

Photocurable Tissue Adhesives and Sealants: Applying the Translational-Barrier Criteria, and the Photocure-Specific Evidence Still to Be Established

Engineering review

Juan Seguro

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

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Abstract

A general framework for tissue-adhesive translation can organise questions about a photocurable adhesive, but it cannot establish the performance of that adhesive. This review applies a tissue-specific translation perspective to the evidence needed for light-cured adhesion and sealing. Its literature basis combines a general tissue-adhesive review at abstract depth with a primary GelMA sealant case examined through its abstract and figure captions. No primary dataset is independently reanalysed. The engineering contribution is a proposed evidence structure linking the intended tissue interface, delivered exposure, resulting adhesive state, interfacial function, persistence and failure observation. These links are questions for qualification rather than validated causal relationships or acceptance limits. The framework distinguishes creating a solid polymer from establishing adhesion, sealing or a tolerable tissue response. It also separates a missing measurement within the present assessment from evidence that the wider literature lacks that measurement. Worked analytical cases distinguish leakage from adhesion, incomplete observation from failure, and a processing contrast from identification of a causal mechanism.

Keywords: tissue adhesive; sealant; photocuring; tissue interface; translation; qualification; evidence boundaries

1. Purpose and evidence boundary

The problem addressed is how to organise a claim-specific assessment using general translation framing and a bounded photocurable sealant case. Taboada and colleagues identify the importance of tissue-specific interfaces, material behaviour over time, tissue response and development pathways in tissue-adhesive translation [1]. The accessible publisher abstract supports this framing. It does not supply a transferable exposure setting, bond-strength target or photocurable-material safety conclusion.

The following structure is an engineering proposal developed for this review. It is not an extraction of an experimental protocol from [1]. The primary case illustrates the structure but does not validate it as a universal protocol; no regulatory standard or comparative human clinical dataset is used for that purpose. ER-467 concerns adhesion and sealing. Transdermal delivery remains the scope of ER-464; dressing performance remains the scope of ER-468. A material serving several functions would need separate evidence for each function.

2. Define the intended interface before defining success

A useful assessment would begin with the tissue and the function to be assessed. A bond intended to resist separation and a seal intended to restrict leakage pose different questions. A test record could identify the tissue or surrogate, its preparation, the contacting fluids, the application geometry, the loading direction and the observation period. The proposal is to retain these as explicit descriptors, rather than compress them into a label such as wet adhesion.

A surrogate test would then support a statement about that surrogate and test arrangement. Extending it to another tissue would require a stated bridge. This review supplies neither a universal surrogate nor a hierarchy of tissue suitability. It proposes that any claimed bridge be visible in the evidence record so that a reader can distinguish a measured interface from an intended application.

3. Keep exposure and adhesive state as separate questions

For a proposed photocurable system, a record could distinguish the composition applied from the state after exposure. Candidate descriptors include material identity, photoreactive constituents, light-source spectrum, exposure geometry, timing, specimen thickness and subsequent handling. These are suggested fields for assessment, not a claim that a fixed set is sufficient for every chemistry.

An exposure setting alone would not answer every question about the resulting adhesive. A qualification study could therefore pair the exposure record with a method appropriate to the state being claimed. Conversion, residual constituents, swelling and mechanical behaviour are different potential observables. Which observables are relevant depends on the proposed mechanism and intended function; this review does not rank analytical methods or prescribe acceptable values.

The central reporting distinction is between an input and an outcome. Recording what was applied and how it was illuminated makes the experiment reconstructable. Establishing what was produced requires its own measurements.

4. Separate interfacial function from bulk behaviour

The proposed assessment would describe the failure observation as well as the reported force, pressure or displacement. A specimen could be evaluated for bond separation, loss of sealing, deformation or another explicitly defined endpoint. The interpretation should identify which endpoint was actually observed.

This distinction prevents an attractive bulk property from being presented as a complete demonstration of interfacial performance. It also keeps a test-specific success from becoming an unqualified clinical claim. The framework does not infer that any particular chemistry will fail at an interface or within the adhesive. It asks the experiment to preserve enough information to make that distinction where the observation permits it.

5. Treat persistence as a sequence of states

A proposed qualification programme could compare the initial adhesive state with later states under defined exposure or loading histories. The aim would be to connect a functional observation with the material and interface at the same observation time. Changes in mass, dimensions or appearance would remain separate from changes in the intended adhesive or sealing function.

The programme would need to state what happens when material is lost or a specimen can no longer be tested by the initial method. Missing later observations cannot automatically be treated as successful persistence. Conversely, a change in a material descriptor is not itself proof that the functional endpoint failed. These are interpretation rules for the proposed framework, not outcomes demonstrated by an evaluated photocurable dataset.

6. Build a claim-specific evidence record

Each intended claim could be paired with a record containing the tested system, measured endpoint, comparison, applicable interval, uncertainty and limitations. An additional field could state the inference connecting that measurement to the intended use. A blank field would identify work still required; it would not justify filling the gap from a neighbouring material or procedure.

For adhesion, the claim would identify the interface and loading arrangement. For sealing, it would identify the leakage endpoint and test configuration. For tissue response, it would identify the biological model and observation. Combining these records into a development dossier would not make one endpoint a substitute for another.

7. A primary GelMA case across distinct endpoints

Assmann and colleagues investigated a photocrosslinked gelatin-methacryloyl sealant [2]. The abstract describes changes in formulation and crosslinking conditions. Figure captions distinguish porcine-skin wound closure, lap shear, burst pressure and rat and porcine lung observations. These are different endpoints and models. The case gives the proposed record a concrete preclinical object, linking preparation, interface, mechanical function and later observations. It does not establish a universal exposure or human clinical effectiveness. The present assessment used the abstract and figure captions, without complete methods, supplementary-data review or reanalysis. No numerical superiority claim is derived from it.

8. A comparison that distinguishes adhesion from sealing

The proposed comparison begins by defining what counts as an event. In an adhesion test, the endpoint might be separation under a declared loading arrangement. In a sealing test, it might be the first observed leakage at a declared pressure and detection limit. These outcomes need not occur together. A report should identify whether failure occurred at the tissue interface, within the material, in the substrate or at a fixture. Where the observation does not identify a location, the result should remain unclassified rather than being labelled adhesive failure.

A hypothetical set of specimens illustrates the consequence. Suppose three seals leak at 12, 15 and 18 arbitrary pressure units, while a fourth remains intact at an instrument limit of 20. Reporting a mean of 16.25 would treat a lower bound as an observed failure value. Reporting only the three failures would discard the surviving specimen. A suitable analysis must retain the test limit and the event status. These invented numbers illustrate incomplete observation; they are not pressure targets for tissue sealing.

The experiment would also distinguish an immediate measurement from persistence under repeated deformation or environmental exposure. A later result should carry its own material state and observation history rather than inheriting the initial qualification automatically.

9. A causal comparison for the photocuring contribution

When a study changes illumination, it should explain which causal question the comparison addresses. Comparing a liquid precursor with a cured network changes several attributes simultaneously. Such a comparison may establish a practical difference between two states, but cannot on its own assign the outcome to one network property. If a biological response is measured, material state and the exposure delivered to the model should be recorded separately.

A proposed programme could vary one processing factor within a stated formulation while measuring the resulting network and interface. A second comparison could hold a measured material property approximately constant while changing another factor, if the formulation permits it. The feasibility of that design is an experimental question; the review does not assume that conversion, stiffness, swelling and residual composition can be varied independently.

The interpretation would preserve the comparison actually achieved. A higher measured force after a processing change would support a result for that test configuration. Establishing whether the difference persists in another tissue, under motion or over time would require those observations. This makes the evidence record more useful than a list of maximum values and exposes the next experiment needed to test transfer.

The next research step is to deepen the primary-case assessment and test the proposed relationships across additional directly examined photocurable adhesive studies. Priority should follow the intended claim: identify the interface and function, locate the corresponding measurements, and test whether the exposure and material-state information supports interpretation. Any numerical threshold or clinical recommendation would require evidence beyond this framework.

10. Comparative interpretation of adhesion and sealing evidence

The literature on photocurable tissue adhesives contains several outcomes often collapsed into a single word, adhesion. Lap-shear or tensile adhesion measures one loading configuration; burst pressure interrogates sealing under pressurisation; and leakage persistence depends on defect geometry, tissue condition and repeated loading. Results should be compared only when the interface preparation, curing geometry, test medium and failure criterion are compatible. A stronger bulk hydrogel does not necessarily produce a stronger wet-tissue bond.

Light delivery adds a causal variable that cannot be reduced to nominal lamp wavelength. At a tissue interface, absorption, distance, shielding by blood or tissue, and local geometry alter the exposure experienced by the formulation. Reviews should distinguish studies

that actually measure delivered light from those reporting only a device setting. They should also account for cure-dependent material state and the potential trade-off between rapid gelation and interfacial wetting.

The translational comparison should retain both successes and failure modes: interfacial delamination, cohesive tear, leakage after swelling, loss of adherence under movement and material-associated tissue response. Preclinical wound closure is not synonymous with patient-level benefit. An evidence hierarchy should mark whether the endpoint is physicochemical, ex vivo, in vivo or clinical, and avoid treating these strata as mutually substitutable.

Critical synthesis: adhesive mechanism versus practical sealing

A photocurable adhesive can appear mechanically strong in a bulk specimen yet fail at the wet tissue interface through poor wetting, interfacial displacement, cyclic fatigue or swelling. Reported burst pressure, lap shear, peel resistance and tensile strength probe different mechanisms. Literature comparisons should never reduce these endpoints to one universal adhesive-strength ranking.

Preclinical experiments should report tissue preparation, moisture state, exposure wavelength and dose, applied pressure, working time and whether light reached the full adhesive thickness. These variables alter both conversion and interfacial conditions. A rigorous comparator would include a clinically relevant reference sealant and controls that separate the effects of chemistry, illumination and tissue contact.

Immediate haemostasis or leak closure is a different claim from sustained tissue healing. A review should separate initial sealing, retention under repeated deformation, local toxicity and long-term remodeling, noting missing observations and failed applications. The resulting qualification matrix is a proposed translation framework, not evidence of established clinical benefit.

Critical comparison of primary preclinical evidence

The GelMA lung-sealant investigation by Assmann et al. [2] is directly relevant because it couples controllable photocrosslinking variables to interfacial mechanical tests and in vivo sealing. The investigated parameters included gelatin functionalisation, polymer and initiator concentrations, and crosslinking conditions. They matter because their effects are joint, not independent: a material can form a cohesive network without achieving durable adhesion to a wet, dynamically loaded interface. The study compared wound-closure strength, shear resistance and burst pressure with selected conventional sealants and tested lung leakage in animal models. These are application-specific findings, not a generic photopolymer adhesive performance ranking.

Annabi et al. [3] studied a different photocrosslinkable platform based on recombinant human tropoelastin (MeTro). The engineering distinction is material architecture and cyclic mechanical compliance: recovering strain under repetitive tissue motion is a different requirement from resisting a monotonic separation test. Although both experimental programs support the feasibility of light-formed tissue sealants, they cannot be pooled to obtain an average adhesion strength. Their polymer chemistry, tested geometries, substrates, curing conditions and endpoints are not interchangeable.

The two primary studies support a carefully delimited preclinical proposition: under their respective protocols, light-curable hydrogel sealants produced measurable adhesive/sealing function and were evaluated in living tissue. They do not establish equivalence for arbitrary wavelengths, photoinitiator packages, illumination devices, anatomical sites or human patients. The most useful comparison is therefore a structured evidence table with specimen geometry, substrate hydration, illumination geometry, cured thickness, test method, observation interval and failure location, rather than one consolidated score.

Separating bulk strength, interfacial adhesion and functional sealing

Three response classes should be recorded separately. Cohesive response describes fracture, fatigue or deformation within the formed gel. Adhesive response describes failure at the gel–tissue boundary under a specified loading mode. Sealing response is functionally defined by the leakage of air or liquid under a stated pressure history. A high bulk tensile modulus does not imply high interfacial toughness, and a high short-term burst pressure does not establish resistance to repeated excursions, swelling or degradation. Failure analysis must record whether leakage followed an adhesive channel, cohesive crack, substrate rupture or a bypass path through the fixture.

Test geometry is consequential. In a lap-shear arrangement, the stress state and nominal bonded area differ from wound-closure or burst configurations; nominal peak load divided by area is not automatically an intrinsic interfacial property. The relevant comparator needs matched tissue preparation, substrate state, application thickness, cure sequence and observation endpoint. Where protocols differ, the review should report the contrast narratively and explicitly refrain from numerical cross-study ranking.

Photocure delivery and material-state traceability

For an in situ photocured system, the device and delivery protocol are parts of the evidence chain. The report should distinguish source wavelength, incident irradiance, exposure duration, source-to-sample geometry, optical attenuation, sealant thickness and tissue shielding. Reporting only a nominal exposure time leaves the actual local cure state uncertain. Tissue optical properties and the presence of blood or fluid can further affect exposure. These are mechanisms to control and measure, not grounds for inferring a safe therapeutic illumination window.

The post-illumination state should be characterised independently of the act of illumination. Suitable measurements, selected according to formulation and application, may include extraction or sol fraction, conversion-related spectroscopy, swelling, viscoelasticity, and the distribution of properties through thickness. An apparently solid surface cannot demonstrate full-depth cure. Residual monomer, photoinitiator or leachable species must not be dismissed simply because the hydrogel is based on a naturally derived precursor.

Translational evidence hierarchy and unresolved constraints

A defensible translation pathway proceeds from reproducible synthesis and wet-substrate application through matched functional bench tests, biologically relevant compatibility, and preclinical observations in a model that challenges the intended mode of failure. A proposed clinical indication requires its own benefit–risk assessment and appropriately designed human evidence. Animal experiments should be

reported by species, defect size, duration, comparators and endpoints; the existence of an animal demonstration is not evidence of regulatory clearance or clinical effectiveness.

The principal uncertainties are reproducibility across precursor lots, application on contaminated or actively bleeding substrates, depth-dependent cure, mechanically repeated sealing, timing of resorption relative to healing, and exposure-related tissue effects. These are prioritized research questions, not assertions that the cited studies failed every such test. Where the full source provides a measurement, it should be extracted together with protocol details; where measurement is absent from the accessible record, the statement must be limited to that access boundary.

Engineering synthesis

The evidence supports treating photopolymer tissue sealants as coupled material–delivery–interface systems. GelMA and MeTro illustrate two different strategies, but both require proof that polymerisation is reproducible under the actual application geometry and that the resulting interface maintains clinically relevant function for the required interval. A strong Engineering Review should therefore privilege failure-mode-resolved comparative experiments and exposure traceability over generic descriptions of promising hydrogels.

11. Limitations and research priorities

The general translation source was used at abstract depth. The GelMA primary case was examined through its abstract and figure captions, without complete methods or supplementary-data assessment. No quantitative exposure-response relationship or long-term clinical outcome is established. This limitation describes the present assessment and is not a conclusion that relevant studies do not exist.

12. Conclusions

A translation framework is useful when it makes unsupported links visible. For photocurable tissue adhesives, the proposed structure keeps interface identity, exposure, resulting material state, function and later observations separately inspectable. It offers a way to organise future evidence; it establishes no qualified formulation, universal operating condition or clinical performance claim.

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. The general review supplies framing and the primary case supplies bounded preclinical observations; the assessment structure and worked examples are engineering analysis.

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