

From Powder to a Porous Body: Keep the Evidence Linked

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Abstract. A raw-powder result characterizes the supplied material, not every structure later made from it. This guide identifies the additional evidence needed when a calcium-phosphate or bioactive-glass powder becomes a porous body, without assigning universal pore or strength targets.

Keywords: porous body; microCT; processing; mechanical tests; evidence transfer

1. Map the transformation

Create a record linking the incoming lot to the formulation, forming step, binder removal, thermal treatment, cleaning and any subsequent sterilization or packaging. Record which steps were actually applied; do not infer them from the material name.

A powder COA can support incoming identity. It does not describe the final geometry, processing residues, pore network or mechanical response. Decide which attributes are expected to survive processing and which must be measured again.

2. Keep chemical and physical identity separate

For a heat-treated body, compare relevant phases and chemistry before and after processing. Added binders, processing aids or cleaning residues require their own evaluation. A matching nominal HA/TCP ratio does not by itself establish an identical final surface.

FDA documentation examples compare test articles with the final finished device across formulation, processing, sterilization and geometry [1]. That device-level principle explains why raw-powder evidence needs a justified bridge; it does not mandate one fixed test panel for every research scaffold.

5. Evidence-transfer checklist

Hypothetical arithmetic, not product performance: a load of 100 N divided by an initial loaded area of 25 mm² gives a nominal stress of 4 MPa. The same load over 100 mm² gives 1 MPa. Equal failure loads therefore do not establish equal nominal strengths; the failure mode and test conditions still matter.

3. Describe the pore network

Report the method and operational definition for porosity, pore size and interconnectivity. They are different descriptors: equal total pore volume need not mean equal access through the structure.

For microCT, retain voxel size, reconstruction, thresholding, region of interest and the way connected pathways are defined. Resolution and representative volume can affect measured connectivity [2]. A pore feature below the effective resolution should not be reported as reliably measured.

Treat imaging-based accessibility as a structural measurement. It does not independently prove fluid transport, cell penetration or tissue ingrowth. Validate the relevant functional endpoint separately.

4. Compare mechanics on a common basis

Record shape, dimensions, loading direction, rate, fixture alignment, conditioning and the chosen endpoint. Identify dry versus wet testing and retain failures rather than reporting only intact specimens.

Distinguish a measured failure load from an engineering stress or modulus. For porous or anisotropic bodies, geometry and direction can strongly affect the interpretation. This guide supplies no minimum load-bearing criterion.

Stage / attribute	Evidence to link	Limit of the conclusion
Incoming powder	Lot, phase/chemistry, particle attributes and test methods.	Does not qualify the processed body.
Processing history	Formulation, relevant thermal/cleaning steps and deviations.	A process name is not evidence of residue removal.
Final structure	Porosity definition, pore distribution, connectivity method and representative sampling.	One image or mean pore size is insufficient.
Mechanical response	Specimen geometry, orientation, conditioning, loading method, failures and variability.	Do not transfer one result to a different structure.
Finished-form assessment	Representative final article and a documented rationale for any surrogate.	Powder screening is not finished-device clearance.

6. A bounded development decision

Advance a formulation only against the predefined structural and processing objectives for that article. If an upstream material changes, first identify which final attributes could change, then compare those attributes with a matched control. Record the remaining evidence gap rather than describing the powder as universally suitable for bone repair.

Relation to the existing series

KB-TG-008, 009 and 012 address particular formulation or processing variables. This guide addresses the chain of evidence between incoming powder and a finished porous article. It does not claim biological equivalence, clinical efficacy or suitability for a load-bearing indication.

References and evidence boundaries

[1] FDA. Component and Device Documentation Examples for Test Articles or Previously Marketed Devices. Biocompatibility Assessment Resource Center. Official FDA resource. Based on Attachment F of the September 2023 guidance; device-specific applicability remains with the manufacturer.

[2] Nair M, Shepherd JH, Best SM, Cameron RE. MicroCT analysis of connectivity in porous structures: optimizing data acquisition and analytical methods in the context of tissue engineering. J R Soc Interface. 22 April 2020;17:20190833. doi:10.1098/rsif.2019.0833. Imaging-method evidence, not a validated scan setting for every ceramic.

Sources checked 30 October 2026. Research planning guidance only; no Kannrybio lot-performance, clinical or regulatory-approval claim.

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