

Vat-Photopolymerised Materials for Custom Orthoses and Prosthetic Interfaces: Device Mechanics, Workflow Qualification and Evidence Boundaries

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Statement of Significance

“Orthotics and prosthetics” is not one materials problem. A wrist-hand orthosis shell, a compliant skin interface, an adaptive shape-memory element and a load-bearing lower-limb prosthetic socket impose different mechanical, biological and regulatory evidence requirements. VPP/DLP has direct peer-reviewed evidence for customised upper-limb orthoses and emerging 4D hand-orthosis concepts, but the load-bearing prosthetic-socket literature remains dominated by other additive-manufacturing routes. This review therefore builds a device-function qualification framework instead of transferring results from one component, process or patient-contact scenario to another.

Keywords: vat photopolymerisation; DLP; orthosis; prosthesis; prosthetic socket; wrist-hand orthosis; patient-specific manufacturing; 4D printing; shape-memory polymer; fatigue; creep; biological evaluation; ISO 22523; ISO 10328

Abstract

Patient-specific additive manufacturing can integrate scanning, digital design and customised geometry into orthotic and prosthetic workflows. For vat photopolymerisation, the strongest direct evidence currently concerns customised wrist-hand orthoses, including DLP printability studies, clinical workflow comparisons and shape-memory 4D orthosis demonstrations. Evidence for load-bearing prosthetic sockets is broader in additive manufacturing but is not yet sufficient to infer equivalent performance for VPP materials. This review separates four material roles - structural orthotic shell, compliant interface, adaptive/4D element and load-bearing prosthetic component - and maps each to geometry, mechanical durability, environmental conditioning, finished-article biological evaluation and workflow controls. ISO 22523:2006 is used as the general external prosthesis/orthosis requirements reference, ISO 10328:2016 is restricted to its lower-limb structural-testing scope, and ISO 10993-1:2025 is used only for biological evaluation within risk management. 3Dresyns material families are presented as implementation profiles, not as approved medical-device materials.

1. Scope and evidence-selection method

The review prioritises peer-reviewed studies that report patient-specific orthosis design/printing, DLP/VPP orthosis fabrication, shape-memory photopolymer orthoses, clinical workflow outcomes, or structural testing of additively manufactured prosthetic sockets [1–8]. It does not treat generic “biocompatible resin”, flexibility, hardness or tensile data as proof of orthotic/prosthetic suitability. The lower-limb prosthetic literature is used to define structural-evidence expectations and gaps, not to transfer FFF/SLS/MJF results to VPP. This note is a topic-specific Engineering Review in the 3Dresyns ER series; the shared evidence-to-decision and qualification method is defined once in RP-02, Evidence-to-Decision Qualification Framework for Vat Photopolymerisation, and is not reproduced here.

Standards are used only inside their declared scope. ISO 22523:2006 remains current as of August 2026 but is under revision [S1]. ISO 10328:2016 remains the published lower-limb prosthetic structural-testing standard while an edition-3 FDIS is in progress; it is not a prescription guide and its tests do not automatically validate a customised socket or a different device class [S2]. ISO 10993-1:2025 frames biological evaluation of a finished medical device within risk management and does not allow biological suitability to be inferred from a resin label [S3].

2. Separate the device function before selecting the material

Table 1. Orthotic/prosthetic material roles require different evidence.

Material role	Typical engineering objective	Critical evidence	Do not infer
Rigid/semi-rigid orthotic shell	Immobilisation, positioning, ventilation and patient-specific fit.	Geometry, stiffness, fracture/fatigue, edge integrity, fit, workflow reproducibility.	Clinical effectiveness from coupon strength alone.
Compliant interface / padding	Pressure accommodation, local comfort, flexibility and repeated deformation.	Compression/relaxation, tear/fatigue, cleaning/environmental ageing, contact assessment.	Human-contact suitability from “soft” or “silicone-like” wording.
Adaptive / 4D element	Thermally or otherwise triggered shape/stiffness adjustment.	Transition window, recovery force, cycling, dimensional stability and failure mode.	Safe therapeutic force or clinical benefit from shape recovery alone.
Load-bearing prosthetic component/socket	Transfer gait loads while maintaining interface geometry and safety.	Device-level static/cyclic structural testing, attachment zones, ageing and inspection.	ISO 10328 conformity from material tensile data or from another AM process.

3. Digital geometry, fit and printability

Patient-specific geometry is one of the principal attractions of additive orthotic manufacture, but geometry and material cannot be qualified independently. Popescu, Lăptoiu and Căruțașu investigated customised wrist-hand orthoses produced by both material extrusion and DLP, examining design, build orientation, process parameters, printability and usability [1]. Thin walls, extensive ventilation openings and long curved geometries create orientation and support constraints that can change production time and local mechanical behaviour. A successful CAD fit is therefore only the first state in the evidence chain; the printed, post-processed and conditioned geometry must also be verified.

Clinical workflow evidence likewise depends on the actual process. von Haller, Couchman and Honigmann compared DLP-printed wrist orthoses with conventional low-temperature thermoplastic orthoses in a clinical setting and found a longer total production time for the studied 3D-printing workflow [2]. Those timings are not universal printer benchmarks; they show that scan/design/printing/post-processing time belongs in implementation qualification alongside mechanical performance.

4. Current evidence for upper-limb orthoses

The clinical evidence base for 3D-printed hand and upper-limb orthoses remains heterogeneous. Oud et al. mapped 17 studies and concluded that most evidence was based on small samples and limited methodological quality, with clear needs for better controlled trials, patient-related outcomes, production-time analyses and longer follow-up [3]. Schwartz and Schofield similarly found promising feasibility but persistent barriers involving equipment, software, training and production complexity [4]. These reviews span several AM technologies, so they establish the evidence landscape rather than VPP-specific superiority.

For VPP specifically, the 2024 DLP studies provide direct evidence that customised photopolymer wrist/hand orthoses can be designed and fabricated [1,2]. What they do not establish is a universal resin class, universal wall thickness or transferable exposure recipe. Each material/printer/post-cure combination remains a manufacturing system that must be qualified for the actual orthosis geometry.

5. Adaptive and 4D orthoses

Barmouz and co-workers demonstrated a customised hand orthosis using a DLP-printable shape-memory photopolymer and reported repeated shape-memory operation within that experimental system [5]. A companion materials study examined a DLP shape-memory photopolymer modified with carbon black and its relevance to an orthotic concept [6]. These papers establish feasibility of an adaptive photopolymer orthosis, but they do not justify transferring activation temperature, recovery force, cycle life or therapeutic effect to other formulations.

A defensible 4D orthosis claim therefore needs two linked qualifications: material-state evidence (transition, recovery kinetics/force, cycling, creep and environmental stability) and device-level evidence (fit trajectory, force distribution, failure mode and intended clinical protocol). Shape recovery without controlled force can be mechanically successful yet clinically inappropriate.

6. Load-bearing prosthetic sockets: a different evidence threshold

Lower-limb prosthetic sockets are safety-critical structural interfaces. A 2025 state-of-the-art review emphasised that load-bearing socket adoption requires explicit mechanical and digital-workflow controls and commonly refers to ISO 10328-derived structural testing [7]. A systematic review of socket structural testing found that many published methods adapt ISO 10328 but that socket-specific details remain insufficiently standardised [8]. Direct structural studies of additively manufactured sockets also show process/material dependence and distinct failure modes [9].

These findings are deliberately not converted into a statement that VPP photopolymers are suitable for load-bearing sockets. Most socket evidence concerns extrusion, powder-bed or other AM technologies, and ISO 10328 itself warns against using the standard as a prescription guide [S2]. For a VPP socket, the evidence chain would have to begin again with the exact formulation, build orientation, post-cure, socket geometry, attachment architecture, conditioning and device-level static/cyclic test plan.

7. Mechanical durability and environmental conditioning

Table 2. Mechanical evidence should follow the actual failure mode.

Domain	Why coupon data are insufficient	Suggested qualification evidence	Reporting minimum
Stiffness / flexibility	Local shell curvature, openings and thickness change structural response.	Coupon + representative subcomponent + finished-device deflection/fit.	Orientation, thickness, geometry, temperature and conditioning.
Fracture / tear	Edges, strap holes and attachment zones create stress concentrations.	Notched/tear or fracture-relevant tests plus device inspection after loading.	Failure location and initiation mode.
Fatigue	Orthoses and sockets see repeated load cycles rather than one tensile event.	Cyclic loading at application-relevant amplitude and environment.	Cycles, waveform, frequency, load ratio and residual properties.
Creep / stress relaxation	Photopolymer fit and interface pressure can drift over time.	Time-dependent deformation under relevant temperature/load.	Load, time, temperature, recovery and dimensional change.
Environmental ageing	Sweat, water, cleaning, heat and UV/post-cure state can change polymers.	Conditioned mechanical and dimensional re-test.	Fluid, temperature, duration and drying/recovery protocol.

8. Biological and contact boundary

Where a finished orthosis, liner or prosthetic interface contacts the body, material selection must be embedded in a device-specific biological risk process. ISO 10993-1:2025 frames biological safety around the finished device, contact nature/duration and risk management [S3]. The relevant state is therefore the exact printed, washed, post-cured, finished and aged article - not the liquid resin name and not a generic material-family label.

This distinction is particularly important for soft or adaptive photopolymers, where residual species, extraction, washing, post-cure, surface finish and repeated flexing can change the exposure profile. No statement in this review should be read as medical-device approval, clinical effectiveness or finished-article biological suitability.

9. Manufacturing workflow qualification

Table 3. Minimum manufacturing-state controls.

State	Control	Evidence generated	Release question
Digital model	Scan quality, fit offsets, wall thickness, openings and attachment geometry.	Traceable CAD/version and dimensional targets.	Does the design encode the intended fit/load path?
Printing	Printer, wavelength, irradiance, exposure, orientation, supports and resin lot/version.	Build record and dimensional/process acceptance.	Was the exact material-process combination controlled?
Cleaning/post-cure	Solvent/cleaner, time, drying, post-cure wavelength/dose/temperature.	Finished-state conversion/extraction/dimensions as relevant.	Is the tested state the state delivered for use?

State	Control	Evidence generated	Release question
Finishing	Support removal, edge smoothing, straps/fasteners, liner/interface assembly.	Visual/dimensional/attachment inspection.	Did finishing introduce stress raisers or surface hazards?
Conditioning/testing	Temperature, humidity/fluid exposure, load history and ageing.	Mechanical, dimensional and biological evidence.	Does performance persist in the intended use environment?

10. Decision framework for evidence escalation

Table 4. Evidence escalation by intended role.

Intended role	Minimum preclinical evidence	Additional evidence before device claim	Hard boundary
Research/fit prototype	Print fidelity, geometry, basic mechanics and workflow traceability.	Application-specific durability if handled repeatedly.	No clinical or contact claim from prototype fit alone.
Non-load-bearing orthotic shell	Representative mechanics, fatigue/creep, finishing and environmental conditioning.	User/device study plus risk controls where medically intended.	No universal wall-thickness rule.
Compliant body-contact interface	Compression/relaxation, tear/fatigue, cleanability and finished-article chemistry.	ISO 10993 risk-based biological evaluation as applicable.	“Soft” does not mean skin-safe.
Adaptive/4D orthosis	All above plus transition/recovery force, cycling and dimensional stability.	Device-level force/fit validation and clinical/regulatory evidence as intended.	Shape-memory demonstration is not therapeutic validation.
Load-bearing lower-limb prosthetic component/socket	Device-level static/cyclic structural plan, attachment-zone analysis and ageing.	Applicable ISO 22523/10328 conformity pathway and clinical/regulatory controls.	Do not transfer evidence from another AM process or coupon.

11. 3Dresyns implementation examples

The following examples describe available material-response profiles only. They are manufacturer evidence and do not establish suitability, medical-device status, human-contact safety or clinical performance for an orthosis or prosthesis.

- NextGen 3Dresyn TFD80 is a single tough/foldable photopolymer grade with a manufacturer-stated Shore hardness of D80 (ISO 868); it is not a product family, and it must not be conflated with the separately sold NextGen TFD70, TD80/TFD80 50/50, 3Dresyn EP2 TFD80 or 3Dresyn VAM UTFD80 Bio grades, which share part of the designation [M1]. It can serve as an engineering example of a comparatively rigid yet deformation-tolerant shell profile. Its controlled product page carries the manufacturer wording "Biocompatible (final part validation required)" together with the statement that the material is not marketed as a finished medical device. That wording is reproduced here as part of the controlled product identity and is expressly not adopted as evidence: this review makes no biological, skin-contact, patient-contact or medical-device claim for TFD80 or for any orthosis printed from it. Device-level stiffness, fatigue, fit, environmental performance and finished-article biological evaluation under ISO 10993-1:2025 [S3] must be established for the exact geometry and workflow.
- 3Dresyn Soft SR is a single silicone-like soft photopolymer grade with a manufacturer-stated Shore hardness of A30 (ISO 868), offered alongside a Hard SR grade at Shore A70; the manufacturer states that this collection is not a broad continuum of elastomer grades but two anchor routes [M2]. It can serve as an example of a compliant-material profile. "Silicone-like" describes mechanical and handling intent; it is not evidence of biological equivalence to medical silicone or of suitability as a skin-contact liner. It is recorded here, as a matter of accurate manufacturer-evidence reporting, that the Soft SR product page makes no biocompatibility, skin-contact, dermal, ISO 10993 or medical claim of any kind; the absence of such a claim is consistent with the boundary drawn in Section 8 and must not be read as an implied clearance for patient contact.
- 4Dresyn F-HV1 v1.4 is a high-viscosity flexible 4D photopolymer with a documented temperature-dependent change from more rigid behaviour below about 15 °C to flexible behaviour above about 25 °C under the stated source conditions [M3]. Its controlled TDS explicitly states that it does not establish biocompatibility, medical-device status or human-contact suitability; all functional and biological behaviour requires validation of the finished article.

12. Conclusions

- Orthoses, compliant interfaces, adaptive elements and load-bearing prosthetic components are separate material/device problems and require different evidence.
- DLP/VPP already has direct feasibility evidence for customised upper-limb orthoses, but the clinical evidence base remains heterogeneous and should not be converted into universal material rules.
- 4D photopolymers add an adaptive design axis, but activation temperature, recovery force and cycling must be validated at device level.
- Load-bearing prosthetic sockets require a substantially higher structural evidence threshold; evidence from extrusion or powder-bed AM cannot be inherited by VPP.
- Finished-article biological evaluation, where applicable, belongs inside the intended-use risk process and cannot be inferred from resin naming or formulation-level screening.

Limitations

This review is not a clinical guideline and does not establish medical-device conformity or therapeutic effectiveness. Direct VPP evidence is strongest for upper-limb orthoses and experimental 4D concepts; lower-limb load-bearing prosthetic evidence is mainly from other AM technologies. Material and device properties are highly dependent on geometry, orientation, printer, exposure, post-processing, conditioning and service loading. Standards cited here must be applied only within their current published scope and checked for revision at the time of formal conformity work.

Author contributions

Juan Seguro: conceptualisation, literature synthesis, engineering interpretation, writing, review and final approval.

Competing interests

The author is founder, CEO and CTO of 3Dresyns by Resyner Technologies S.L. Manufacturer examples are segregated from peer-reviewed evidence and are not presented as clinical validation.

Data availability

No new patient, mechanical or biological dataset was generated for this review. Scientific statements derive from the cited literature and standards; manufacturer examples derive from controlled 3Dresyns documentation.

Company information

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