

Photopolymer Microneedles: Geometry, Insertion, Fracture, Payload, Dissolution and Skin-Interface Qualification

A qualification framework connecting printed needle geometry to mechanical insertion and delivery performance

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Abstract

Photopolymer microneedles combine sharp microgeometry, fracture resistance, payload architecture and a biological interface, so qualification must preserve the distinction between insertion mechanics and delivery function. This review examines printed solid, coated, hollow and dissolving microneedle concepts with emphasis on geometric fidelity, tip quality, insertion force, failure load, payload state and skin-interface evidence. Recent reviews document rapid expansion of 3D-printed microneedle manufacturing, while two-photon literature provides the microfabrication context for high-resolution structures. The central engineering ratio is not strength alone but structural margin relative to the force required for insertion under the intended skin model. For dissolving or drug-loaded designs, payload distribution and release add separate state variables. A qualification sequence is proposed that connects tip and shaft metrology to mechanical insertion, fracture margin, delivery or dissolution, and biological-interface controls without treating these endpoints as interchangeable.

Keywords: microneedle; photopolymer; stereolithography; two-photon polymerisation; insertion; fracture; drug delivery; skin interface

1. Significance and scope

Microneedles fail in several fundamentally different ways: they may be too blunt to penetrate, strong enough to penetrate but prone to brittle fracture, mechanically successful but unable to deliver the intended payload, or functionally adequate in a model substrate yet incompatible with the intended tissue interface. The manufacturing review must therefore separate geometry, mechanics, payload and interface evidence and must state which skin model and insertion protocol support each claim.

1.1 Corpus boundary

ER-334 owns microneedle geometry, insertion, fracture and payload/dissolution qualification. ER-251 retains biological-evaluation planning, ER-252 cytotoxicity-test artefacts, and ER-438 immune-interactive material response. ER-334 uses tissue models only to qualify the microneedle-device interface and does not make broader biocompatibility or clinical claims.

2. Geometry controls both insertion and stress

Tip radius, taper, length, base diameter and array spacing alter insertion force, bending stress and local skin deformation. Printed geometry should be measured after cleaning and post-cure because staircase error and tip rounding can materially change performance [1-3].

3. Strength must be compared with insertion demand

Axial fracture force alone is insufficient. A useful safety margin compares fracture or buckling load with insertion force under a defined skin model, insertion speed and support condition [1,2].

4. Payload changes the structural problem

Solid, coated, hollow and dissolving microneedles have different failure modes. Coatings change tip geometry; hollow needles add lumen patency and pressure loss; dissolving systems require dissolution kinetics and residual-fragment assessment [1,2].

5. Skin-interface qualification

Insertion depth, pore formation, delivery fraction, irritation and recovery should be characterised with a declared tissue model. Mechanical success cannot be equated automatically with dose delivery or biocompatibility.

6. Qualification architecture

Qualification begins with tip radius, shaft cross-section, length and array registration, followed by axial and off-axis mechanical tests that establish fracture mode. Insertion into a declared skin surrogate or tissue model is then measured independently. A useful mechanical margin compares the distribution of failure loads with the distribution of insertion loads; neither mean value is adequate when brittle failure or tip damage is possible.

7. Minimum evidence for transfer

Transfer evidence should record device class (solid, coated, hollow or dissolving), material state, print orientation, post-cure, tip and shaft dimensions, insertion fixture, speed, skin model and conditioning. Payload-bearing devices add loading distribution, recovery and release/dissolution measurements. Full bibliographic and test-state traceability is especially important because recent microneedle reviews cover multiple additive-manufacturing modalities with different material constraints [1,2].

7.1 Evidence hierarchy and transfer

Strong evidence links a measured geometric or material change to both mechanical and delivery consequences. For example, an enlarged tip radius should increase insertion demand before any fracture result is interpreted, while hydration of a dissolving matrix can alter both strength and release. Controls should therefore be ordered so that a downstream failure is not attributed to the wrong upstream state variable.

7.2 Research priorities

Priority work includes standard insertion surrogates with traceable mechanical properties, agreed methods for reporting tip damage after use, and statistical design margins between insertion and failure distributions. For payload-bearing systems, manufacturing studies should report dose uniformity across an array rather than only total recovered mass.

Table 1. Minimum qualification matrix for photopolymer microneedles.

Microneedle state	Minimum measurement	Qualification purpose
Geometry	tip radius, length, base and lumen dimensions	defines insertion mechanics
Mechanical	fracture/buckling and insertion force	establishes safety margin
Delivery	payload mass or flow and delivered fraction	tests dose transfer
Interface	insertion depth and tissue response	tests skin interaction
Stability	storage and sterilisation retest	tests retained performance

8. Interpretation matrix

Incomplete insertion, shaft fracture, tip blunting and variable dissolution produce different signatures. The matrix pairs each with a geometry, force-displacement, imaging or payload control so that a failed delivery test does not automatically become a 'material strength' conclusion.

Table 2. Diagnostic interpretation matrix for microneedle insertion and delivery failures.

Observed failure	Plausible mechanism	Discriminating control
Needle bends without fracture	insufficient column stiffness	compression plus lateral deflection test
Good fracture load, poor insertion	blunt tip or skin model mismatch	tip metrology and insertion-force profile
Low delivered dose	coating loss, incomplete dissolution or lumen blockage	mass balance and imaging
Array edge needles fail first	load nonuniformity or backing compliance	force mapping across array

9. Limitations and evidence gaps

Skin models, insertion velocities and definitions of successful penetration vary widely. Mechanical data from one substrate cannot be transferred directly to another tissue state, and a biological response endpoint cannot be inferred from mechanical insertion alone. This review therefore defines an engineering qualification boundary rather than a clinical performance standard.

10. Conclusions

A photopolymer microneedle is qualified only when its realised geometry, insertion behaviour, fracture margin and intended delivery mechanism are jointly supported under a declared interface model. Separating these evidence layers prevents a sharp image or high

failure load from being mistaken for successful delivery. ER-334 therefore treats manufacturing state and skin-interface testing as linked but non-substitutable parts of qualification.

References

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Competing interests

The author is Founder, CEO and CTO of 3Dresyns by Resyner Technologies S.L. No comparative product recommendation is made.

Data availability

No new experimental dataset was generated for this review.