degradation and biological endpoints. Primary demonstrations [2,3] now support the existence of a defined DLP route; stronger performance claims still require independent, endpoint-matched replication and device-level evidence.

8. Minimum reporting set

Report material identity, photopolymer route, device geometry, strut dimensions, post-processing state, radial test method, deployment method, cyclic loading where used, fluid or flow conditions, degradation environment and time, and the biological endpoint if healing is discussed. Every result should remain attached to that state.

9. A coupled support and degradation assessment

A stent qualification proposal needs a time axis shared by geometry, material state and mechanical function. An initial radial measurement describes one state of one device; it does not describe the support available after conditioning, deployment or material change. The proposed study would therefore specify the manufactured state, the deployment history and the observation times before comparing retention. Different specimens may be required for destructive measurements, so their relation to production lots must remain visible.

Let $S(t)$ denote a declared measure of device support and $D(t)$ a use-specific demand expressed in compatible units. The inequality $S(t)$ greater than $D(t)$ can organise a proposed assessment, but it is not itself a validated clinical model. Both trajectories need evidence, and neither can be supplied by the word bioresorbable. A retained fraction $S(t)/S(0)$ should always be accompanied by the absolute values: retaining a high fraction of an inadequate starting value would not establish adequate support.

For a hypothetical example, devices A and B begin at 10 and 6 arbitrary support units. At a later observation they retain 60% and 90%, respectively, corresponding to 6 and 5.4 units. Ranking only by percentage retention would reverse their ordering by remaining support. The calculation illustrates a reporting problem; it sets no device requirement.

10. Build the comparison around the delivered device

The proposed comparison would keep material loss, dimensional change, fragmentation and functional support in separate columns. A decrease in mass is not a direct measurement of the load path. Likewise, a radial result does not replace observations concerning deployment, recoil, fatigue or biological response. Which endpoints are required must follow the specific vascular application and its evidence base.

Printing a different strut architecture can change both the quantity of material and the way it carries load. A study comparing formulations would therefore state whether geometry was fixed, whether the actual geometry was measured and whether the outcome was a device-level quantity or a derived material property. Normalisation should not obscure a clinically relevant device difference.

An expanded review should group studies first by anatomical use and manufacturing route, then by endpoint and observation period. Airway and oesophageal demonstrations may inform general fabrication questions but cannot populate a vascular performance column. Within vascular studies, a common research group or formulation lineage should remain visible so that successive developments are not counted as independent replication. This approach supports a critical comparison without requiring a pooled estimate from incompatible tests.

11. Direct photopolymer vascular-stent evidence

A DLP study reported bioresorbable vascular stent prototypes based on methacrylated poly(dodecanediol citrate) (mPDC), incorporating S-nitroso-N-acetyl-D-penicillamine as a nitric oxide donor [2]. The experimental contribution is not simply an additive-manufacturing concept: it identifies a defined photo-crosslinkable material system, constructs vascular-stent structures and measures nitric oxide release under aqueous exposure. The abstract reports release rates of $20\text{--}160\text{ pmol cm}^{-2}\text{ min}^{-1}$, varied with donor loading. These are formulation- and test-condition-dependent measurements, not a general target or a demonstrated clinical antithrombotic benefit.

A subsequent study investigated a photocurable nitric-oxide-releasing copolyester for 3D printing of bioresorbable vascular stents [3]. This establishes a second directly pertinent literature record, although shared investigators and formulation lineage must be checked before treating these publications as independent external replication. The production route, photo-crosslinking chemistry and biological motivation are important; claims of arterial patency, restenosis reduction and long-term clinical safety require separate in vivo and clinical evidence. Neither proof of fabrication nor a release profile is equivalent to validated treatment.

This distinction materially changes the evidence statement of the earlier draft. It would be incorrect to report that no primary photopolymer vascular-device studies exist. It would be equally incorrect to claim that primary feasibility work qualifies every DLP resin or geometry for vascular implantation. A critical review must keep those propositions separate.

12. Release kinetics, mass transport and coupled device function

For a drug-eluting or nitric-oxide-releasing scaffold, release flux should be reported together with donor loading, specimen area, medium composition, volume, temperature, exchange schedule and the analytical assay. A short-time flux may be influenced by initial swelling or accessible donor at the surface and cannot predict sustained exposure throughout healing. The reported $20\text{--}160\text{ pmol cm}^{-2}\text{ min}^{-1}$ range in [2] is an observed range within that study, not a universal performance window. A robust comparison needs full time-resolved curves, replicate-level dispersion and an explicit definition of surface area.

Drug release and scaffold resorption are not synonyms. Release may follow diffusion, hydrolysis, dissolution, water uptake or combinations of mechanisms. Parallel assessment should therefore track molecular or chemical change, mass balance, dimensional stability and mechanical support. Reporting one end point, such as mass loss, cannot establish the time course of the other endpoints. The central engineering question is whether a given combination of therapeutic exposure and radial support is maintained during the clinically relevant interval, which differs by disease, vessel and deployment context.

13. Radial loading, crimping and durability: test comparability

A vascular stent must be assessed as a delivered device and not solely as a tensile coupon. Radial force, collapse resistance, recoil, bending and cyclic endurance probe different failure modes. Geometry affects the stress concentration at strut junctions; cure heterogeneity, oxygen inhibition, extraction and post-curing can alter the local fracture response of photo-crosslinked networks. These are hypotheses and design risks to test, not measured defects attributable to the devices in [2,3]. Mechanical comparisons should document diameter, lattice pattern, strut cross-section, printed orientation, dimensional deviations, test fixture, conditioning time and temperature.

ISO 25539-2:2020 addresses evaluation of vascular stents and delivery systems and expressly includes absorbable scaffolds, while acknowledging that the standard is not comprehensive for absorption characteristics or drug-elution properties [4]. ASTM F3067 provides guidance on radial loading, and ASTM F3036 is a guide for testing absorbable stents [5,6]. Citing these documents provides a framework for choosing and reporting tests; it does not establish conformity, nor does an unverified photocured prototype inherit the evidence of a metallic reference device.

14. Hemocompatibility, healing and failure pathways

An in vitro observation of cytocompatibility, if available, cannot alone establish endothelial recovery under blood flow.

Hemocompatibility includes contact activation and thrombogenicity, whereas vascular healing concerns endothelial coverage, inflammatory response, vessel remodeling and restenosis. These outcomes require different models and follow-up horizons. Chemical

exposure to photoinitiator remnants, extractables and degradation products must be related to the final cleaned and post-cured device, not to a nominal resin formulation.

An appropriate failure-mode matrix should connect each candidate mechanism to an observed endpoint: inadequate radial support to lumen recoil or collapse; strut fracture to structural discontinuity and embolic risk; excessive early or late material change to loss of support or persistence of fragments; and unfavorable blood-interface response to thrombogenic or inflammatory outcomes. The existence of a possible failure mechanism does not prove its occurrence. Each row needs a relevant assay and stated acceptance rationale rather than an invented numeric limit.

15. Evidence hierarchy and prospective research design

The literature should be separated into process feasibility, bench-level device function, biological evidence and clinical outcomes. A primary DLP fabrication experiment belongs in the first category unless it reports further testing. Bench reports can strengthen device performance claims only for the tested geometry, material state and environment. In vivo healing and controlled clinical evidence are not interchangeable with either fabrication or laboratory release data. The review should explicitly mark absent categories, rather than interpolating them from favorable early-stage results.

A useful future study would preregister the material and intended vessel application, quantify actual as-printed dimensions and residuals, report release flux and degradation kinetics on common time axes, and test radial and cyclic function both before and after conditioning. Biological endpoints would be selected according to contact duration, implantation site and device function. Independently manufactured lots and suitably powered replicate groups would help distinguish process variability from study-to-study differences. Such a program is a proposed qualification pathway, not evidence that a particular device has passed it.

16. Coupled radial support, degradation and local biological exposure

A bioresorbable vascular scaffold cannot be qualified using a single time-zero radial-strength value. Support must persist long enough for the intended healing process while structural degradation, local release chemistry and vessel response evolve. The mechanically relevant history includes crimping, expansion, recoil, cyclic deformation and progressive loss of integrity. Material coupons can illuminate these mechanisms but cannot replace device-level testing in the deployed geometry.

A critical review should maintain a distinction between evidence obtained from a photocurable formulation and evidence obtained from the final scaffold after all processing. Optical exposure, cleaning and post-curing can influence network state and potential extractables; degradation adds further time-dependent chemical exposure. A hemocompatibility observation at one time point cannot establish safety over the full absorption interval. Claims must be indexed to test material, biological system and exposure duration.

Where a device contains a released active species, three functions have to be assessed separately before their interaction is interpreted: mechanical scaffolding, delivery kinetics and biological response. An improved early marker does not demonstrate reduced restenosis or durable clinical benefit. The review should identify the needed longitudinal controls and avoid transferring performance measured in a simplified test environment directly to human clinical outcomes.

Critical synthesis: coupled support, degradation and vascular response

The clinically relevant mechanical question is not whether an initial scaffold has high compressive strength. It is whether radial support remains sufficient through the intended healing interval as molecular degradation, creep and geometry evolve. Bench reports should therefore specify expansion history, recoil, radial force, cyclic loading, crack initiation and dimensional change at multiple degradation states. Single-time-point tensile data do not establish an acceptable support trajectory.

For a bioresorbable implant, the chemical and biological evidence streams are coupled but not interchangeable. Measurements of mass loss, molecular-weight change and soluble degradation products should be distinguished from haemolysis, thrombogenicity, inflammation and vascular healing. Drug or nitric-oxide release adds spatial and temporal exposure questions, which cannot be resolved by an in-vitro release curve alone.

The review must preserve the separation between feasibility demonstrations of printed devices, preclinical animal outcomes and controlled human clinical evidence. A qualified research pathway would couple radial mechanics and degradation profiles with validated blood-contact tests and local tissue-response observations, all performed on the final processed article. None of those proposed qualification activities constitutes regulatory approval.

17. Limitations

The earlier evidence record relied on one secondary review read in part; this revision additionally identifies direct photopolymer vascular-device investigations [2,3]. Their experimental scope does not permit broad extrapolation to long-term clinical performance. Primary DLP vascular-stent demonstrations are available [2,3], but do not establish a general clinically qualified photopolymer stent platform. This review therefore does not claim validated performance limits.

18. Conclusions

Direct DLP demonstrations establish research feasibility for photocurable, resorbable vascular stent materials and nitric-oxide-releasing prototypes [2,3]. They do not by themselves establish safety, fatigue durability, therapeutic benefit or clinical performance. Device-specific verification, degradation trajectories and biological evaluation remain decisive.

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.

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