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Narrative Review

Beyond grinding: How metal additive manufacturing could redefine nickel-titanium rotary instrument engineering in endodontics

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Abstract

Nickel-titanium (NiTi) rotary instruments transformed endodontic shaping by combining flexibility, superelasticity, and improved preservation of canal curvature. The earliest endodontic NiTi file study showed substantially greater flexibility than stainless steel instruments. Subsequent work established that shaping outcomes depend on canal anatomy, instrument design, and clinical technique. During the past three decades, instrument innovation has focused on thermomechanical treatment, cross-sectional refinement, motion control, and surface finishing. Heat-treated alloys and controlled-memory instruments have improved flexibility and cyclic fatigue resistance. However, most commercially available instruments continue to be produced from cylindrical wire blanks using subtractive or near-subtractive manufacturing processes. This review examines metal additive manufacturing as a potential next engineering paradigm for NiTi rotary instrument design. Metal additive manufacturing can build complex metallic structures directly from digital three-dimensional models. Laser powder bed fusion (LPBF) has already been explored for superelastic NiTi endodontic self-adjusting file structures. The central argument is that additive manufacturing should not be regarded merely as another production method for existing file designs. Its greater importance lies in expanding the design space toward hollow cores, lattice architectures, functionally graded stiffness, adaptive canal-contact surfaces, and patient-specific geometries. Translation will require addressing hurdles such as resolution control, surface finishing, reproducible phase transformation behavior, fatigue reliability, corrosion resistance, and regulatory validation. Nevertheless, additive manufacturing may shift future endodontic instrument innovation from incremental alloy and flute modifications toward digitally engineered, anatomy-responsive NiTi systems.

Keywords: additive manufacturing; cyclic fatigue; laser powder bed fusion; metal 3D printing; nickel-titanium; rotary instrumentation; shape-memory alloy

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Introduction

Nickel-titanium (NiTi) alloys transformed endodontic instrumentation by introducing a material with mechanical behavior that was better matched to curved root canal anatomy than stainless steel. Nitinol root canal files were substantially more flexible than comparable stainless steel instruments (Walia et al., 1988). This advantage reflects the lower elastic modulus and superelastic behavior of NiTi, which permit instruments to negotiate curved canals with less permanent deformation (Thompson, 2000). The clinical value of this material shift lies in canal preservation. Shaping outcomes depend on anatomy, instrument design, working length, apical enlargement, and technique (Peters, 2004). Procedural errors such as transportation, ledging, zipping, and perforation are particularly relevant when instrument stiffness forces preparation away from the original canal path (Gambill et al., 1996; Pettiette et al., 1999; Van der Vyver et al., 2019; Teerawanitsan et al., 2025). Although contemporary NiTi instrumentation enabled more efficient canal enlargement, it did not eliminate procedural risk (Savitha et al., 2022; Grande et al., 2023).

Subsequent progress in rotary instrumentation occurred through increasingly refined metallurgical, geometric, kinematic, and surface-engineering strategies. Contemporary systems differ in alloy processing, thermomechanical treatment, cross-sectional design, taper, pitch, and motion (Zanza et al., 2021). Heat-treated and proprietary NiTi alloys can improve flexibility, cyclic fatigue resistance, and angle of deflection at failure compared with conventional NiTi instruments (Zupanc et al., 2018; Tabassum et al., 2019). Controlled-memory instruments further illustrate how phase constitution and heat treatment influence mechanical behavior and clinical handling (Shen et al., 2013). These advances are clinically important because instrument separation can occur through cyclic fatigue, torsional overload, or combined mechanisms (Cheung, 2009).

Despite these improvements, most NiTi rotary instruments are still produced from cylindrical wire or rod blanks by subtractive or near-subtractive processes. These processes include grinding, machining, twisting, electrical discharge machining, electropolishing, and thermal treatment (Chien et al., 2022; Zupanc et al., 2018). This manufacturing route creates a persistent design boundary. Changes in taper, flute depth, helical angle, pitch, radial lands, offset rotation, and cross-section can modify performance. Nevertheless, the instrument must still be generated by removing or reshaping material from a preformed blank. As a result, contemporary file engineering is governed by linked trade-offs: increasing flexibility may reduce torsional strength, increasing core diameter may reduce bending compliance, and improving one mechanical property can create vulnerability in another (Cheung, 2009). Surface integrity is also important because machining grooves, residual stresses, and microscopic defects can serve as crack-initiation sites during cyclic loading in curved canals (Chan et al., 2022; Thompson, 2000). Recent work on NiTi surface modification reinforces that surface engineering can improve performance, yet it still operates within the same wire-based design envelope (Agrawal et al., 2024).

Metal additive manufacturing offers a different manufacturing logic. Instead of removing material from a blank, additive manufacturing builds structures layer by layer from digital three-dimensional models (Gibson et al., 2021; Zhou et al., 2024). Reviews of metal additive manufacturing emphasize that this approach enables complex geometries and internal architectures that are difficult to obtain using conventional manufacturing (Herzog et al., 2016). Dentistry is already adopting additive manufacturing for multiple applications (Ebrahimi et al., 2026). For endodontic instruments, the potential importance is not reproduction of existing file designs, but expansion of the design space toward hollow cores, lattice-reinforced shafts, regionally graded stiffness, adaptive canal-contact surfaces, and internal pathways for irrigation or debris movement. These concepts are compelling because metallic additive manufacturing links digital geometry to process-structure-property

relationships governed by laser energy input, thermal history, melt-pool behavior, microstructure, residual stress, porosity, and defects (DebRoy et al., 2018).

Nickel titanium alloy is an attractive but demanding candidate for this approach. Additive manufacturing of titanium-based alloys has already been investigated. However, NiTi introduces additional difficulties because transformation behavior is highly sensitive to composition, oxygen uptake, porosity, residual stress, precipitates, and post-processing history (Tshephe et al., 2022). Reviews of NiTi additive manufacturing emphasize the challenge of controlling chemical composition, transformation temperatures, functional superelastic behavior, and defect populations during printing (Elahinia et al., 2016; Dzogbewu & de Beer, 2023). Heat-treatment studies of NiTi fabricated by laser powder bed fusion (LPBF) from elemental powders further show that chemical and phase homogeneity, oxygen control, and secondary phases can determine whether a printed component achieves useful functional properties (Chmielewska et al., 2022). These issues are especially severe for endodontic instruments because files are miniature, slender, fatigue-sensitive, and subjected to repeated flexural and torsional stresses in chemically aggressive clinical environments.

The strongest direct evidence connecting additive manufacturing to endodontic instrumentation is the LPBF fabrication study of superelastic NiTi self-adjusting file structures. Pre-alloyed NiTi powder was used to investigate resolution factors for manufacturing superelastic instruments for root canal treatment (Chernyshikhin et al., 2022). The authors identified apparatus, software, and resolution constraints that affect miniature NiTi file production. That study is important because it moves the field beyond speculation. Metal 3D printing of endodontic NiTi structures is feasible. However, translation depends on whether printed instruments can meet the mechanical, metallurgical, dimensional, and surface-quality demands of clinical use.

This review examines how metal additive manufacturing may affect the future of endodontic NiTi rotary instrument engineering. It first traces the evolution of NiTi instruments from material substitution to metallurgical optimization, geometric refinement, motion control, and surface engineering. It then summarizes metal additive manufacturing principles and the specific difficulties of printing NiTi shape-memory alloys. The final sections evaluate AM-enabled instrument architectures, scientific and clinical barriers to translation, and research priorities required before printed NiTi instruments can be considered clinically realistic. The article is a narrative review and perspective. The literature was selected to clarify engineering concepts, translational barriers, and research priorities, and not to provide a systematic evidence synthesis.

Why Conventional NiTi Instrument Engineering Has Reached a Manufacturing Boundary

The transition from stainless steel to NiTi established flexibility and superelastic recovery as central requirements for shaping curved canals. The stress- and temperature-dependent transformation behavior that gives NiTi its superelastic and shape-memory properties is summarized in Figure 1. Conventional NiTi instruments improved canal preservation but they also introduced a new design problem. That is, instruments must remain flexible in curvature and strong enough to resist fatigue and torsional overload during rotation.

The first generation of NiTi instruments solved much of the stiffness problem of stainless steel but exposed fatigue and torsional limitations (Bayram & Bayram, 2026). Continuous rotation subjects a file to repeated tensile and compressive strain as it rotates inside a curved canal. Pruett et al. (1997) established curvature angle and radius as major determinants of cyclic fatigue life. Ferreira et al. (2017) further showed that motion kinematics influence fatigue

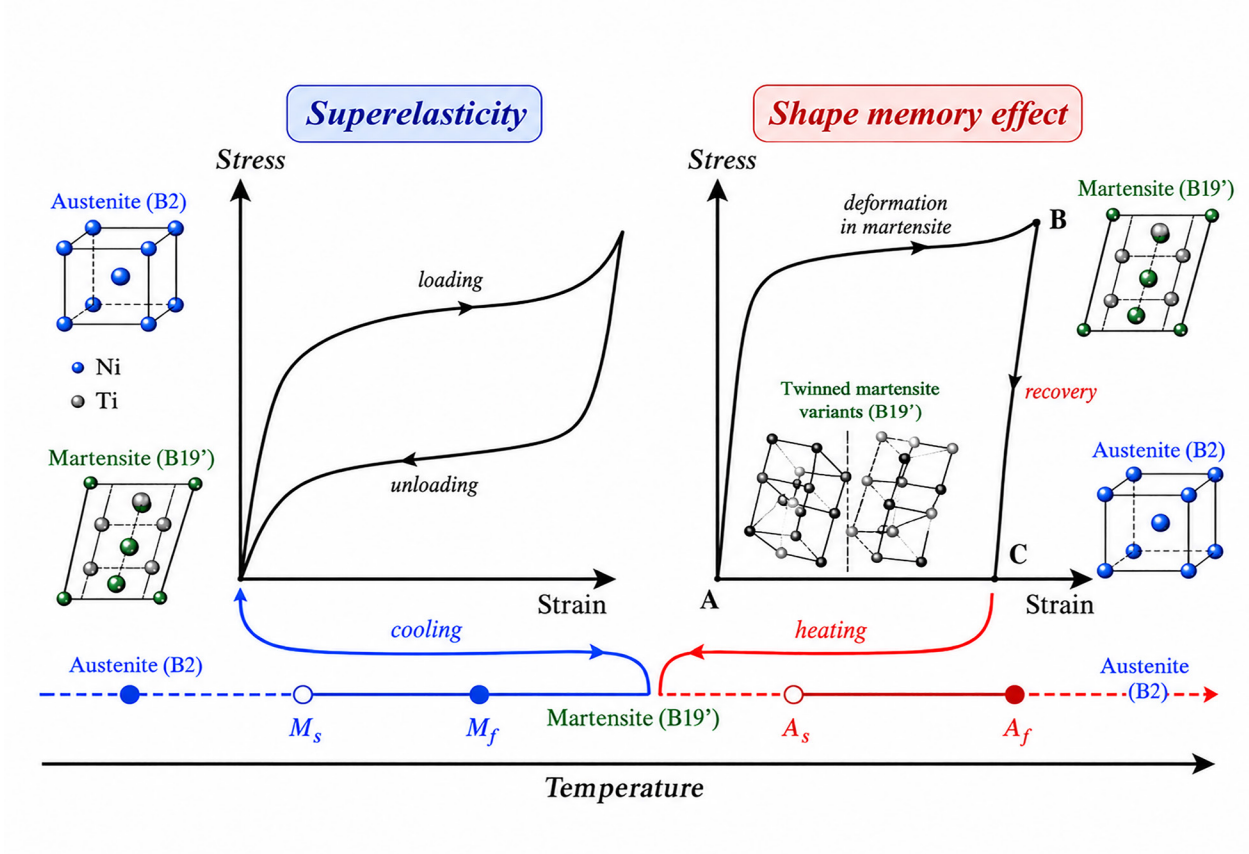


Fig. 1. Stress- and temperature-dependent phase transformation behavior of NiTi.
Schematic illustration of the two principal functional responses of NiTi alloys. In the superelastic condition, NiTi is in the austenitic B2 phase above the austenite finish temperature. Mechanical loading induces transformation to B19′ martensite, and unloading permits reverse transformation to austenite, producing recoverable strain. In the shape memory effect, deformation occurs in martensite below the martensite finish temperature. Twinned martensite variants reorient into detwinned martensite during loading and remain deformed after unloading. Heating above the austenite finish temperature drives reverse transformation to B2 austenite and restores the original shape. Af, austenite finish temperature; As, austenite start temperature; Ms, martensite start temperature; Mf, martensite finish temperature.

resistance, confirming that fracture is not simply an alloy property. Torsional overload occurs when the file tip binds against dentin but the shank continues to rotate. Instrument separation may therefore involve cyclic fatigue, torsional overload, or combined mechanisms (Cheung, 2009). A systematic review by Yon et al. (2021) reinforced that defects and safety concerns in NiTi instruments remain clinically relevant despite decades of design improvement.

Subsequent innovation focused on thermomechanical treatment (Yum et al., 2025). M-Wire, controlled-memory wire, Gold-treated alloys, Blue-treated alloys, and other proprietary treatments were developed to alter phase constitution, transformation temperature, residual stress, and flexibility. Otsuka and Ren (2005) described the physical metallurgy of NiTi as a system governed by reversible transformation among B2 austenite, B19′ martensite, and, in some conditions, the R phase. Duerig and Bhattacharya (2015) emphasized that the R phase can strongly influence superelastic response. These materials science principles were translated into endodontic instruments through heat-treated alloys with greater martensitic character, improved flexibility, and increased resistance to cyclic fatigue (Zupanc et al., 2018). Shen et al. (2013) showed that controlled-memory instruments differ metallurgically from conventional superelastic NiTi. Ye and Gao (2012) demonstrated that M-Wire undergoes microstructural change during low-cycle fatigue.

These studies explain why instruments made from the same nominal alloy may behave differently. Performance depends on processing history, phase state, and temperature, not alloy name alone.

However, thermomechanical improvement has not removed the underlying manufacturing constraint. Most NiTi instruments continue to begin as cylindrical wire or rod blanks. Chien et al. (2022) characterized wire types used for rotary instrument manufacture, emphasizing that file production continues to be anchored in wire-based material forms. Conventional instruments are then shaped by grinding, machining, twisting, electrical discharge machining, electropolishing, heat treatment, or combinations of these procedures (Zupanc et al., 2018). Each method can improve one aspect of performance, but the instrument is limited by the need to create flutes and tapers from a preformed blank. Twisting R-phase wire may reduce some grinding-related damage. Electrical discharge machining can create a different surface and geometry. Heat treatment can improve flexibility. Yet these strategies still modify a wire-derived structure; they do not allow free design of the instrument architecture.

Geometry and kinematics represent the next level of optimization within the same boundary. Contemporary rotary instrument systems differ in cross-section, taper, pitch, helical angle, rake angle, radial lands, offset rotation, and reciprocating or adaptive motion (Grande et al., 2023; Zanza et al., 2021). These modifications are clinically significant because they influence cutting efficacy, canal centering, screw-in tendency, debris removal, cyclic fatigue, and torsional resistance. Nevertheless, every geometric change creates a trade-off. Increasing core diameter may improve torsional resistance but reduce bending flexibility. Reducing metal mass may improve fatigue resistance but compromise torsional safety. Increasing cutting efficiency may increase engagement and taper lock. Reciprocation may reduce fatigue accumulation and torsional stress, but it does not change the basic architecture of the instrument (Ferreira et al., 2017). Despite these modifications, the file remains as an externally machined or shaped structure generated from a solid wire.

Surface engineering has improved the same platform but has not changed it. Grinding marks, machining grooves, surface microcracks, residual stresses, inclusions, and other defects can serve as crack-initiation sites during clinical loading (Chan et al., 2022). Surface treatments, electropolishing, ion implantation, coatings, and functionalization strategies may reduce defects, improve corrosion behavior, or alter cutting performance (Agrawal et al., 2024). Although these approaches are important, they still operate on the external surface of a conventionally manufactured instrument. They cannot create internal channels, hollow regions, lattice-reinforced shafts, local stiffness gradients, or region-specific architectures.

This is the manufacturing boundary now facing NiTi instrument engineering. The field has optimized alloy state, surface condition, cross-sectional geometry, taper, and motion with considerable success. Nevertheless, most advances are confined to modifications of a solid wire-derived file. Additive manufacturing is important because it may remove this boundary. It could permit internal architecture, spatially graded stiffness, hollow or lattice cores, anatomy-responsive flexibility, and integrated pathways for irrigation or debris movement. The central question is therefore not whether metal additive manufacturing can reproduce NiTi files. The more important question is whether it can create instrument architectures that conventional wire-based manufacturing cannot produce.

Metal Additive Manufacturing Technologies Relevant to NiTi

Metal additive manufacturing includes processes that fabricate three-dimensional metallic components from digital models. For NiTi shape-memory alloys, the most relevant methods include LPBF, electron beam melting, directed energy deposition, wire arc additive manufacturing, binder-based or sinter-based methods, and fused filament fabrication (Setiawan et al., 2026) (Figure 2). These approaches differ in energy source, feedstock, resolution,

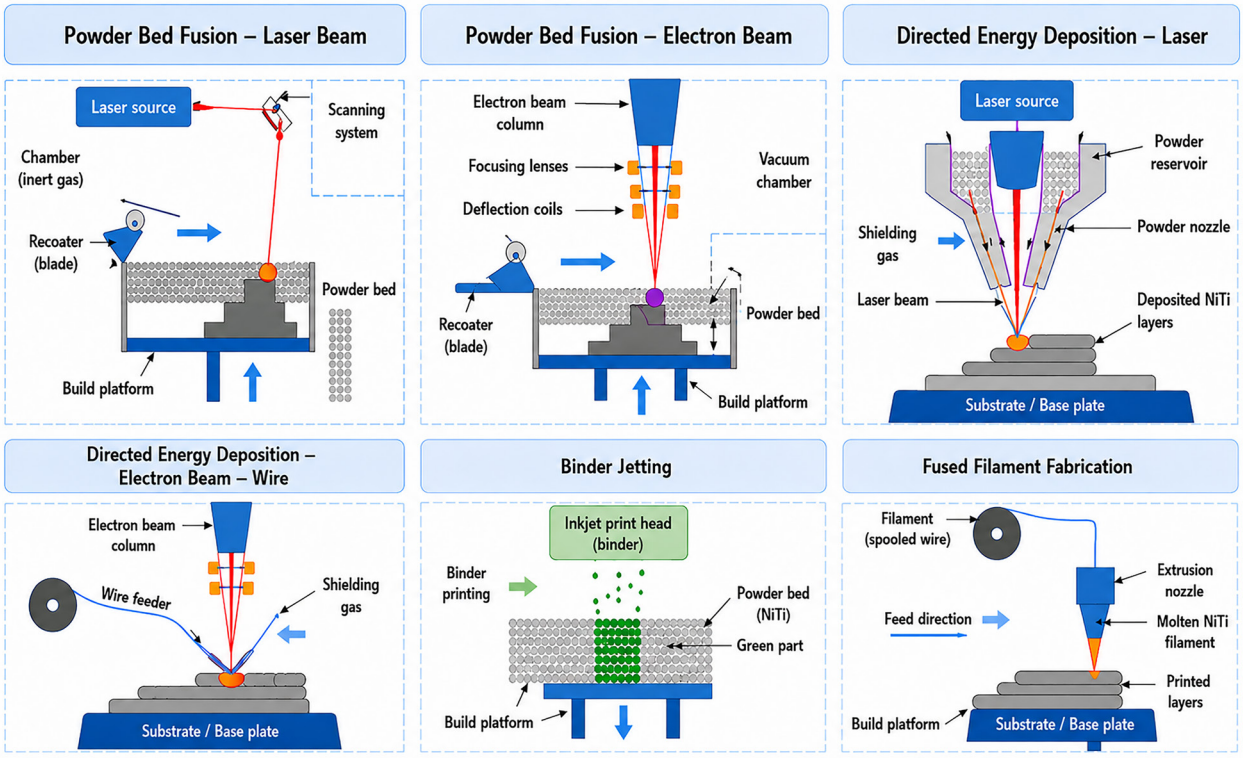


Fig. 2. Schematic comparison of additive manufacturing methods used for fabrication of NiTi shape memory alloy components. The illustrated processes include powder bed fusion using a laser beam, powder bed fusion using an electron beam, directed energy deposition using a laser, directed energy deposition using an electron beam with wire feed, binder jetting, and fused filament fabrication. Each method differs in energy source, feedstock form, resolution, and post-processing requirements, which in turn influence densification, geometric complexity, surface quality, and the functional behavior of printed NiTi parts. Among these methods, powder bed fusion is generally the most suitable for producing fine, intricate NiTi structures, whereas directed energy deposition is more applicable to larger components, and binder jetting and fused filament fabrication require subsequent debinding and/or sintering. All of these approaches have the potential to produce NiTi shape memory alloy components, but the final properties depend strongly on process parameters and post-processing.

surface quality, density, and post-processing demands (Kubášová et al., 2024). For miniature endodontic instruments, the most important selection criteria are dimensional accuracy, thin-wall resolution, surface quality, defect control, and reproducible phase transformation behavior.

Dzogbewu and de Beer (2023) identified LPBF as the dominant and most widely investigated additive manufacturing method for NiTi because it offers favorable geometric precision, densification, and functional property control compared with other routes. In LPBF, a thin layer of metal powder is spread over a build platform, and a laser selectively melts regions defined by the digital model. The process is repeated layer by layer until the three-dimensional component is completed (Chowdhury et al., 2022) (Figure 3A). For NiTi, this apparently simple layer-by-layer process is complicated by melt-pool phenomena, including metal circulation, vapor formation, recoil pressure, and local redistribution of nickel and titanium before solidification (Rangaswamy et al., 2026) (Figure 3B). Nevertheless, this manufacturing process is especially attractive for miniature endodontic devices because laser power, scan speed, hatch spacing, layer thickness, build orientation, and scan path can all be adjusted to influence both geometry and microstructure (Adekanye et al., 2026).

Electron beam melting is also a powder bed fusion process but uses an electron beam under vacuum instead of a laser (Palmquist et al., 2023). It can produce NiTi components and has advantages such as vacuum processing, reduced oxidation, and lower residual stress due to elevated build temperatures. However, its larger beam size and larger melt pool generally reduce feature resolution. Electron beam

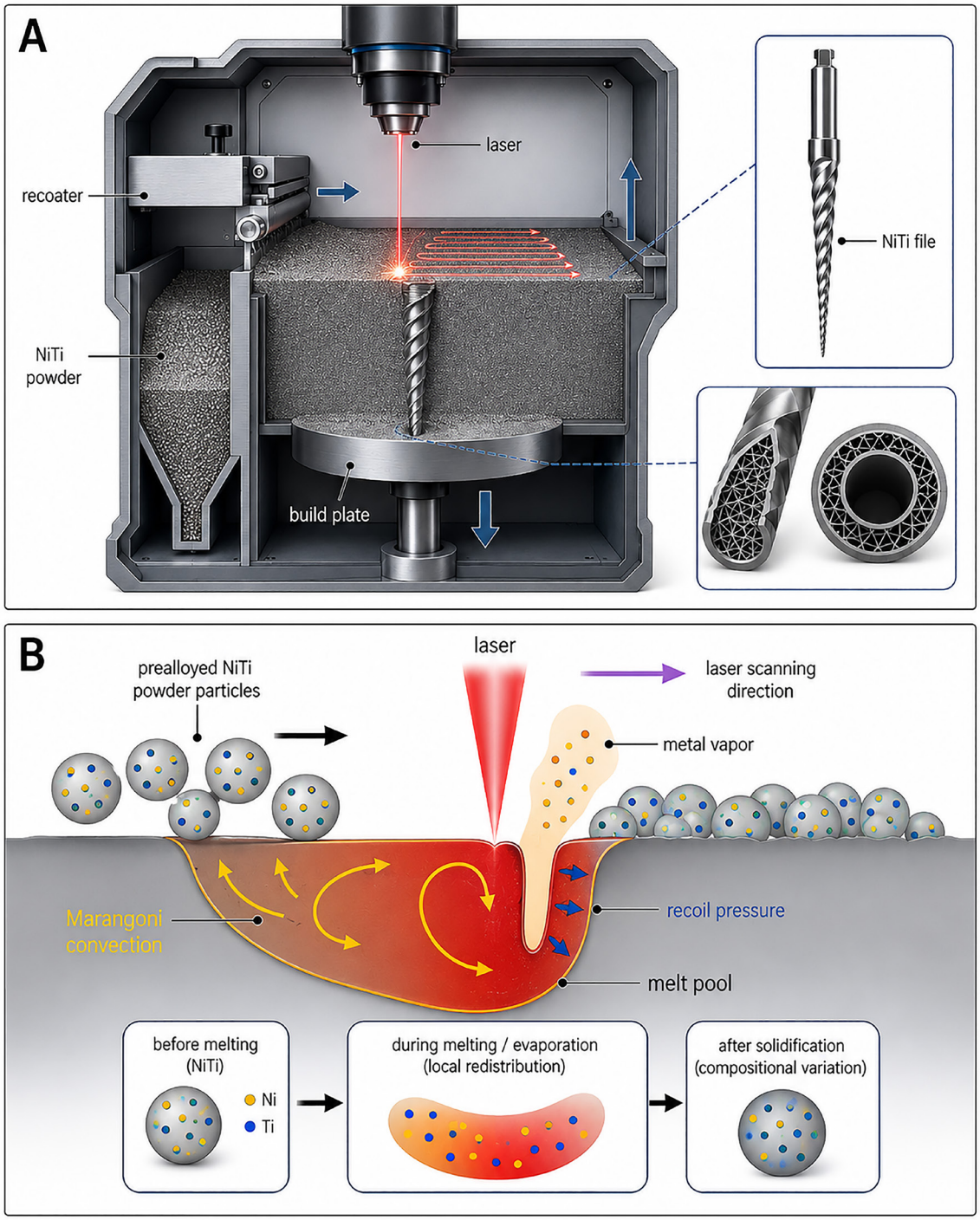


Fig. 3. Laser powder bed fusion of NiTi endodontic instruments and melt-pool phenomena that influence printed NiTi properties. (A) Conceptual overview of laser powder bed fusion fabrication of a NiTi endodontic instrument. A recoater spreads NiTi powder over the build plate, and a focused laser selectively melts the powder according to a programmed scan path. Layer-by-layer melting can generate a printed NiTi file with architectures that are difficult to produce by wire grinding, including hollow cores and lattice-reinforced regions. (B) Schematic representation of local melt-pool behavior during laser powder bed fusion of NiTi. The laser creates a small molten region, or melt pool, within the NiTi powder bed. This melt pool may be imagined as a tiny liquid puddle of metal. Within it, molten metal circulates because of surface-tension-driven flow, known as Marangoni convection. At the laser interaction zone, intense heat may also generate metal vapor, and this vapor can push back against the liquid metal as recoil pressure. These melt-pool events can redistribute nickel and titanium before solidification, causing local compositional variation and microstructural heterogeneity. This is especially important for NiTi because even small changes in nickel-titanium balance or thermal history can alter transformation temperature, superelasticity, fatigue resistance, and clinical performance. Thus, successful fabrication of printed NiTi instruments requires control of the external file shape as well as the microscopic melt-pool behavior that determines the final material properties.

melting is less suited to highly intricate geometries because it has lower geometric precision and may require more post-processing (Dzogbewu & de Beer, 2023). This limitation is important because endodontic file architecture requires fine cutting edges, thin walls, narrow spaces, and controlled surface quality.

Directed energy deposition uses a focused thermal source to melt powder or wire as material is deposited. It is useful for repair, cladding, larger components, and functionally graded structures. However, it has lower feature resolution than LPBF and is not well suited for thin endodontic microfeatures (Dzogbewu & de Beer, 2023). Wire arc additive manufacturing is best regarded as a subtype of directed energy deposition because it uses wire feedstock and an arc heat source. Wire arc additive manufacturing has lower dimensional precision and lower geometric accuracy than LPBF, electron beam melting, and directed energy deposition. For that reason, wire arc additive manufacturing is relevant to the broader NiTi additive manufacturing landscape, but it is unlikely to be a practical route for rotary endodontic files.

Binder jetting and fused filament fabrication belong to the sinter-based family of additive manufacturing. Binder jetting deposits a binder into a powder bed, followed by debinding and sintering. Fused filament fabrication uses metal-polymer filament, followed by debinding and sintering. These methods offer lower equipment cost and larger build volume. However, shrinkage, porosity, impurity uptake, and transformation-temperature control are major concerns for NiTi. Abel et al. (2021) showed that fused filament fabrication may be used to produce NiTi components and can be hybridized with LPBF to add filigree structures. However, the authors also emphasized that LPBF is the method of choice for small, filigree, and geometrically complex NiTi features. For endodontics, fused filament fabrication is therefore best considered a complementary or hybrid route, and not the primary method for manufacturing the active cutting portion of a miniature rotary file.

Direct evidence for endodontic application comes from the LPBF study of superelastic NiTi self-adjusting file structures. Chernyshikhin et al. (2022) used pre-alloyed NiTi powder with a 15–45 µm particle fraction and an LPBF system with a 55 µm nominal laser spot diameter to fabricate thin-wall and self-adjusting file samples. Their optimized condition used 100 W laser power, 850 mm/s scanning speed, and 20 µm layer thickness for producing self-adjusting file structures with the required resolution (Figure 4). The authors also identified physical, apparatus-related, and software-related limits to LPBF resolution. This study establishes LPBF as the most credible near-term route for miniature NiTi endodontic devices. However, it also shows that printing file-like structures requires device-specific process optimization.

Additive manufacturing of NiTi alloys

Nickel-titanium is more difficult to print than conventional structural metals because its value depends on reversible martensitic transformation. A dense printed part is not sufficient. The part must also have the intended transformation temperature, superelastic recovery, fatigue resistance, surface integrity, corrosion resistance, and wear behavior. Selective laser melting (SLM), a term previously employed for LPBF, creates a unique microstructure because the material experiences rapid melting, solidification, repeated reheating, steep thermal gradients, and local chemical changes. These features directly influence phase transformation behavior and functional properties.

Composition control is the first major challenge. Nickel-titanium transformation temperatures are highly sensitive to the Ni/Ti ratio. Small changes in nickel content may shift the martensitic and austenitic transformation temperatures enough to alter whether the printed component behaves as austenite, martensite, or mixed phase at clinical temperature. Wang et al. (2018) noted that nickel evaporation, oxygen uptake, precipitate formation, residual stress, dislocation density, and microstructural heterogeneity can all influence transformation behavior. This is highly relevant to endodontic files because flexibility and recoverable

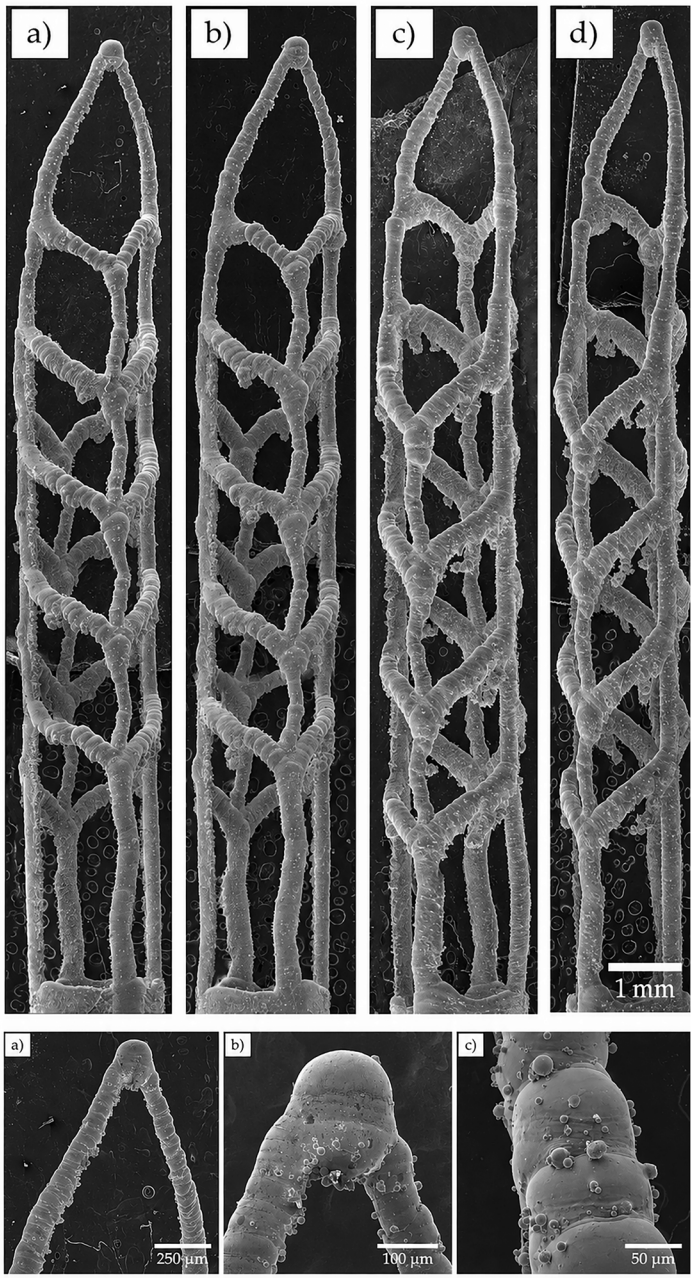


Fig. 4. Laser powder bed fusion fabrication of NiTi self-adjusting file structures and associated surface features. A. Scanning electron microscopy images of 3D-printed self-adjusting file structures fabricated using four LPBF processing regimes. The processing code indicates laser power and scanning speed; for example, P100V850 denotes 100 W laser power and 850 mm/s scanning speed. The four regimes shown are a) P100V850 (100 W, 850 mm/s; linear energy density approximately 0.12 J/mm), b) P150V1100 (150 W, 1100 mm/s; approximately 0.14 J/mm), c) P100V400 (100 W, 400 mm/s; approximately 0.25 J/mm), and d) P50V200 (50 W, 200 mm/s; approximately 0.25 J/mm). The P100V850 condition was identified as the optimal regime for fabricating single-track self-adjusting file structures, using a 20 µm layer thickness. The P150V1100 condition also produced a file-like structure, whereas the lower scanning-speed regimes, P100V400 and P50V200, showed lower resolution and more pronounced surface agglomeration. The original study defined low-resolution regimes as those producing upper strut diameters greater than 150 µm and attributed the poor resolution at low scanning speeds to longer melt-pool lifetime and increased powder-particle retraction into the melt pool. B. Higher-magnification views of the P100V850 specimen showing a) the upper file region, b) the tip, and c) the strut surface. These images illustrate typical high-resolution LPBF surface features, including layer-by-layer striations, adhered powder particles, local tip thickening, and irregular strut surfaces. These surface irregularities are important because they become more influential as the printed NiTi structure approaches the dimensional limit required for miniature endodontic file fabrication. [Reproduced from Chernyshikhin et al. (2022) under the Creative Commons Attribution 4.0 International License].

deformation depend on the phase state of the file during clinical use.

Elementally blended Ni and Ti powders are more difficult to control because alloy formation occurs during printing, increasing the risk of chemical heterogeneity, oxygen contamination, and brittle secondary phases. Chmielewska et al. (2022) fabricated NiTi by LPBF from blended Ni and Ti powders and showed that the as-built material contained chemical and phase heterogeneity. Heat treatment improved homogeneity, but oxygen pickup promoted oxygen-stabilized secondary phases, including $Ni2Ti_4O$. The authors found that two-step heat treatment improved chemical and phase homogeneity, but oxygen control continued to be a major concern. For printed endodontic instruments, this finding highlights the importance of careful powder selection, strong atmospheric control, and validation of phase homogeneity along the active file portion.

Feature size is another important variable. Qu et al. (2023) showed that process optimization based on bulk cubes, cylinders, or dog-bone specimens may not predict the behavior of thin, intricate NiTi structures. Their high-precision LPBF study used a 25 µm beam, 0–25 µm powder, and 10 µm layer

thickness. Triply periodic minimal surface (TPMS) is a smooth three-dimensional lattice architecture that repeats in all spatial directions and may be used to create lightweight structures with continuous pores and controlled mechanical behavior (Hossain et al., 2025). When the wall thickness of gyroid TPMS (G-TPMS) structures decreased below 130 μm, the optimum volumetric energy density decreased from 167 J/mm³ to 140 J/mm³ (Qu et al., 2023) The result indicates that thin lattice features require process parameters different from those used for bulk specimens. This finding is directly relevant to endodontics because a printed file may contain thin flutes, narrow struts, lattice regions, hollow cores, and small tips that experience different thermal histories during printing.

Scan strategy must also be treated as a functional design variable. Andani et al. (2026) compared 45°, 67°, 90°, island, and hexagonal scan strategies in LPBF-fabricated NiTi with consistent energy input. The 90° rotation strategy produced a strong <001> fiber texture, approximately 6% superelastic recovery, and minimal plastic strain. The use of island and hexagonal strategies reduced transformation onset stress but produced incomplete recovery because austenite finish temperatures increased to approximately 32–34 °C. This finding is central to printed NiTi file design because laser trajectory can alter texture, residual stress, transformation temperature, and superelastic recovery without changing the nominal alloy composition.

Post-print conditioning may become part of the manufacturing process for future NiTi endodontic instruments. Zhang et al. (2025) showed that mechanical training (pre-strain/cyclic compression treatment) of LPBF-fabricated Ni-rich NiTi produced a nearly twofold improvement in wear resistance. The specimens were first compressed to 9% strain, and then subjected to 15 compression cycles at the same compressive strength. This treatment modified dislocation structures and improved martensitic transformation behavior, cyclic compression superelasticity, and adhesion stress during wear. Although the authors did not study endodontic files, the concept is highly relevant because rotary instruments contact canal walls repeatedly and are exposed to friction, cutting stress, cyclic bending, torsional engagement, irrigants, and sterilization. A future printed NiTi file may therefore require a complete process chain: powder specification, LPBF parameter selection, scan strategy, heat treatment, surface finishing, mechanical training, sterilization validation, and fatigue testing.

The variables that determine the behavior of printed NiTi instruments may be organized as a process–structure–property chain, in which powder chemistry, LPBF parameters, scan strategy, post-processing, and surface finishing jointly influence transformation behavior and clinical performance (Table 1).

Current applications of printed NiTi and implications for endodontics

Printed NiTi has attracted attention in biomedical, aerospace, actuator, and functional-device applications because it combines shape-memory behavior, superelasticity, damping, low modulus, and geometric freedom (Dzogbewu and de Beer, 2023). However, the requirements for a rotating endodontic file are more severe than those for many larger implants or actuators.

Biomedical applications provide the closest translational analogy. Sun et al. (2024) evaluated an LPBF-fabricated NiTi alloy with high tensile performance and reported tensile strain of approximately 15.6% and tensile strength of approximately 700 MPa. Their in vitro study also found favorable biocompatibility and bioactivity compared with Ti-6Al-4V alloy. This finding is encouraging because it links printed NiTi to biological performance. However, endodontic translation would require additional testing in NaOCl, EDTA, repeated sterilization cycles, simulated canal curvature, torsional binding, cutting contact, and cyclic fatigue resistance.

Miniature and flexible medical devices are especially relevant. Qu et al. (2023) fabricated a robotic cannula tip by high-precision LPBF and

demonstrated recovery after bending greater than 90° at room temperature. The endodontic significance is that thin, functional NiTi architectures may be printed when feature size, energy density, and superelastic behavior are optimized together. This is best illustrated by the printing of NiTi self-adjusting file structures by Chernyshikhin et al. (2022).

Wear-resistant applications also provide lessons for rotary instruments. Zhang et al. (2025) showed that LPBF NiTi wear behavior can be improved through mechanical training. This is important because future printed endodontic NiTi rotary instruments will not function as passive implants. They will rotate, cut, abrade against canal walls, accumulate cyclic strain, and contact irrigants. Mechanical training, surface finishing, and post-print heat treatment should therefore be evaluated as part of a manufacturing workflow.

The current evidence indicates that LPBF is capable of fabricating intricate NiTi structures, miniature file-like architectures, and flexible superelastic components. The next research question should therefore be more demanding than whether a NiTi file can be printed. The clinically relevant question is whether additive manufacturing can create a file architecture with safer fatigue behavior, controlled torsional response, predictable cutting, reproducible phase transformation, and better adaptation to canal anatomy than wire-based instruments.

Opportunities for Future Endodontic Instrument Design

Expanded design freedom

The most important opportunity created by metal additive manufacturing is expansion of the instrument design space. The extent of this design

Table 1. Additive manufacturing variables that control printed NiTi instrument behavior.

Variable	Main effect in printed NiTi	Relevance to endodontic instruments
Powder composition	Controls Ni/Ti ratio and transformation temperature.	Determines whether the file behaves as austenitic, martensitic, or mixed-phase at clinical temperature.
Oxygen control	Limits oxide formation and oxygen-stabilized secondary phases.	Reduces brittleness, phase instability, and crack-initiation risk in slender file structures.
Laser power and scan speed	Control melt-pool size, Ni evaporation, density, cooling rate, and microstructure.	Influence dimensional accuracy, phase behavior, and defect formation along the active file portion.
Layer thickness	Controls vertical resolution and layer-by-layer thermal history.	Critical for thin walls, file tips, lattice struts, and fine flute geometry.
Hatch spacing	Affects density, remelting, heat accumulation, and track overlap.	May influence fatigue resistance, torsional safety, and local phase transformation behavior.
Feature size	Alters cooling rate, heat accumulation, and local microstructure in miniature structures.	Requires file-specific parameter optimization because thin flutes, struts, and tips may behave differently from bulk test coupons.
Scan strategy	Controls texture, residual stress, heat distribution, and transformation response.	May permit spatial tuning of flexibility, recovery, and fatigue behavior along different file regions.
Heat treatment	Alters precipitates, residual stress, chemical homogeneity, and transformation temperatures.	Needed to obtain reproducible superelastic or controlled-memory behavior after printing.
Surface finishing	Reduces roughness, adhered particles, layer marks, and surface-connected defects.	Essential for reducing canal-wall friction, crack initiation, and cyclic fatigue vulnerability.
Mechanical training	Applies controlled cyclic deformation after fabrication to condition dislocation structures and martensitic transformation behavior.	May improve cyclic superelastic recovery and wear resistance during repeated canal-wall contact.

Abbreviations: LPBF = laser powder bed fusion; NiTi = nickel-titanium.

Data obtained from Chernyshikhin et al. (2022) for miniature endodontic file resolution and LPBF parameters, Qu et al. (2023) for feature-size-specific energy-density optimization, Andani et al. (2026) for scan strategy and superelastic recovery, Chmielewska et al. (2022) for powder chemistry, oxygen, and heat treatment, and Zhang et al. (2025) for mechanical training and wear resistance.

freedom is illustrated by additively manufactured woven NiTi structures, including tubular, spherical, toroidal, and knotted geometries, which demonstrate how LPBF can produce complex superelastic architectures beyond simple cylindrical forms (Aguilar Vega et al., 2026) (Figure 5)

Conventional rotary files are designed around a solid wire or rod blank. This starting geometry permits changes in taper, flute depth, pitch, helical angle, cross-section, and surface treatment, but does not permit free control of internal architecture. Additive manufacturing changes the design question. Future NiTi instruments would not have to begin as solid cylinders. They could be designed as digitally defined structures in which external cutting geometry, internal architecture, and local mechanical behavior are developed together. This transition from a solid wire-based instrument to a digitally engineered architecture is illustrated in Figure 6.

These design possibilities include hollow cores, lattice-reinforced shafts, controlled wall thickness, internal channels, and region-specific metal distribution. Lattice and cellular structures have already been examined extensively in metal additive manufacturing (Maconachie et al., 2019; Yu et al., 2022; Biffi et al., 2024; Polo et al., 2025). This is because they allow stiffness, mass, energy absorption, and permeability to be adjusted through unit-cell geometry, strut diameter, and porosity. These concepts are relevant to NiTi files because the clinical problem is not simply cutting dentin. The file must enlarge the canal, preserve curvature, resist

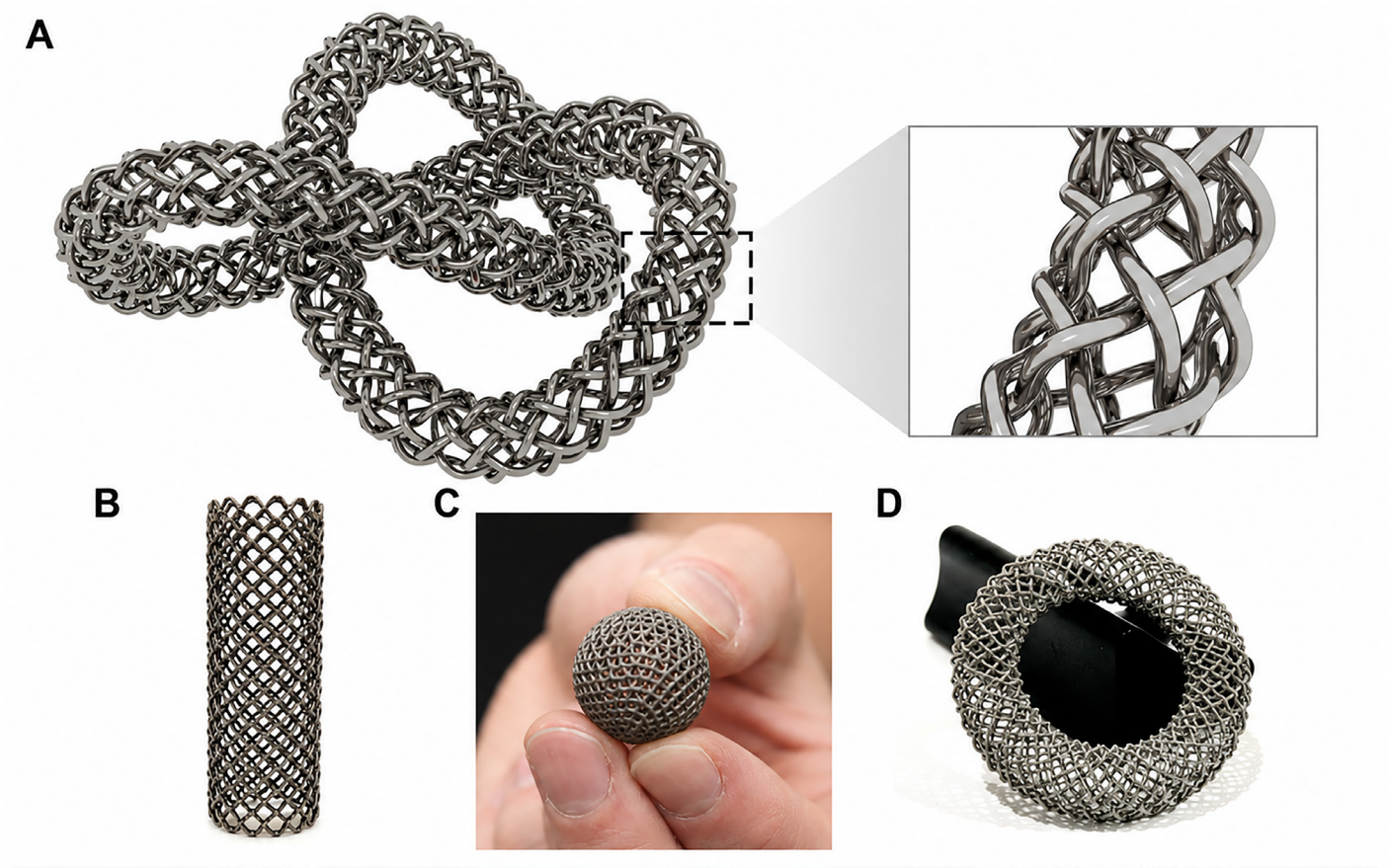


Fig. 5. Representative examples of complex-shaped additively manufactured woven NiTi structures. (A) CAD rendering of a trefoil knotted woven structure with a magnified view showing the interlaced fiber architecture. (B) Printed tubular woven mesh prototype. (C) Printed woven spherical prototype. (D) Printed woven toroidal prototype. Together, these examples illustrate how additive manufacturing can generate shape memory NiTi architectures with complex three-dimensional geometries beyond simple cylindrical lattices, thereby expanding the design space for future adaptive medical and endodontic devices. The original prototypes were produced with a fiber cross-sectional diameter of approximately 400 μm. [Reproduced from Aguilar Vega et al. (2026) under the Creative Commons Attribution-NonCommercial 4.0 International (CC BY-NC 4.0) license].

torsional binding, tolerate cyclic bending, and avoid excessive dentin removal.

A printed NiTi file could therefore be conceived as an architecture and not simply as an alloy with flutes. The coronal shaft might contain greater metal volume for torsional resistance. The apical portion might incorporate lower metal volume, a hollow center, or a flexible lattice to improve bending compliance. Cutting edges could be placed only where dentin engagement is desired. Non-cutting zones could be designed to reduce screw-in tendency or canal transportation. Internal voids or longitudinal channels could also be explored for debris displacement or irrigant movement. These concepts would require careful validation for clogging, cleaning, strength loss, and manufacturing reproducibility. Although Chernyshikhin et al. (2022) provided the first direct indication that LPBF can fabricate miniature NiTi self-adjusting file-like structures, that work should not be interpreted as evidence that printed rotary files are clinically ready. At present, the literature demonstrates printability of NiTi structures, not validated rotary-file performance.

Functionally graded instruments

Additive manufacturing may also permit functionally graded NiTi instruments. A functionally graded file would not have uniform stiffness, mass distribution, or phase behavior along its length. Instead, the mechanical response could be intentionally varied from the shank to the tip. This concept is attractive because the mechanical demands of a rotary file differ by location. The coronal and middle portions must transmit torque and resist unwinding. The apical portion must negotiate curvature, maintain centering, and avoid transportation. A single homogeneous geometry cannot fully satisfy these competing requirements. This concept is illustrated in Figure 7, in which the coronal portion is designed as a denser load-bearing region, the middle portion provides a transition zone, and the apical portion contains a more open architecture to increase flexibility.

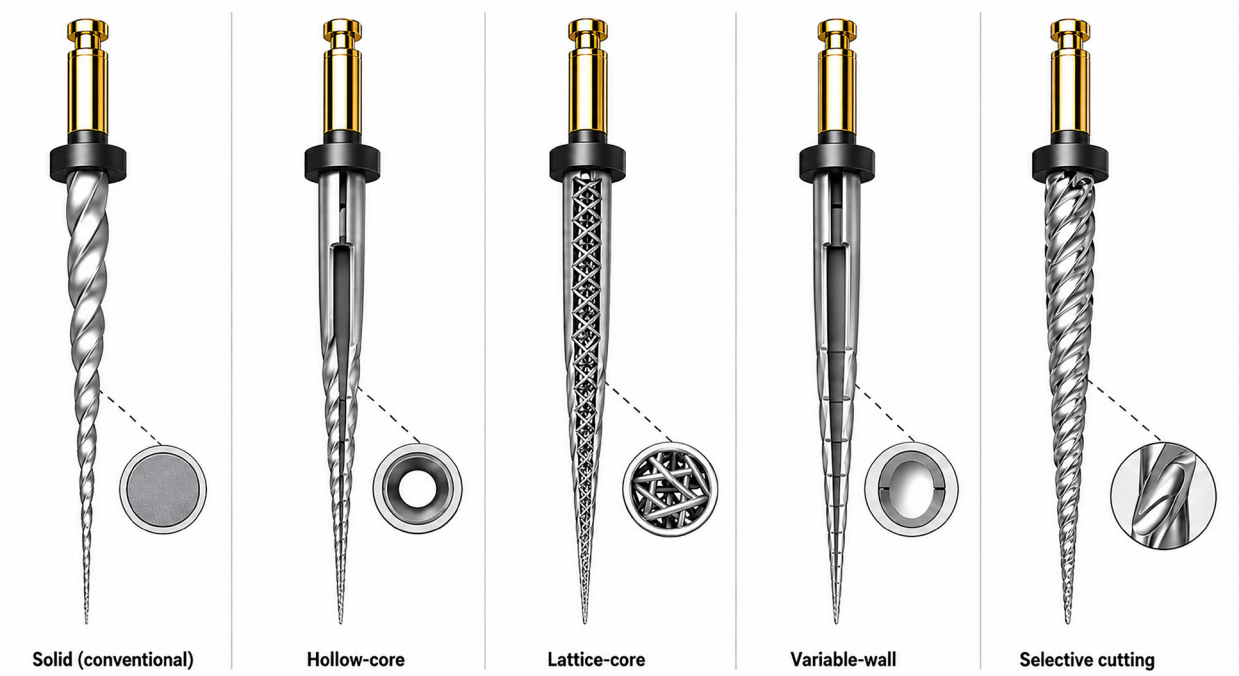


Fig. 6. Expanded design freedom for additively manufactured NiTi endodontic instruments. Conceptual comparison between a conventional solid NiTi rotary instrument and potential additively manufactured designs. Conventional files are derived from solid wire or rod blanks, limiting design control mainly to external flute geometry, taper, cross-section, and surface finishing. Additive manufacturing may permit more complex internal and external architectures, including hollow-core instruments, lattice-core instruments, variable-wall designs, and selectively active cutting regions. These design concepts could allow regional control of flexibility, torsional resistance, canal-wall contact, debris space, and cutting activity. The illustrated architectures are conceptual and require validation for print resolution, surface quality, phase transformation behavior, cyclic fatigue resistance, torsional safety, irrigant compatibility, sterilization stability, and clinical performance.

Functional grading could be achieved in several ways. The simplest approach would be geometric grading. Local core diameter, wall thickness, porosity, lattice density, and unit-cell shape could be varied along the file. A denser coronal lattice could increase torsional stiffness. A more open apical lattice could increase flexibility. A gradual transition between these zones could reduce abrupt stress concentration. Additively manufactured lattice materials are particularly suited to this type of design because mechanical response can be controlled by cellular architecture as well as by the base alloy (Biffi et al., 2024).

A second approach would be process-based grading. Laser parameters, scan path, hatch spacing, layer thickness, and build orientation can influence local thermal history and microstructure. In NiTi, these variables may alter transformation temperatures, texture, residual stress, and superelastic recovery. This creates the possibility of linking geometry-based grading with metallurgical grading. For example, a file could theoretically be designed with regions favoring greater recoverable deformation apically and greater torsional stability coronally. This possibility is scientifically attractive but technically demanding because NiTi phase transformation behavior is highly sensitive to composition, thermal history, and post-processing.

Graded designs would also need to respect the clinical failure modes of NiTi files. Increasing apical flexibility is useful only if torsional safety is preserved. Increasing coronal stiffness is valuable only if stress does not concentrate at the transition zone. The goal should therefore be balanced mechanical gradients, not maximal flexibility at one end and maximal stiffness at the other. Additive manufacturing provides a platform for exploring such gradients systematically.

Adaptive and patient-specific instruments

A further opportunity is the development of adaptive and anatomy-responsive instruments. Root canals vary substantially in curvature, ovality, diameter, isthmus anatomy, and calcification. A single standardized file sequence cannot match every canal form. Additive manufacturing raises the possibility of instruments designed for anatomical categories, canal phenotypes, or, in selected cases, individual anatomy.

The most realistic near-term approach is probably not a unique file for every patient. Individualized production would face cost, sterilization, validation,

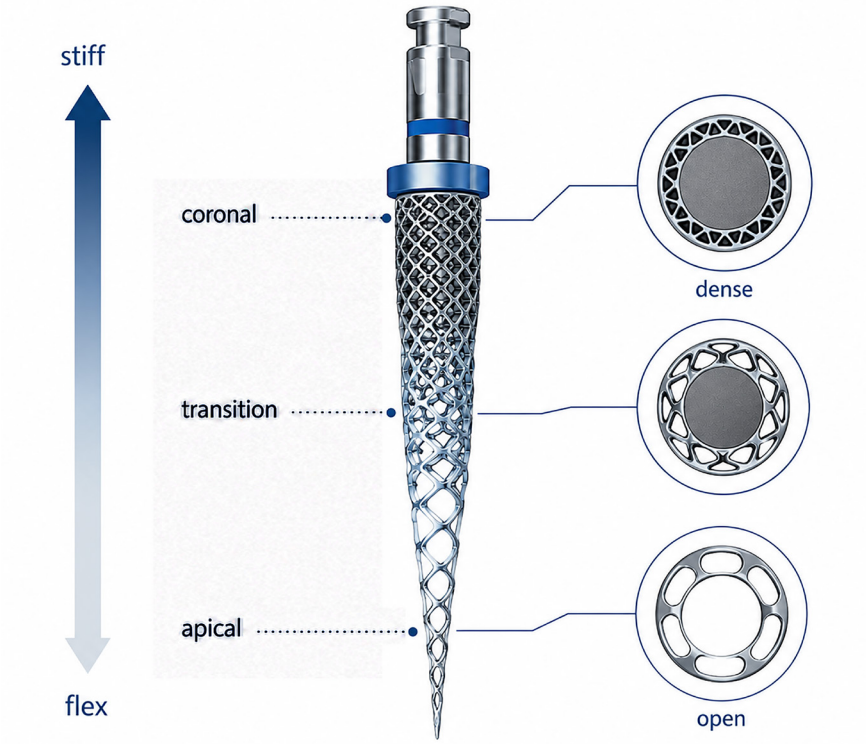


Fig. 7. Functionally graded additively manufactured NiTi endodontic instrument. Conceptual schematic of a printed NiTi instrument with region-specific architecture along its working length. The coronal portion contains a denser lattice architecture to increase stiffness and torque transmission. The middle portion provides a gradual transition in lattice density and wall structure to reduce abrupt stress concentration. The apical portion contains a more open architecture to increase bending compliance and canal-centering ability in curved canals. The cross-sectional insets illustrate progressive architectural changes from dense to open structures. This design concept shows how additive manufacturing could permit regional control of stiffness and flexibility that is difficult to achieve with conventional wire-based grinding.

and regulatory barriers. A more practical pathway would be families of anatomy-responsive instruments. For example, different printed architectures could be developed for severely curved canals, long oval canals, calcified canals, or retreatment situations. Each architecture could be designed around a different balance of flexibility, canal contact, cutting activity, debris displacement, and torsional safety. This concept is illustrated in Figure 8, which shows families of additively manufactured NiTi instruments designed for curved, oval, calcified, and retreatment canals, each emphasizing a different balance of flexibility, canal contact, cutting activity, debris displacement, and procedural safety.

Patient-specific instrument design would require integration of imaging, segmentation, digital modeling, and manufacturing. Cone-beam computed tomography could define broad anatomical constraints, although its resolution is insufficient for full canal microanatomy. Micro-computed tomography is valuable for research but not routine clinical design. Therefore, patient-specific printed files should be regarded as a long-term possibility. The nearer opportunity is anatomy-informed design: using large anatomical datasets to create printed instruments optimized for common canal classes.

Integration of computational design

The full value of additive manufacturing will depend on computational design. Without computation, printed files may simply reproduce shapes that are already familiar. With computation, file architecture

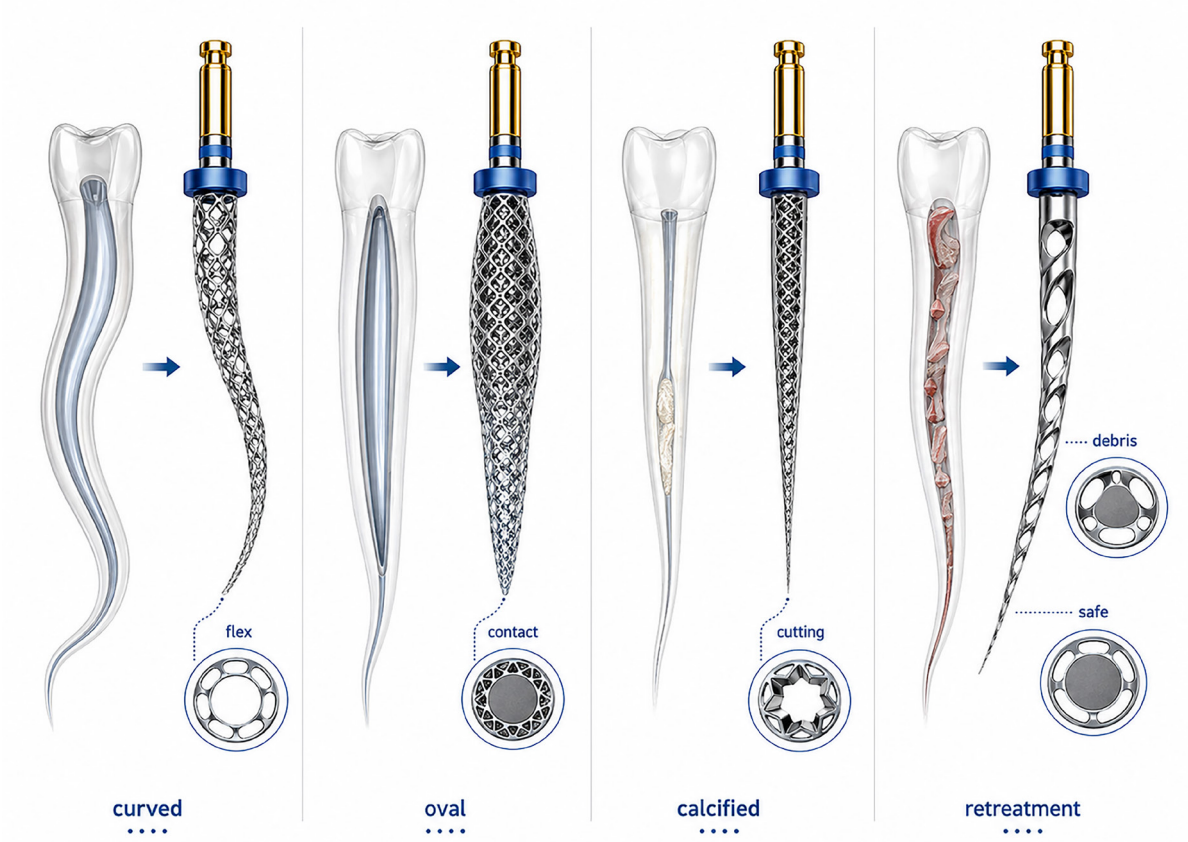


Fig. 8. Conceptual anatomy-responsive families of additively manufactured NiTi endodontic instruments. Schematic illustration of four categories of printed NiTi instruments designed for different clinical canal configurations. The curved-canal design emphasizes flexibility to improve bending compliance and canal-centering ability in severe curvature. The oval-canal design emphasizes broader canal contact to improve engagement of elongated canal walls. The calcified-canal design emphasizes controlled cutting activity to improve penetration through constricted pathways. The retreatment design emphasizes debris displacement and torsional safety to facilitate removal of existing filling materials and reduced risk of instrument overload. The cross-sectional insets represent different internal architectures matched to these clinical objectives. The figure illustrates a practical near-term strategy in which additive manufacturing is used to create families of anatomy-responsive instruments not a unique file for every individual patient.

can be optimized for bending, torsion, fatigue, cutting contact, canal centering, and manufacturability before fabrication. Figure 9 illustrates a digital engineering workflow in which canal anatomy, instrument design, computational optimization, LPBF fabrication, and mechanical testing are linked in an iterative loop.

Topology optimization and cellular-structure design are especially relevant. These methods can distribute material only where it contributes to a defined mechanical objective, such as stiffness, compliance, mass reduction, or stress reduction (Liu et al., 2024; Shi et al., 2025). In additively manufactured metals, topology optimization has been used to create porous structures, lattice frameworks, and print-ready designs with controlled mechanical behavior (Cheng et al., 2019; Ibhadode et al., 2023; Tajima & Yamada, 2023). Mechanical metamaterials are architected materials whose mechanical behavior is governed primarily by geometry (Biffi et al., 2024). In printed NiTi, lattice density, fiber orientation, pore architecture, and woven topology can be adjusted to tune stiffness, compliance, recovery, and energy absorption without changing the base alloy (Xu et al., 2026). This principle is directly relevant to additively manufactured endodontic instruments because file flexibility, torsional response, and canal-contact behavior could potentially be controlled through architecture instead of only through alloy treatment or external flute design. The effect of architecture on mechanical behavior is illustrated in Figure 10, which compares 9-thread printed NiTi lattice and woven metamaterials under axial and lateral compression. For endodontic instruments, similar methods could be used to create files that flex in preferred directions, resist torsion at specific locations, or reduce stress concentration near the transition from the active file to the shank.

Finite element analysis would be needed to test

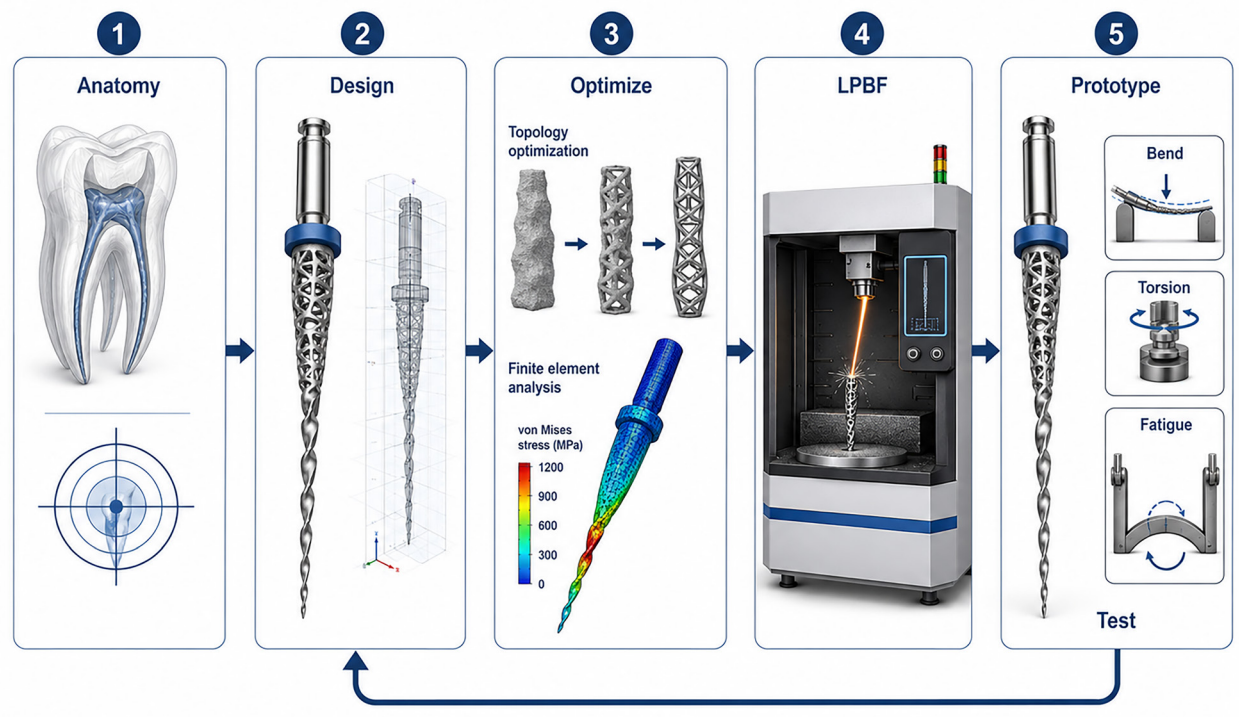


Fig. 9. Computational design workflow for additively manufactured NiTi endodontic instruments. Conceptual workflow showing how computational design could be integrated with laser powder bed fusion to develop future NiTi endodontic instruments. Canal anatomy provides the initial design context. Digital modeling converts the design objective into a candidate instrument architecture. Topology optimization and finite element analysis are then used to refine lattice geometry, stress distribution, bending behavior, torsional resistance, and fatigue-sensitive regions before fabrication. The optimized design is manufactured by laser powder bed fusion and tested as a physical prototype under bending, torsion, and cyclic fatigue conditions. Testing outcomes are returned to the design stage to refine the next prototype. This iterative workflow links anatomy, digital design, simulation, additive manufacturing, and mechanical validation

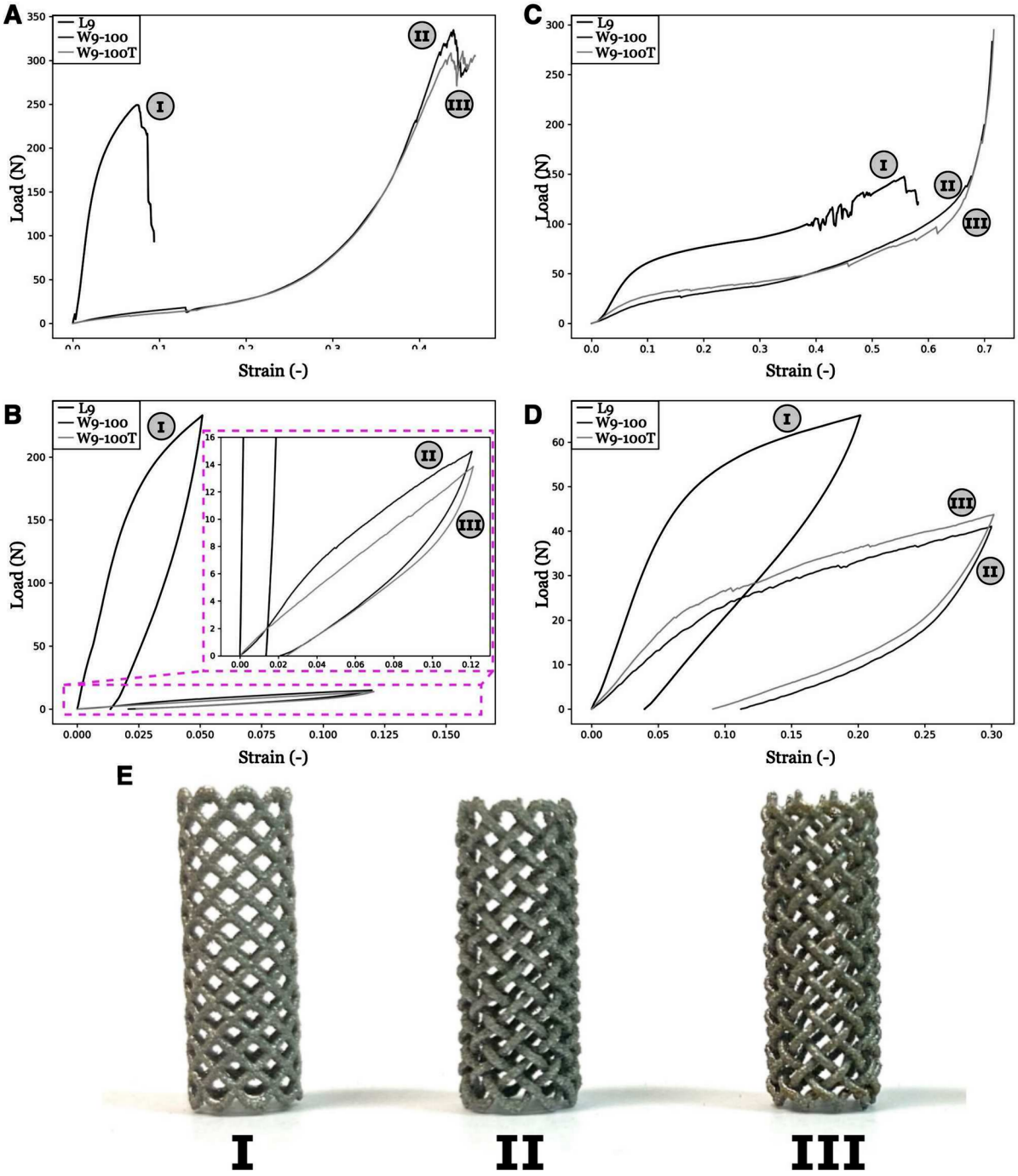


Fig. 10. Mechanical behavior of additively manufactured NiTi lattice and woven metamaterials. Comparative mechanical evaluation of 9-thread laser powder bed fusion-fabricated NiTi lattice and woven structures. (A) Axial loading response. (B) Axial loading-unloading response. (C) Lateral loading response. (D) Lateral loading-unloading response. (E) Printed prototypes corresponding to the tested designs: I, L9 lattice; II, W9-100 woven structure; and III, W9-100T woven structure with tangent fiber endings. The figure illustrates how computationally designed architecture can markedly alter load-strain behavior, compliance, and recovery in printed NiTi structures. This concept is relevant to future additively manufactured endodontic instruments because changes in lattice or woven architecture could be used to tune flexibility, torsional response, and region-specific mechanical behavior before fabrication. Reproduced from Aguilar Vega et al. (2026) under the Creative Commons Attribution-NonCommercial 4.0 International License.

candidate designs virtually before printing (Chen et al., 2024). Simulations could examine bending in curved canals, torsional locking, canal-wall contact, stress distribution, and fatigue-sensitive regions. Computational fluid dynamics could also be used if internal channels are designed for irrigant or debris movement (Abdollahzadeh et al., 2025). The models would need validation against mechanical testing, simulated canal studies, and fracture analysis.

A future workflow might begin with canal anatomy datasets, define mechanical objectives, generate candidate architectures, screen them computationally, print prototypes by LPBF, and test them under clinically relevant fatigue, torsion, wear, and irrigation conditions. In that workflow, additive manufacturing would become part of a digital engineering loop that connects anatomy, design, simulation, metallurgy, and clinical performance.

Scientific and Clinical Challenges

Additive manufacturing does not remove the clinical constraints that govern NiTi rotary instruments. It intensifies them. A printed file would have to satisfy requirements for precise geometry, stable phase transformation, cyclic fatigue resistance, torsional safety, corrosion resistance, sterilization tolerance, and reproducible batch production (Kubášová et al., 2024; Rangaswamy et al., 2026). These requirements are more stringent than those for many printed NiTi implants because an endodontic file is a slender instrument that rotates in a constrained, curved, wet, and chemically aggressive canal space.

The main translational question is whether a printed file can deliver predictable clinical behavior after powder handling, laser melting, post-processing, cleaning, sterilization, packaging, and use. This distinction is essential because additive manufacturing can create architectures that are mechanically attractive in principle. However, endodontic instruments must also cut dentin, transport debris, resist separation, preserve canal anatomy, and remain biologically safe.

Surface quality

Surface quality is the first barrier to clinical translation. Laser powder bed fusion produces surfaces that are influenced by powder particle size, layer thickness, scan-track overlap, melt-pool stability, local energy input, and post-processing (Chowdhury et al., 2022; Kubášová et al., 2024). The microscopic melt-pool behavior illustrated in Figure 3B is therefore clinically relevant because local instability can create adherent particles, balling, re-solidified spatter, layer striations, and rough strut surfaces (Rangaswamy et al., 2026).

These features are not merely cosmetic defects. In rotary endodontic instruments, surface irregularities may act as stress concentrators during repeated flexural loading and may accelerate fatigue crack initiation (Cheung, 2009; Plotino et al., 2009). This concern is magnified for printed files because the active portion is small; a surface particle or notch that appears minor on a larger implant may represent a substantial local defect relative to file diameter or strut thickness (Figure 4B).

Post-processing will therefore be mandatory for any printed NiTi endodontic instrument. Electropolishing, passivation, laser finishing, chemical polishing, abrasive flow finishing, and micro-machining could reduce surface defects. However, each method may also change flute geometry, edge sharpness, taper, cross-sectional area, and transformation behavior. Dimensional control after finishing should be evaluated against endodontic instrument requirements. These requirements include tip size, taper, active cutting geometry, and resistance to deformation (International Organization for Standardization, 2020).

Surface finishing also raises a design conflict. A smoother surface may improve fatigue resistance and corrosion behavior, but aggressive polishing may blunt cutting edges or narrow lattice openings intended for flexibility, debris displacement, or irrigation exchange. For printed NiTi files, the type of surface treatment cannot be an afterthought; it must be part of the original digital design and manufacturing workflow.

Mechanical performance

Conventional NiTi rotary instruments fail mainly through cyclic fatigue, torsional overload, or a combination of both mechanisms (Cheung, 2009; Plotino et al., 2009; Yon et al., 2021). Printed NiTi

instruments would need to satisfy the same failure thresholds, but with the added complexity of internal architecture, anisotropic build orientation, residual stress, porosity, surface roughness, and local phase heterogeneity.

Cyclic fatigue testing should include static and dynamic canal models with clinically relevant curvature, radius, rotational speed, temperature, and irrigant exposure. Plotino et al. (2009) noted that cyclic fatigue results depend strongly on testing geometry and experimental conditions. This issue becomes even more important for additively manufactured files because small differences in local architecture could change the bending strain distribution along the active portion. Torsional resistance also requires careful evaluation. A printed lattice or hollow-core file may become more flexible. However, excessive reduction in polar moment of inertia could increase the risk of plastic twisting or separation when the tip binds. The ISO 3630-5 standard provides baseline requirements for endodontic instruments. Additive manufacturing-specific validation should extend to repeated torsional loading, cyclic torsion, and combined bending-torsion testing that is not currently addressed by the ISO 3630-5 standard (International Organization for Standardization, 2020).

The same architecture that improves flexibility may alter cutting efficiency, screw-in tendency, debris removal, and canal transportation. Lattice or variable-wall designs could reduce restoring force against canal walls. Yet, they may also reduce cutting edge support or change flute space. Therefore, mechanical testing should be paired with shaping experiments in standardized resin blocks, extracted teeth, and micro-computed tomography models that quantify centering ability, transportation, untouched canal wall area, debris accumulation, and preparation time. Printed NiTi metamaterials show that stiffness and recovery can be tuned by design. Aguilar Vega et al. (2026) demonstrated that printed NiTi lattice and woven architectures can produce markedly different load-strain behavior under axial and lateral compression. That principle is attractive for future endodontic file designs. Nonetheless, direct extrapolation to rotary instrumentation would be premature because most mechanical testing and finite element analyses have been performed on larger printed specimens or simplified architectures. Testing on fully printed objects with the size, slenderness, taper, and rotational loading conditions of an endodontic file has not yet been demonstrated.

Biological considerations

Biological safety must be evaluated independently from mechanical performance. Nickel-titanium has a strong clinical history because its titanium-rich oxide layer contributes to corrosion resistance and biocompatibility. However, nickel release is a concern for any Ni-containing medical material (Navratilova et al., 2024; Liu et al., 2025). Printed NiTi rotary instruments add new variables, including surface roughness, residual porosity, partially melted particles, heat-affected regions, oxygen uptake, and local composition changes that may alter oxide stability.

Sun and colleagues (2024) reported favorable in vitro biocompatibility for an SLM/LPBF-fabricated NiTi alloy with strong tensile properties. Although this finding is encouraging, it does not establish biological safety for printed endodontic files. Root canal instruments are exposed to sodium hypochlorite, EDTA, irrigant agitation, repeated autoclave sterilization if reusable, dentin debris, blood, inflamed tissue remnants, and microbial biofilms. These conditions may alter corrosion behavior and nickel ion release (Sussman et al., 2022).

The ISO 10993-1:2025 standard provides the overarching risk-management framework for biological safety evaluation of medical devices, including devices produced by additive manufacturing (International Organization for Standardization, 2025a). ISO 5092:2025 adds an additive manufacturing-specific medical-device perspective for additively manufactured non-active implants (International Organization for Standardization, 2020, 2025b), whereas ISO 3630-5:2020 provides the closest endodontic instrument framework for shaping and cleaning instruments. These standards should be considered complementary for LPBF-fabricated NiTi files because none is specific to printed endodontic rotary instruments. Final-device testing should therefore

Table 2. Biological, chemical, and cleanability considerations for LPBF-fabricated NiTi endodontic instruments.

Issue requiring evaluation	Significance for printed NiTi files	Suggested evaluation	Relevant framework or guidance §
Corrosion in clinically relevant irrigants	Printed surface roughness, adhered particles, porosity, and finishing may alter oxide stability during exposure to NaOCl, EDTA, saline, and dentin debris.	Test final as-finished instruments after irrigant exposure. Examine surface change, corrosion behavior, and post-exposure mechanical performance.	ISO 10993-1; ISO 10993-15; device-specific irrigant testing
Nickel ion release after sterilization and chemical exposure	Ni/Ti balance, oxide chemistry, surface roughness, and post-processing may influence nickel release.	Measure nickel and titanium release after sterilization, irrigant exposure, and simulated use, followed by toxicological risk assessment.	ISO 10993-18; ISO 10993-17
Cytotoxicity of polished and unpolished surfaces	Incompletely finished LPBF surfaces may retain roughness, particles, oxides, or residues not present on conventional NiTi files.	Evaluate extracts from final finished devices and worst-case minimally polished surfaces.	ISO 10993-5; ISO 10993-12
Particulate generation and wear debris	Partially melted particles, rough struts, or fragile internal features may detach during canal instrumentation.	Collect irrigant and debris after simulated canal preparation. Characterize particles by microscopy, particle counting, and elemental analysis.	ISO 10993-1; ISO 10993-18; device-specific wear and debris testing
Cleaning and endotoxin validation	Hollow cores, lattices, channels, and porous regions may retain powder, polishing residues, organic soil, microorganisms, or endotoxin.	Validate cleaning with worst-case geometries that contain high surface area, internal voids, and tortuous pathways.	FDA additive manufacturing guidance; ISO 10993-1
Sterilization compatibility	Sterilization may affect surface oxide, residual stress, transformation behavior, corrosion response, and fatigue performance.	Validate the intended sterilization method using final cleaned and packaged devices. Reassess surface and mechanical behavior afterward.	Relevant sterilization standards; ISO 10993-1
Debris retention within printed internal features	Internal voids, lattice windows, and channels may trap dentin debris, metal particles, or biofilm.	Use canal-like instrumentation models with irrigants, followed by micro-CT, microscopy, and flushing studies.	Device-specific testing; FDA additive manufacturing guidance
Final finished-device biological evaluation	Bulk NiTi biocompatibility data are insufficient because LPBF processing and post-processing determine the final patient-contacting surface.	Perform biological evaluation on the final finished, cleaned, packaged, and sterilized device.	ISO 10993-1; FDA additive manufacturing guidance

Abbreviations: LPBF, laser powder bed fusion; NiTi, nickel-titanium

§ISO 5092:2025 is included as an additive manufacturing-specific medical-device framework. Because it addresses additively manufactured non-active implants, its relevance to LPBF-fabricated NiTi endodontic instruments is indirect. ISO 3630-5:2020 provides the closest endodontic instrument framework, and ISO 10993-1:2025 provides the biological risk-management framework. These standards should be interpreted together with device-specific validation testing.

Selected standards and guidance cited in Table 2

U.S. Food and Drug Administration. (2017). Technical considerations for additive manufactured medical devices: Guidance for industry and Food and Drug Administration staff. https://www.fda.gov/media/97633/download

International Organization for Standardization. (2020). Dentistry — Endodontic instruments — Part 5: Shaping and cleaning instruments (ISO Standard No. 3630-5:2020). ISO. https://www.iso.org/obp/ui/en/#iso:std:iso:3630:-5:ed-2:v1:en

International Organization for Standardization. (2025a). Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process (ISO Standard No. 10993-1:2025). ISO. https://www.iso.org/standard/10993-1

International Organization for Standardization. (2025b). Additive manufacturing for medical — General principles — Additive manufacturing of non-active implants (ISO Standard No. 5092:2025). ISO. https://www.iso.org/obp/ui/en/#iso:std:iso:5092:ed-1:v1:en

International Organization for Standardization. (2009). Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity (ISO Standard No. 10993-5:2009). ISO.

International Organization for Standardization. (2021). Biological evaluation of medical devices — Part 12: Sample preparation and reference materials (ISO Standard No. 10993-12:2021). ISO.

International Organization for Standardization. (2019). Biological evaluation of medical devices — Part 15: Identification and quantification of degradation products from metals and alloys (ISO Standard No. 10993-15:2019). ISO.

International Organization for Standardization. (2023). Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents (ISO Standard No. 10993-17:2023). ISO.

International Organization for Standardization. (2020). Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process (ISO Standard No. 10993-18:2020). ISO.

reflect the printed geometry, surface condition, cleaning protocol, sterilization method, and clinical chemical exposures. The major biological, chemical, and cleanability issues requiring validation are summarized in Table 2.

In addition, a single-use printed file may require different validation from a reusable file that undergoes sterilization cycles. A hollow or lattice-containing instrument may also require more stringent cleaning validation because internal pores, channels, and lattice spaces could retain organic debris or microorganisms. For this reason, printed endodontic file design should avoid inaccessible internal surfaces unless cleaning, sterilization, and manufacturing residues can be convincingly controlled.

Manufacturing and economic feasibility

Manufacturing feasibility is the final translational barrier. Laser powder bed fusion can create complex NiTi structures. Producing a research prototype, however, is different from producing a regulated, quality-assured, commercial endodontic instrument (Chernyshikhin et al., 2022). Powder chemistry, powder reuse, particle-size distribution, oxygen control, laser calibration, build orientation, scan strategy, support removal, post-processing, cleaning, inspection, and packaging would all require documented control (Chowdhury et al., 2022; Rangaswamy et al., 2026).

Modeling and process simulation may reduce development time by linking powder behavior, melt-pool physics, heat transfer, residual stress, and defect formation. Abdollahzadeh et al. (2025) described computational fluid dynamics modeling of LPBF-fabricated NiTi as a route for understanding coupled thermal and fluid-flow behavior. Such models could eventually help define safe processing windows for miniature endodontic designs. However, they must be validated against dimensional accuracy, phase transformation behavior, surface quality, and mechanical testing.

The ISO/ASTM 52920:2023 standard provides qualification principles and requirements for industrial additive manufacturing processes and production sites (International Organization for Standardization & ASTM International, 2023). It is relevant to process control, documentation, production-site qualification, and quality assurance. However, it is not specific to medical devices or endodontic instruments. ISO 5092:2025 has a different role: it provides a medical additive manufacturing framework for non-active implants. For printed NiTi files, both frameworks would need to be interpreted together with ISO 3630-5:2020, ISO 10993-1:2025, and device-specific testing.

Economic feasibility is equally important. Conventional NiTi files are already manufactured at scale by wire drawing, heat treatment, grinding, twisting, electropolishing, and coating. Fully printed files would need to justify higher production cost through a clinically meaningful advantage, such as improved safety in severe curvature, controlled torsional release, better canal adaptation, or specialized retreatment function. Early adoption is therefore more likely to involve specialty instruments, hybrid manufacturing, or limited high-value designs than routine replacement of all conventional rotary files.

Commercialization will also depend on regulatory classification and evidence. A printed NiTi endodontic file would probably be treated as a new device design and not merely a new manufacturing route. The evidence package should therefore include manufacturing validation, sterilization validation, biological risk assessment, mechanical testing, bench-top canal shaping, preclinical studies, and eventually clinical evidence. Until these requirements are satisfied, additive manufacturing should be presented as a promising engineering pathway, and not as an imminent replacement for established NiTi file manufacturing.

Future Directions

To date, no additively manufactured NiTi endodontic rotary file is commercially available for clinical use. This point should be stated clearly because the current field is still at the proof-of-concept stage. Printed NiTi structures, including file-like and lattice-based geometries, demonstrate that additive manufacturing can create shapes that are difficult or impossible to obtain by wire grinding

(Chernyshikhin et al., 2022; Aguilar Vega et al., 2026). However, these studies do not establish clinical readiness for rotary instrumentation.

The next stage should move from printing feasibility to file-scale validation. Future studies should fabricate complete endodontic instruments with clinically relevant tip sizes, tapers, flute geometry, slenderness, and working lengths. These instruments should then be tested in simulated canals, extracted teeth, and canal-like mechanical models, including cyclic fatigue in curved canals, torsional loading, bending stiffness, cutting efficiency, debris removal, canal transportation, and fracture behavior. Testing should also include repeated sterilization, NaOCl exposure, EDTA exposure, corrosion behavior, nickel ion release, and cleaning of internal channels or lattice regions.

Process control will be equally important. LPBF-fabricated NiTi files would require reproducible powder quality, validated scan parameters, control of nickel-titanium composition, predictable transformation temperatures, surface finishing, residual powder removal, and final-device inspection. Micro-computed tomography, surface metrology, differential scanning calorimetry, mechanical testing, and corrosion testing should be integrated into the validation pathway. Although ISO 3630-5:2020, ISO 10993-1:2025, ISO 5092:2025, and ISO/ASTM 52920:2023 may provide useful frameworks, none of these standards alone is sufficient for printed NiTi endodontic rotary instruments.

A realistic near-term goal is not fully patient-specific instrumentation. A more practical pathway is the development of standardized families of anatomy-responsive printed files for curved canals, long oval canals, calcified canals, and retreatment procedures. Until file-scale mechanical, biological, manufacturing, and clinical data are available, additively manufactured NiTi endodontic instruments should be regarded as a future engineering opportunity, not a current clinical product.

Conclusion

Metal additive manufacturing could expand NiTi endodontic instrument design beyond the limitations of wire-based grinding by enabling hollow regions, lattice architectures, graded stiffness, and anatomy-responsive geometries. These possibilities are attractive because they may allow future files to balance flexibility, torsional safety, cutting efficacy, and canal preservation in ways that are difficult to achieve with conventional manufacturing. However, printed NiTi endodontic rotary files are not currently available for clinical use. Existing evidence is limited to printed NiTi specimens, lattice structures, and preliminary file-like geometries. Translation will require file-scale validation of print resolution, phase transformation behavior, cyclic fatigue resistance, torsional performance, surface finishing, corrosion behavior, cleaning, sterilization, and biological safety. At present, additively manufactured NiTi files should be viewed as a promising engineering direction, not an established clinical technology.

Acknowledgements

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