Route-Dependent Porosity, Transformation Stability, and Surface Control in Additively Manufactured NiTi Implants

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Abstract: The unique combination of superelasticity, shape-memory property, high corrosion resistance, and relative softness makes nickel-titanium (NiTi) shape-memory alloys an ideal choice for biomedical fixing elements, porous scaffolds, and load-sharing devices personalized for the specific patient. Additive manufacturing technology allows incorporating architected porosities into design, as well as anatomically tailored designs, but introduces process-dependent challenges concerning such factors as nickel volatilization, oxygen absorption, residual stress, surface roughness, pore imperfections, appearance of secondary phases, and nickel ions release. The key problem discussed in this article is what kind of relation should be established between processes of laser powder-bed fusion (LPBF), electron beam powder-bed fusion (EPBF), and directed energy deposition (DED) and various implant types according to geometry, transformation stability, mechanical compatibility, surface conditions, and biological safety criteria. Evidence concerning the use of NiTi in additive manufacturing process is presented below depending on the type of parts: dense transformation-sensitive elements, porous load-sharing structures, and patient-specific fixation devices. LPBF technology is recommended for precise geometry patient-specific implants and for stiffness-controlled fixation systems owing to the ability to provide dense material and create lattice structures, although it requires a highly controlled scanning pattern, atmosphere, hatch distance, and finishing process. DED technology can be justified in the case of porous bulk NiTi parts when lowering stiffness and achieving effective load sharing is critical, with reported porosity ranging from 12 to 36%, reversible strains from 2 to 4%, elastic modulus of about 18 GPa, and smaller tribocorrosion tracks than those of DED Ti-6Al-4V specimens. EPBF technology allows using vacuum conditions and lower contamination risk, but has biomedical applications restricted owing to inconsistent reports on phases composition and superelastic behavior. All the technologies require careful surface treatment due to the importance of this feature for corrosion resistance, osseointegration, nickel ions release and bacterial attachment: polishing, oxidation, electropolishing, nanotubes growth, HA-coating application, and polymer brush coating have been studied for this purpose.

Keywords: NiTi; additive manufacturing; laser powder-bed fusion; electron-beam powder-bed fusion; directed energy deposition; biomedical implants; porous scaffolds; surface engineering; nickel release; route selection

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1. Introduction

The modern expectation for metallic implants is for them to act as engineered interfaces rather than inert substitutes for compromised anatomy. Load transmission, adequate rigidity to ensure stability, avoidance of excessive stress shielding, tolerance of cyclic micromotion, resistance to corrosion and wear, and creation of a surface suitable for tissue integration are required. Additive manufacturing has come to play an important role in this context, in which the digital design of the implant can be turned into a part with controlled structure, internal porosity, and customized geometry without being constrained by traditional manufacturing tools. There is considerable precedent in the broader field of additive manufacturing demonstrating the benefit of layered production in the manufacture of complex metallic parts, but also revealing significant dependency on process

selection, powder quality, melt-pool stability, energy input, and post-processing [1–5]. For biologically relevant metal alloys, however, this dependence is no peripheral issue of process engineering. It is an integral component of the device itself since differences in defect density, surface condition, and microstructure can lead to entirely distinct biological and mechanical properties even for geometries with the same specifications.

One of the most interesting and challenging biomedical alloys within this manufacturing context is NiTi. This alloy has been used due to several attractive features including its transformation at a critical stress, shape memory properties, superelasticity, fatigue-tolerance, and corrosion resistance. Together, these attributes provide a unique combination of flexibility and mechanical performance compared to other candidate alloys such as stainless steel, cobalt–chromium alloys, and traditional titanium alloys [6–9]. NiTi has found application in numerous forms such as wire and stent for orthodontic treatment, vascular implants, bone fixation devices, porous structures, dental devices, and custom devices. Lower modulus is one potential strength of the alloy but does not solve the stiffness mismatch with bone alone. Apparent stiffness must be carefully controlled in load-bearing implants [10–13].

The properties of NiTi that make it desirable also make it sensitive to the process of manufacturing. Chemical fluctuations, such as nickel variation, may induce temperature changes that could affect whether a product exhibits superelastic, martensitic, or mixed behavior under physiological loads. Thermomechanical processing, including melting, fast-solidification, and remelting, may lead to residual stresses, non-equilibrium microstructures, texture, grain size evolution, precipitation, porosity, cracking, lack of adhesion [14–16]. The restriction imposed by the biomedical applications is even stronger since the factors controlling the nickel release, the stability of the oxide layer, surface roughness, and the material reaction to tribocorrosion must be taken into account. Previous studies of biocompatibility and ion release from NiTi demonstrate that surface chemistry and the condition of the passive film play significant roles in addressing these issues [17–20]. Thus, an additively manufactured NiTi implant cannot be considered complete as it comes out of the build environment. At best, it represents the starting point for manufacturing a biomedical device where the final route, microstructure, architecture, and surface finishing will define its functionality.

The study of the traditional methods employed in NiTi processing may help to address the challenge. Vacuum arc remelting, vacuum induction melting, powder metallurgy, microwave sintering, spark plasma sintering, and extrusion have been used to manufacture NiTi and porous NiTi products, emphasizing the need for homogeneity, purity, and control of the pore morphology [21–26]. The limitation of such approaches is that they offer limited possibilities to customize an implant. Each type of a biomedical NiTi product imposes different requirements. Geometry fidelity needs accurate geometry definition and controlled dimensional accuracy. Porous structure implies a demand for interconnectivity, compression behavior, and reliable struts. Transformation-sensitive implants require phase analysis and precise compositional control. Not a single additive route allows one to satisfy all these requirements equally well.

Further expansion of the literature background indicates that porous metal implants should not be evaluated based on material name or elasticity only. Porous structure is necessary for bone ingrowth, and porosity influences the fluid flow, curvature, and connectivity, while mechanical properties are determined by structural factors such as strut continuity, stress distribution, and lack of significant local defects. Research concerning the influence of porous structures on the mechanical behavior of metals, including porous scaffolds and additively manufactured porous metal implants, demonstrates the potential of architecture for stiffness reduction and improvement of mechanical compatibility, although inadequate design or manufacturing may contribute to increasing fatigue sensitivity and stress concentrations [27,28]. It should be especially emphasized in relation to the present case because the use of a porous NiTi scaffold will make the surface larger and the role

of its passivation and corrosion resistance more significant. The literature background demonstrates a combined problem of geometry, transformation, and surface chemistry.

Finally, the problem of the NiTi implant interface is added. Although NiTi was always considered a biocompatible metal due to the possibility of forming a passive titanium-rich surface film, the effectiveness of such protection depends on the conditions of loading. Damage of surface, fretting, low pH environment, chloride fluids, and mechanically assisted corrosion may affect passivation and change the passive state of the surface. Therefore, earlier research on the cytotoxicity and nickel ion release from NiTi should still be considered when evaluating this material regardless of the fabrication route used [29]. This means that further surface treatment cannot be considered as additional processing but must become an integral part of production. The printed shape, the printed microstructure, and the finished surface together determine whether a NiTi implant can satisfy its mechanical and biological purpose.

The question explored in this paper is thus not whether NiTi implants are producible by additive manufacturing in some broad sense. Rather, it is one of how LPBF, EPBF, and DED might usefully be deployed to produce different classes of implants when considered in light of architecture, phase stability, mechanical performance, surface properties, and risk of nickel release as described in the published literature. Such an approach does not provide for a straightforward prioritization of technologies. LPBF may indeed offer the advantages of fine lattice geometries and even patient-specific bone fixation, but the risks of high thermal gradients and nickel vaporization must be mitigated through process controls. EPBF promises the advantages of a vacuum environment and heated powder bed but presents an inconsistency in the scientific literature on functional transformation and phases produced. DED is able to create porous and mechanically tough NiTi architectures and has evidence of better tribocorrosion compared with DED Ti–6Al–4V, but the post-processing burden for biomedical surfaces is higher in many cases [30–35].

This paper gives an account of NiTi implant manufacture that is both process-specific and focused on the surface of the final product. The numerical values presented here are specific measurements from published papers and include density for LPBF around 99.9%, porosity for DED between 12% and 36%, strain range for DED at 2% to 4%, porous Young's modulus around 18 GPa, wear track width on DED NiTi around 210 μm compared with 420 μm for DED Ti–6Al–4V, a 40% faster build rate achieved in mixed argon-helium environments, grain sizes ranging from 190 to 478 nm due to varying hatch distance, and 46% reduction in charge transfer resistance for increased LPBF scan speed [36–39]. These values are interpreted according to the implant decision they support: geometric precision, porous load sharing, phase stability, corrosion resistance, or surface safety.

1.1. Basis for Comparison and Comparative Process

This analysis is an organized synthesis of scientific literature related to the topic rather than a meta-analysis based on statistics. The data is organized on the basis of manufacturing capabilities, quantitative properties, geometry, surface conditions, and potential for post-processing related to the manufacturing process in question. Processes of LPBF, EPBF, and DED were used as examples since they constitute the most prominent metal-based approaches in AM of NiTi implants, with clear links to dense components, porous structures, and patient-specific parts. Processes of binder jetting, material extrusion, photopolymerization, and sheet lamination fall under the category of less prominent methods in the AM sphere and are less relevant for biomedical applications in relation to load-bearing metallic parts of NiTi with controllable transformation response [5,36].

For the purpose of organizing data, implant applications were divided into three types, depending on their functionality. Transformation-sensitive parts, or those in which phase structure, ability to undergo superelastic recovery, accuracy, and minimal contamination become important, are classified accordingly. Parts of the second class can be described as load-sharing scaffolds, wherein the focus is on the ability to provide high enough modulus of elasticity and porosity, along with being deformable and strong enough. Parts of the third

class relate to patient-specific hardware that involves anatomical shaping, stiffness tuning, creation of thin structures, and post-processing, namely polishing. Such classification has been chosen due to its relevance and practicality regarding the issue.

The process scope in Table 1 explains why the paper focuses on LPBF, EPBF, and DED. What matters for manufacturing is not the multiplicity of additive processes, but which of them offer a potential to control chemical composition, structure, and surface of NiTi implants. Powder bed fusion offers the best connection from digital design to precision medical geometry, while DED is best at proving existence of porous bulk metallic NiTi with low apparent stiffness. Future possibilities may include indirect or polymer templating approaches, but current evidence does not yet justify their inclusion in NiTi additive manufacturing paths.

Table 1. Route scope for NiTi implants.

Process family	Relevant variants	Role in NiTi implant manufacturing
Powder-bed fusion	LPBF, selective laser melting, direct metal laser sintering, EPBF, electron-beam melting	Defines the main route for fine metallic NiTi geometry, dense parts, lattice fabrication, and patient-specific constructs. LPBF has the strongest evidence for detailed biomedical NiTi architecture, while EPBF offers vacuum processing with conditional functional evidence [15,31,32,34].
Directed energy deposition	Laser-engineered net shaping and blown-powder DED	Supports larger or porous load-bearing NiTi structures, graded deposition concepts, and mechanically robust porous architectures, although surface finishing and dimensional precision are more demanding [40,41].
Indirect or polymer-template routes	Binder jetting, material extrusion, photopolymerization-assisted shaping	Provides background for additive design but is less directly supported for fused metallic NiTi implants requiring controlled transformation response and load-bearing performance [5,36].

The classification also acknowledges that published papers on additive manufacturing of NiTi vary in the type of evidence provided. Papers may focus on density and microstructure, transformation temperatures, or surface corrosion resistance and ion release, or demonstrate implant applications. However, each type of evidence answers a specific design question; density measurements show viability of the printing process, but not recovery, transformation temperatures are indicative of functional materials, but not of geometries' ability to preserve function, surface studies show acceptance by body tissue, but not suitability of structure for bone integration. While corrosion and ion release tests demonstrate surface suitability, they are not evidence that the mechanical design is correct for bone. Thus, the route-class strategy evaluates each test based on the design questions it can really answer.

The analysis did not rely on the conversion of any body of work to numbers alone. There is no way in which density, porosity, corrosion resistance, surface roughness, modulus and geometric resolution will all be equally important features for any one implant. Surface roughness, while potentially detrimental to the fatigue-resistance of a screw hole, may be beneficial for the bone-facing side if the issue of corrosion and nickel release is properly managed. Similarly, porosity may be ideal for a scaffold yet damaging to a superelastic NiTi implant. In other words, route choice cannot be generalized as an index without due regard to trade-offs inherent in any particular manufacturing process.

In analyzing relevant literature, the route–property–surface strategy was applied. First, every route had to be investigated in terms of its capacity to fabricate a given structure. Secondly, reported data had to be interpreted in light of specific features like density, porosity, reversible strain, modulus and tribocorrosion or corrosion performance. Thirdly, surface-related information had to be taken into account to make a decision about the sufficiency of a chosen fabrication route for biomedical applications. This final point was vital due to the sensitive nature of NiTi materials. Even if a material with a high modulus was considered, it may prove undesirable if there was too much internal oxidation or nickel release from internal surfaces. Even a fine LPBF fixation plate may need intensive

polishing or surface conditioning when roughness, particle adhesion, or thermal surface modifications make biological or mechanical risks possible.

The panels in Figure 1 provide physical proof rather than using only process names for the route assignment. The LPBF coupon is an example of the high-density precision route, while the porous DED specimen illustrates the load-sharing scaffold route, whereas the dense NiTi coupon exemplifies the transformation-sensitive route. Additionally, the tray image indicates that route selection is based on device fabrication considerations. Based on this information, LPBF, DED, and EPBF are different routes that may be used complementarily depending on geometry, transformation stability, surface conditions, and function [30–32,34,35].

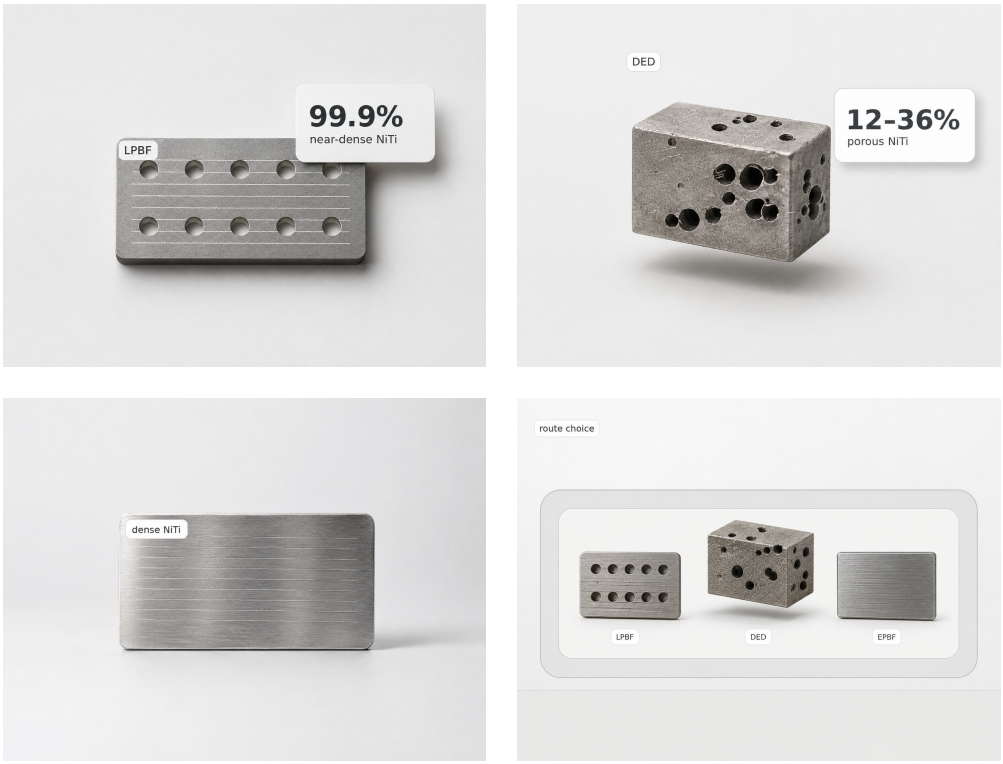

Figure 1. Route-specific NiTi specimen evidence.

The anatomical requirements for each type of implant depicted in Figure 2 explain why the manuscript employs implant class as its organization framework. Implants that serve as anatomical fixation tools must feature contour adaptation, screw-hole quality, and stiffness control; implants with dense recovery functionality must feature verified transformation and cyclic recovery; bone-facing porous implants need void connectivity and the right tissue surface. These criteria cannot be easily swapped out, which explains why the selection of the route in this manuscript is guided by implant purpose and not by some kind of universal prioritization of manufacturing techniques [9,12,13,33,42].

Quantitative data reported in the manuscript are considered route-dependent measurement data instead of universal constants. The high LPBF density close to 99.9% shows that nearly-dense NiTi is technically possible in certain conditions, but it does not imply clinical acceptability of any LPBF combination of parameters. On the one hand, DED stiffness close to 18 GPa indicates that porous NiTi is capable of matching the more desirable range of stiffness, but mechanical fatigue behavior, surface properties, and porosity geometry should be validated. On the other hand, comparison of the 210 μm wear track produced in tribocorrosion testing of DED NiTi with the 420 μm DED Ti–6Al–4V wear track does not prove superior corrosion resistance, but it justifies consideration of DED NiTi where it is a priority [35].

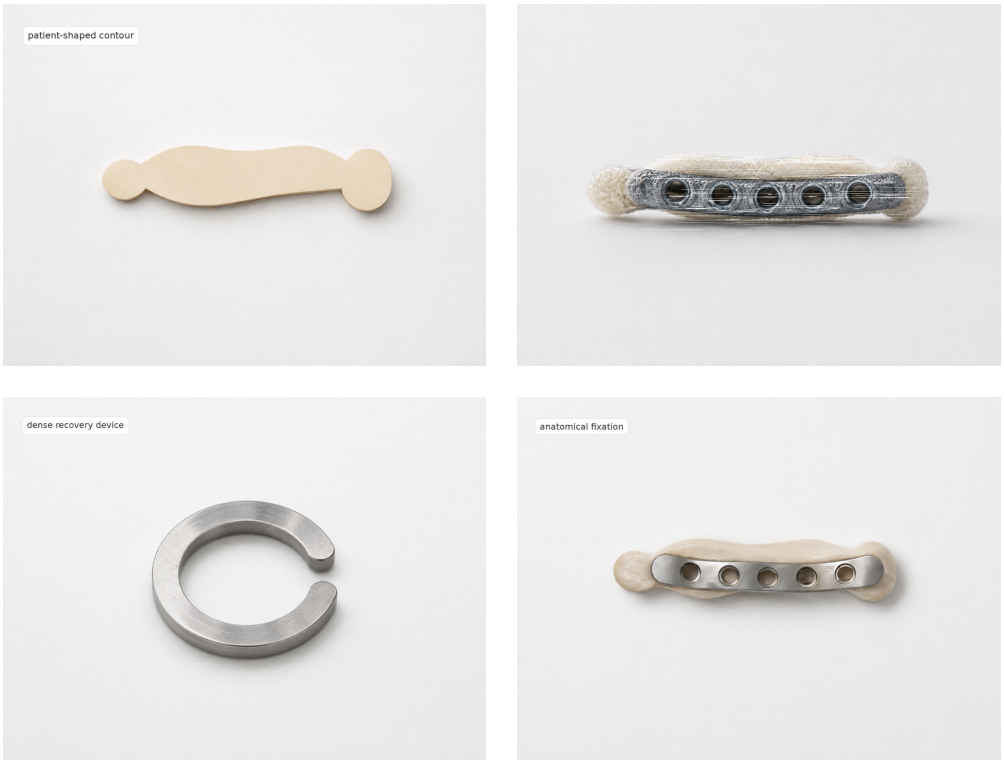

Figure 2. Implant forms used for route assignment.

2. Process–Material Constraints in Printed NiTi

The first constraint is the sensitivity of the alloy's phase response to its composition, which is critical since near-equiatomic NiTi is quite sensitive to changes in nickel composition and will change its transformation temperatures accordingly. The additive manufacturing process exposes the alloy to rapid localized melting and subsequent cooling cycles, with the additional danger of nickel evaporation. LPBF process is likely to produce higher energy densities that will improve fusion but will at the same time cause additional vaporization, oxidation, and thermal gradients. Lower energy densities could decrease evaporation and vapor-related problems but may increase porosity caused by lack of fusion and instability in the melt pool. As a result, density optimization in the process will need to be balanced with the preservation of alloy's chemical composition to obtain an appropriate transformation response [14,32,43].

Another constraint relates to the atmospheric conditions in additive manufacturing. Oxygen, nitrogen, and any other impurities present in the atmosphere could affect the alloy's surface and defect formation in the alloy. LPBF process normally uses inert gas, whereas EPBF uses vacuum conditions combined with higher powder bed temperatures. Studies on mixed gases as a possible way of controlling the atmosphere in powder bed fusion were done because of the influence of thermal conductivity and heat convection properties on plume behaviour, melt pool stabilization, and productivity [37]. In case of the NiTi alloy, however, increased build rate should come second to obtaining correct transformation response of the material.

Hatch distance, scanning speed, layer thickness, and scan strategy constitute another cluster of mutually dependent factors. The changes of grain size observed in a range from 190 to 478 nm associated with variations in hatch distance prove the mutual dependence of geometric parameters and microstructure [38]. Research into the LPBF NiTi shows that the scanning speed affects phase transformation, mechanical behaviour, wear resistance, and corrosion properties. For instance, the 46% reduction in charge transfer resistance with the increase in scanning speed was reported under specified conditions [39]. That means that choosing parameters that ensure the desired dimensional precision or manufacturing

efficiency would simultaneously impact the material electrochemical performance. As far as implants are concerned, the process cannot be assessed solely based on its ability to produce the required shape. The chosen route might impact other characteristics, such as corrosion resistance and surface integrity.

The limitation of the DED technique differs from those discussed above. While this AM route usually provides worse detail in small lattices, it allows creating porous bulk material with the necessary stiffness reduction and mechanical resilience. Several parameters of the DED NiTi fabrication process, including laser power, powder feed rate, travel speed, layer overlap and thermal accumulation, control porosity, strut bonding, HAZ microstructure, and surface roughness. Porosity of 12–36%, reversible strain of 2–4%, and a modulus of 18 GPa are mentioned in the literature on laser-engineered net shaping [30]. Those values are important in light of the fact that stress shielding remains the most common problem in metallic skeletal implants. It is worth noting that reduced stiffness alone does not necessarily mean implant success but increases the mechanical compatibility with bone.

The fourth constraint and possibly the least understood in route comparisons is the surface condition. Additively manufactured parts are characterized by partially melted grains, oxide inhomogeneity, roughness features, pore structures reaching to the surface, and locally varying composition. These features can prove useful in some areas but detrimental in others in terms of mechanical durability, bacterial infection, and corrosion. Surface finishing treatments including polishing, electropolishing, ultrasonic surface nanocrystallization, anodization, oxidation, calcifying agents, hydroxyapatite deposits, and polymer brush layers affect the biomedical meaning of the printed material [44–48]. The manufacturing route needs to be selected in conjunction with a realistic surface processing path. An internal structure of pores and channels cannot be simplified to an easily processed surface as in case of a flat coupon sample.

Heat treatment performed after printing is another constituent element of the manufacturing route. Annealing, homogenization, aging, HIP, and solution treatment change defects, precipitation behavior, transformation temperatures, residual stresses, and fatigue behavior. For Ni-alloyed materials, aging and precipitation processes have strong effects on multistage transformation behavior which makes post-build heat treatment essential in restoring functionality and/or pushing the device outside the design window [7–9]. This means that the route comparison stopping only at the as-built density is incomplete. For medical NiTi alloys, the meaningful manufacturing route encompasses powder chemistry, printing parameters, printing atmosphere, heat treatment, and surface finishing steps followed by phase confirmation.

A further complication is that of coupon performance versus implant performance. A significant number of process studies have utilized small rectangular, cylindrical, or dog-bone coupons since they are well suited for tensile, corrosion, and microscopic evaluation purposes. However, actual implants are comprised of screws, curves, lattices, and overhangs – all of which create different thermal histories and mechanical stresses compared to flat, simple geometries. What works for a coupon may very well fall short of what is needed for a mandibular plate or porous scaffold. While not minimizing the importance of coupon testing, this implies that the end stage of validation must always be performed for each particular implant.

The process views in Figure3 illustrate why route-specific differences must be understood as thermal and chemical differences. LPBF processes a laser track within a single powder layer, EPBF works inside a vacuum chamber with a pre-heated substrate, and DED builds parts using a feedstock within a melt pool of a larger thermal mass. These factors account for the varied hazards that are highlighted in the paper: nickel vaporization and scan window dependence for LPBF, phase constitution validation for EPBF, and surface condition control for DED [1,2,32,34,40].

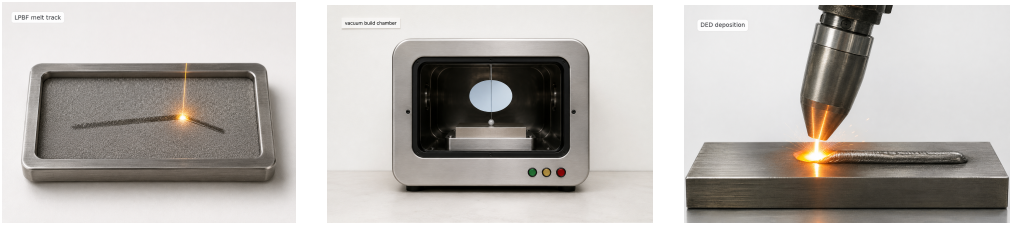

Figure 3. Printing environments for NiTi manufacture.

3. Discussion and Results

The analysis of the routes leads to a definitive yet conditional answer: LPBF, EPBF, and DED each belong in distinct parts of the design space of implants. LPBF remains the best route if anatomy and intricate architecture become paramount. DED is undoubtedly superior if porous material and a reduction in stiffness become the main criteria for success. EPBF has significant potential as an efficient method for minimizing contamination in dense implants; however, the latter must be verified with regard to phase structure and superelasticity before its use in transformational implants. The above route distinction becomes more pronounced when surface engineering is taken into consideration since the printing geometry and bulk behavior alone cannot determine the implant's readiness.

Figure 4's LPBF panels combine precision manufacturing with the route-specific measurement data presented in the text. The fabricated plate and the specimen set demonstrate the suitability of LPBF for thin fixation hardware components, whereas the verification panels ensure that the high-density claim is related to process sensitivity. Density close to 99.9%, grain size variation in the range of 190 to 478 nm, atmosphere-related 40% improvement in the build rate, and the reduction in charge transfer resistance by 46% in response to scan parameters indicate the importance of process control and coupled optimization of melting, atmosphere, microstructure, and surface behavior [15,31,37–39].

Figure 4. LPBF fixation and parameter evidence.

LPBF has the most developed evidence base among all the additively manufactured NiTi implants available. Several papers report successful formation of dense or porous NiTi components, net structures, cages, and fixation devices customized according to

the geometry of patients' bones using LPBF or other selective laser melting techniques [31–33,42,49]. High density close to 99.9% means that defect minimization is attainable but does not mean that LPBF is free from defects. The advantages of high density lie in reduced risk of crack formation, but the resulting component should meet the requirements of composition, microstructure, surface quality, mechanical reliability, biocompatibility, corrosion, and fatigue resistance.

The biomedical potential of LPBF becomes apparent when looking at patient-specific fixation. Plates and mandibles made of stiffness-modulated NiTi bone fixations illustrate how additive manufacturing goes beyond a mere process. Anatomic reconstruction can be translated into a plate or mesh with defined porosity, thickness, and local stiffness, and not merely an object of a uniform material property [33,42]. The device principle behind this approach involves designing an architectural means to control the stress distribution without compromising the mechanical integrity needed for the fixation. In cases of maxillo-facial reconstruction, it becomes essential to consider the compatibility of implant, screw positioning, elasticity, and the bone contacting surface.

The anatomic samples shown in Figure 2, as well as the LPBF manufacturing panels in Figure 4, give a good idea of the reasons behind the selection of LPBF for patient-specific bone fixation devices. The choice seems clear because the main requirements of the technology are the precision of shape, possibility of forming thin features, precise hole formation, and controllable local stiffness. While DED is capable of producing a porous bulk material, it lacks the proof of creating anatomic implants. EPBF, in its turn, allows for producing metallic objects under a vacuum, but there is insufficient information on their design specifics.

Surface-related considerations further complicate the issue of biocompatibility. It is not sufficient to refer to the broad utilization of NiTi alloys in biomedical implants, since the application of additive manufacturing technologies alters the surface morphology and composition of the device in question. The partially fused particles, step features, localized variations in oxide content, and internal surface of the pores may have significant effects on protein adsorption, cell attachment, bacteria adhesion, and corrosion processes. While increased surface roughness may help improve the interlock of the implant with tissues, the same surface roughness will become a source of fatigue cracks or bacterial niches in case they are located improperly. Similarly, increased surface-to-volume ratio needed for bone ingrowth will be of great concern due to possible nickel release in case of insufficient passivation.

The shape memory and superelasticity properties of the material may also be affected by route sensitivity. Measuring the superelasticity properties of NiTi in an ideally shaped and compact specimen will not allow concluding about the superelasticity of a porous lattice or a fixation plate due to stress concentration and non-uniform thermal history of each. For example, porous lattice will have areas where stresses are concentrated at nodes, and thin plates will differ in terms of their thermal history at edges or in screw holes. In other words, the superelasticity property of NiTi needs to be evaluated on specimens of appropriate shape and structure. In future qualification for implants, it is advisable to include coupons alongside appropriate sub-components whose geometry is relevant to the material's response, in a way that the material's reaction will not be divorced from its functional design.

There are, however, some critical risks associated with LPBF that need to be managed before the implant can be deemed finished. These include the risks of nickel evaporation, oxygen uptake, and high residual stress. The scanning strategy could also result in the development of anisotropy and varying sensitivity to phases by different parts of the structure. Research on defect-free LPBF of NiTi, on the other hand, indicates that extremely good superelasticity is achievable if all sources of porosity and cracking are ruled out as well as the risks of nickel evaporation and oxidation [15,43]. This actually strengthens, rather than weakens, the need for careful process control. In summary, for implants based on LPBF of NiTi, the correct characterization is not that the technique is a way to achieve

a functional implant. It is rather a technique that can lead to highly practical implant architecture under proper parameter, atmospheric, and post-processing control.

In the case of LPBF fixation devices, the most critical challenge is one of balancing precision and finishing. Customizable thin plates, screw holes, and porous regions are very useful, but the same attributes can complicate the removal of powder residue and impede polishing of the structures. Indeed, recent research on NiTi plates whose stiffness can be varied demonstrates the need to treat polishing and thermomechanical analysis as an integral part of the manufacturing process [42]. Polishing will be critical not only for lowering the risk of tissue irritation and fatigue but also for ensuring mechanical interlock of the bone-finding region.

The second translational challenge for LPBF is finding the right balance between tunability and repeatability. By manipulating factors such as energy deposition, scan spacing, chamber oxygen content, material composition, and subsequent heat treatment, LPBF can manipulate the transformation properties of NiTi. This would be a significant capability if it were consistent across batch sizes and geometries. An implantable device cannot depend on a processing parameter combination which succeeds under specific lab conditions but provides unpredictable transformation properties when part geometry is varied. Any process map for the use of LPBF in NiTi must show the best performance result and also the degree of repeatability around this point. The margin of safety within which the process can produce a successful result may turn out to be as critical as the peak property value itself.

EPBF falls somewhere in between LPBF and DED. Processing takes place under vacuum, reducing the risk of contamination to some extent, and the increased powder-bed temperature may lower residual stress compared to processes which apply steeper thermal gradients. These features provide advantages in the manufacture of dense parts and oxygen-sensitive applications. Yet the results obtained with EPBF in NiTi alloy fabrication show less consistency in phase stability, transformation properties, and mechanical characteristics than those achieved with LPBF [34,50]. This does not mean EPBF has no relevance.

Transformation-sensitive materials are the most likely EPBF family to be used in the current pathfinding. There may be an application for vacuum operation and minimized residual stresses when creating functional parts, although this alone would not justify a route choice. The real issue is one of whether the processed part will maintain its transformation temperatures, ability to strain recover, and its fatigue and corrosion properties needed for use. It could be that the most useful thing about EPBF is if further study can show consistent connections between laser current, scanning speed, bed temperature, phase content, and surface conditions.

The EPBF panels in Figure 5 illustrate EPBF as a path that demands direct validation rather than assumption of effectiveness. The vacuum build environment can indeed be considered an important strength in terms of contamination avoidance, but the phase check and nickel release views demonstrate the existing biomedical challenges in EPBF. The dense EPBF NiTi samples clearly require documentation of phase composition, transformation temperature, recoverable strain and fatigue behavior, corrosion resistance, and surface nickel release before they can be reliably classified as transformation sensitive [17,19,34,50].

These EPBF data provide additional confirmation that the strengths of a given manufacturing pathway need to be associated with specific endpoints needed by an individual implant. While vacuum-based manufacturing can be expected to lower contamination, the required endpoint for NiTi functionality is not just low contamination, but the proper transformation temperature, recoverable strain, stable cyclic response, reasonable fatigue lifetime, and correct surface response. Higher powder bed temperatures could lower residual stress, but could also affect grain growth and phase precipitation. Accordingly, EPBF must be considered in a similar fashion to LPBF and DED, whereby its true strength is contingent on the actual endpoint being achieved by the printed structure.

DED offers a new kind of evidence. Unlike the best possible geometry, it focuses on porous load-sharing capacity. Porous NiTi scaffolds via laser-engineered net shaping were

shown with porosities of 12-36%, reversible strains of 2-4%, and an apparent modulus close to 18 GPa [30]. The latter figures are highly relevant since they address the issue of mechanical mismatch. A porous NiTi scaffold with an apparent modulus of 18 GPa is much closer to the load-sharing goal than a fully dense NiTi implant. Moreover, these data clearly prove the retention of functional properties in a porous additively manufactured material.

Figure 5. EPBF validation sequence.

The specific relevance of DED can also be seen through its impact on tribocorrosion resistance. In contrast to DED Ti-6Al-4V and DED NiTi immersed in phosphate-buffered saline at 37 °C, the wear track for the former was considerably wider, measuring roughly 420 and 210 μm for DED Ti-6Al-4V and DED NiTi, correspondingly [35]. Tribocorrosion is especially relevant to bone-contacting and joint adjacent implants due to the possibility of mechanically-assisted corrosion in addition to static immersion. Therefore, a material and process combination with relatively low stiffness and good tribocorrosion response is critical in load-bearing designs.

Figure 6. DED porous NiTi performance evidence.

DED images presented in Figure 6 provide quantitative evidence for the porous-scaffold classification of the material. Images of the scaffolds depict the reported 12–36% porosity range, the bending test fixtures demonstrate the 2–4% reversible strain capability of the material, the compression specimen reveals the apparent modulus of 18 GPa, while the wear tracks provide evidence for the approximation of a 210 μm DED NiTi track in relation to the 420 μm DED Ti–6Al–4V track. In other words, based on the presented images, DED NiTi can be classified as porous, load-sharing scaffolds due to the provided experimental data about modulus, strain and wear behavior [30,35].

Potential of DED to produce porous implants must also take into account certain limitations of relying solely on the modulus value of the material. As such, although the elastic modulus serves as a good predictor of stress-shielding potential of implants, their survivability also depends on fatigue strength, load distribution, pore regularity and lack of crack-like imperfections. In essence, a material with a suitably reduced modulus could easily fail even if its struts were not melted or had sharp notches. Therefore, the most relevant finding related to DED manufacturing process was both the reduction of the modulus to 18 GPa and the capability of reversible strain. This combination connects material function with implant architecture in a way that dense-metal comparisons cannot capture.

The tribocorrosion result also merits cautious interpretation. While a smaller wear track under simulated conditions may indicate promising mechanical-assisted corrosion properties for DED NiTi, in-vivo conditions are more complex and involve proteins, cells, different pH levels, and prolonged time. The significance of the result is in its comparison at the process level and its applicability to the surface degradation mechanisms. This result confirms the feasibility of using DED NiTi for load-bearing implants, though further work must explore the combination of tribocorrosion testing, nickel release, surface chemical properties, and fatigue testing following appropriate surface treatment.

Similarly, the DED process calls for some caution. With a rougher as-cast surface, increased melt pool size, reduced resolution, and possible thermal accumulation, DED poses challenges regarding fatigue and corrosion behavior. Porosity, in addition, must be better managed since non-uniform pores may lead to stress concentration. Surface finishing will also pose extra difficulties due to inaccessible interior surfaces. None of these issues discredit the suitability of DED for porous implants, but they outline the way forward. For example, the DED NiTi scaffold should be characterized via pore geometry, compressive response, fatigue, corrosion, tribocorrosion, and nickel release; mere porosity is insufficient.

The measured values are summarized in Table 2. The table intentionally is brief because the interpretation of the numbers consists in their implications for the selection of implant classes. The number itself becomes significant as part of a route and surface characterization scheme.

The experimental results listed in Table 2 demonstrate why route choice should always be conditional and case-dependent. LPBF is effective due to its ability to deliver maximum density and optimal architecture; however, its corrosion and transformation behavior should be validated under the given parameter set. DED is advantageous by virtue of its mechanical porosity values being directly comparable to skeletal load-sharing; however, surface engineering and fatigue properties have to be accounted for at the very onset of the process. EPBF offers an advantage through its vacuum-based process conditions, although there are fewer critical measurements in favor of implant-ready superelastic behavior in the table.

Surface engineering is the outcome shared by all three routes. Surface properties and chemistry play an instrumental role in NiTi biocompatibility and performance in contact with bodily fluids. Previous studies on the biocompatibility, cytotoxicity, allergic reactions, and nickel leaching from the metal explain why the passive state of the surface cannot be disregarded [17–20]. Such considerations gain additional importance in additive manufacturing due to the increased surface area and presence of potential nucleation sites

in the form of roughness, powder deposits, local oxidation, or internal pores. All three AM routes may fail in meeting medical requirements due to improper surface management.

Table 2. Reported quantitative values.

Reported measurement	Reported value	Route context	Manufacturing interpretation
Near-dense fabrication	Approximately 99.9% density	LPBF	High-density NiTi is feasible, but phase and surface validation remain necessary [31,32,36].
Porous scaffold range	12–36% porosity	DED	Porosity can be used as a designed stiffness-control variable [30].
Functional porous response	2–4% reversible strain	DED	Porous NiTi can retain recoverable deformation [30].
Low apparent stiffness	Elastic modulus near 18 GPa	DED	The stiffness range supports skeletal load sharing [30].
Tribocorrosion wear width	About 210 μm for DED NiTi and 420 μm for DED Ti–6Al–4V	DED comparison	DED NiTi shows favourable wear under simulated physiological tribocorrosion [35].
Atmosphere productivity effect	Approximately 40% build-rate increase	Powder-bed fusion atmosphere study	Shielding gas composition can affect productivity and thermal behaviour [37].
Hatch-distance microstructure shift	Grain size from about 190 to 478 nm	LPBF	Hatch spacing functions as a microstructural control variable [38].
Scanning-speed corrosion response	46% decrease in charge-transfer resistance	LPBF	Scan speed can alter electrochemical behaviour [39].

There are a number of possible surface treatments. Polishing and electropolishing help to eliminate asperities and detached particles. Ultrasonic nanocrystalline surface treatment helps in improving surface quality and tribological performance of additive manufacturing NiTi [44]. Surface anodization can produce TiO_2 structure, resulting in changes in wetting, biocompatibility and corrosion characteristics [45,47]. Calcium phosphate and hydroxyapatite coatings increase osteogenic response and bone incorporation [46,48]. Each coating will be applied in consideration of implant type. While in case of a fixation plate, smooth surface and specific bone-contacting roughness are needed, in porous scaffold, the chemistry of the surface should act even within its internal structures.

The panels in Figure 7 show that surface properties are now regional properties of the implant that can involve passivation reaching inaccessible struts, polishing, controlled surface texture, or oxide or coating modifications affecting corrosion, bacteria response, and cell adhesion. Such a view is consistent with work on ultrasonically processed surface modifications, electrochemical polishing for anodic oxidation, nanotube growth, and hydroxyapatite coatings of NiTi [44,45,47,48].

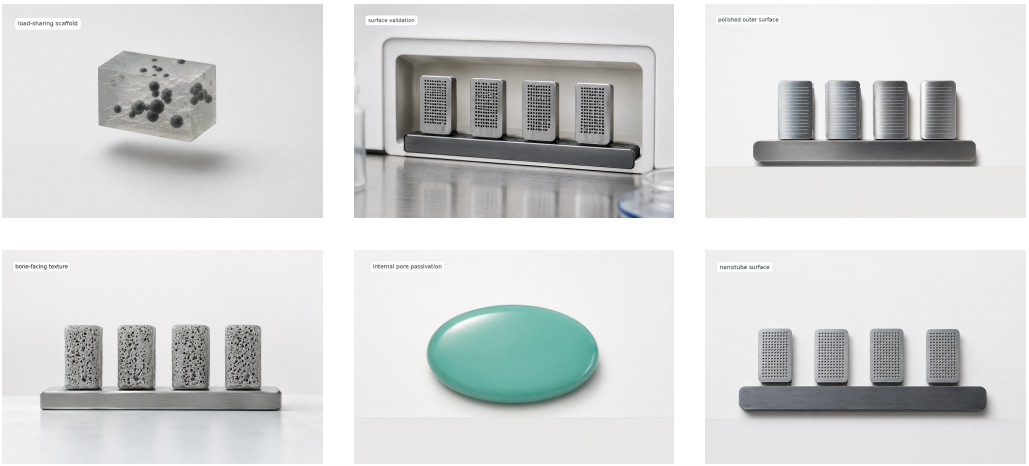

Figure 7. Region-specific surface states.

Route classification can now be made according to this analysis. LPBF clearly takes first place for fine-tuned patient-specific devices due to geometry and architecture being top criteria. DED clearly takes first place for load-sharing porous scaffold due to the

quantitative published data on these properties. In cases in which density and vacuum processing are critical, EPBF is still the route of choice, but the choice for transformation-sensitive devices needs direct measurements of phase transformation and superelastic recovery. All three routes require surface engineering, and none should be considered implant-ready just because they have printed parts close to net shape.

Table 3 provides the pragmatic solution to our research problem. The critical route is one that takes into account the criticality of the corresponding implant risks. In the case of geometric mismatch and thin feature control being critical factors, the LPBF becomes the critical route. However, if stress shielding and porous load sharing become the critical risks, then DED is the critical route. In case contamination control and dense processing emerge as the key risks, then EPBF becomes a potential candidate but needs validation due to transformation response. This is the reason why surface treatment is listed as required in all cases.

Table 3. Implant-class route assignment.

Implant requirement	LPBF	EPBF	DED	Decision basis
Fine anatomical geometry	Strong	Conditional	Moderate	LPBF has the clearest evidence for detailed patient-specific fixation and lattice design [32,33,42].
Porous stiffness reduction	Strong	Conditional	Strong	DED has direct evidence for 12–36% porosity and modulus near 18 GPa, while LPBF remains useful for fine designed lattices [30,49].
Dense transformation-sensitive function	Conditional	Conditional	Conditional	All routes require phase verification because chemistry and thermal history can shift transformation response [14,34,43].
Low-contamination environment	Moderate	Strong	Moderate	EPBF benefits from vacuum processing, although functional evidence must be confirmed [34,50].
Tribocorrosion-relevant porous bulk	Moderate	Conditional	Strong	DED NiTi has direct comparative evidence of a narrower wear track than DED Ti–6Al–4V [35].
Surface-controlled biological readiness	Required	Required	Required	Corrosion, nickel release, bacterial adhesion, and osseointegration depend on route-specific surface treatment [44,45,47,48].

The qualification panels in Figure 8 further indicate how the route evidence must be translated into an implant specification. After selecting the right process route, the next steps include parameter confirmation, testing of the architecture, surface characterization, and mechanical/electrochemical analysis of the specimens representing the final product. Therefore, the last panel reiterates the most significant finding: LPBF works best for patient-specific implants, DED works best for porous load-bearing structures, and EPBF needs to be confirmed by transformation and surface characterization for the dense functional components [30,35,42,45].

Figure 8. Device qualification pathway.

The more extended discussion above also highlights that the NiTi design for biomedical purposes requires abandoning the notion of printable and non-printable features of additively manufactured products. In particular, the printed product may be dense and non-functional, porous and non-mechanically reliable, or accurately-shaped but bio-incompatible. Consequently, the proper evaluation procedure should consider process parameter influence on the chemistry, microstructure, surface quality, architecture, and specific class of biomedical implants. It is especially relevant because there are numerous

scientific publications discussing coupon-level data related to additive manufacturing while biomedical implants have complex shapes, internal pores, screw holes, thin struts, and load paths.

This paper's implication for future research is not merely to conduct more process studies. Future research should report implant-specific datasets on each process in a form that is conducive to route classification decisions. In LPBF studies, data such as density, transformation temperature, nickel loss, oxygen content, surface roughness, corrosion response, and impact of post-polishing must be provided. In DED studies, data on pore structure, strut morphology, fatigue performance, tribocorrosion, and nickel ion leaching from internal surfaces are needed. In EPBF, data on phase composition, tensile-superelasticity, cyclic recovery performance, and surface chemistry under controlled beam and bed temperature must be reported. In general, biological testing must relate to actual surface states in device design rather than to polished coupons.

One important conclusion arising from the above interpretation is that the optimal route could change even within a single implant design. For example, in a reconstructive medical device that consists of regions that need to be dense and fixated, porous, and polished for contact with soft tissues, LPBF may have an advantage in geometrical accuracy. However, depending on whether each region contacts tissues directly or indirectly, its surfaces will require polishing, secondary processing, or special surface modification, respectively. Hence, in designing such a device, the selection of route must start with the expected failure mode; the selection of specific routes may differ for different regions.

The importance of failure-mode-based selection of routes has been noted above. It is important to note that each type of failure mode has a unique combination of material and process properties that can lead to better device performance. For example, in the case of stress shielding, architectural and modulus properties dominate. In the case of screw-hole fatigue, surface finish is crucial; for functional transformation loss, composition and thermal history determine device behavior, while surface oxide integrity and surface chemistry govern biological reactions. Thus, the proposed approach offers engineers better insight into selecting between LPBF, EPBF, and DED processes.

4. Implications of Manufacturing Processes on Implant Design

The first implication of the manufacturing processes is that when the architecture is the principal performance criterion, LPBF should be used. In cases where patient-specific implants, such as fixation plates, mandibular reconstruction assemblies, thin porous meshes, and cage-like devices are designed, there must be a seamless transition from computer-generated models of anatomy to the actual device geometry. LPBF is an ideal technique for this application, as it is characterized by the ability to incorporate intricate features and small-scale architectures through a layer-by-layer powder-bed process. The technique is chosen not because post-processing steps are eliminated but due to the necessity for exact geometry and architecture.

The second implication is that when porous mechanics outweigh the need for surface finish, DED becomes the preferred choice. It is appropriate for scaffold and load-sharing applications, where the goal is to have a low apparent modulus and resilient porous deformation. The specific figures for DED-porous NiTi become significant because they reflect the mechanical properties necessary in porous materials. A modulus of about 18 GPa with reversible strains of 2–4% provide a better indication of the suitability of NiTi porous skeletons than just referring to its flexibility. What must be borne in mind is that there is still some work to do with respect to DED conditions and pore morphology.

The final implication is that EPBF is a validation-dependent manufacturing route for dense parts and contamination-sensitive architectures. The benefits of vacuum deposition are clear, but the biomedical functionality goes beyond atmosphere. Validation will need to cover the transformation temperature, superelastic cycling, corrosion, and nickel release from a real EPBF NiTi implant following realistic finishing procedures. EPBF is likely to become more compelling as process maps improve, but the current categorization should

reflect the inconsistency of the functional properties as compared to LPBF architecture and DED porous mechanics.

The final implication is that surface engineering must be included in the design specification. It cannot suffice to assert that the implant is made out of NiTi and thus is corrosion-resistant. Surface roughness, oxidation behavior, and nickel or titanium enrichment at the surface are sensitive to the route of fabrication. Treatment techniques must be consistent with the particular geometry involved. Electropolishing may be appropriate for external LPBF implants designed to hold tissue fixation devices in place, whereas nanotubes or bioactive surfaces may be preferred for bone-implant contact surfaces. This geometrically-based approach is required to successfully implement NiTi-printed implants.

Table 4. Surface strategy by implant class.

Implant class	Preferred surface emphasis	Reasoning
Dense transformation-sensitive component	Uniform oxide, low nickel release, minimal roughness-induced fatigue sites	Functional reliability depends on phase stability and surface passivation; corrosion and release testing should follow finishing rather than as-built printing [19,29,45].
Porous load-sharing scaffold	Internal-surface passivation, bioactive chemistry, retained pore interconnectivity	High surface area increases release and corrosion relevance; coatings must not close transport pathways or alter designed stiffness [27,28,48].
Patient-specific fixation hardware	Smooth external regions, controlled bone-facing roughness, accessible polishing strategy	Anatomical plates and meshes require fit, fatigue tolerance, screw-hole integrity, and surface states matched to tissue contact [33,42,44].

Surface strategy in Table 4 illustrates the tangible implication of surface governance. One size does not fit all when designing a surface for an implant. Different areas of an implant require different surface qualities because surfaces exposed to soft tissues, surfaces facing bones, surfaces around screw hole edges, and surfaces within pores play different roles. The implication is that any future manufacturing of NiTi implants will require region-specific surface design, whereby the printing process will dictate the structure while the surface process will dictate function.

In this light, a practical qualification process can be developed using the same principles. The first step will involve route identification according to the dominating requirement for the implant. The second step will require validation of parameters through density assessment, defect characterization, compositional analysis, and phase evaluation. Step three will involve architectural validation through use of geometry-specific specimens, including pores, struts, screw hole structures, or curved plates. The fourth step will entail surface validation using the real finishing route. The last step will involve mechanical and electrochemical testing under device-representative conditions. This approach addresses the problem of validating the surface properties of a polished coupon rather than those of the actual implant, which features rough internal surfaces and complex geometry. This is a process that eliminates the usual problem of confirming a smooth coupon when the finished implant is rough inside and has complex geometry.

The communication of the results of negative or conditional nature is also critical. If the EPBF produces an alloy with high density but a poor phase transformation consistency, the problem shall be communicated as a restriction of the route rather than being implied by the density readings. Similarly, in case the LPBF produces excellent geometry yet the pre-polishing stages release a lot of nickel, the use of surface treatment is a must. In the case where the DED creates a highly porous material and high roughness inside the struts, the feasibility of finishing should be part of conclusions. The transparent disclosure of limitations would greatly enhance the value of literature on the subject, helping the design of implants since it will show clearly what process is capable of being used to produce devices of a particular category and what is still a mere material processing route experimentation.

The last implication relates to the criteria of reporting in such studies. A study of NiTi implants must include not just the process parameters and values, but also the condition of the surface, the stage in which the measurements have been made, the accessibility of the internal pores to surface treatment, and nickel release data measured in the appropriate conditions. Without that information, the comparison of manufacturing routes will be ineffective as the same printed material may look safe or unsafe depending on the surface treatment procedure used.

An additional manufacturing aspect pertains to when surface treatment takes place. While surface finishing is usually mentioned after printing, for NiTi implants it should affect routing selection before the process commences. A design incorporating internal cavities that cannot be accessed through direct line-of-sight could rule out a surface route. In the case of a fixation plate with threaded screw holes, edge finishing and roughness adjustments might need to take place before mechanical testing, since an unfinished edge will likely predominate fatigue behavior. An implant designed for bone integration might call for a surface route that enhances bioactivity without sacrificing porosity. This indicates that 'manufacturability' needs to be considered not only in terms of printability but also of finishability.

The same rationale can be applied to heat treatments and mechanical tests. If a particular heat treatment is required to stabilize transformation behavior, it needs to be evaluated on the final product or on a selected substructure. Thin-strutted LPBF scaffolds, DED walls, and dense EPBF coupons can exhibit a very different response to the same thermal treatment due to differences in their local cooling history and defect distribution. Mechanical testing, accordingly, should comprise both material-level and architecture-level tests. The former would help understand the material response, while the latter would indicate if such response can be preserved under the expected loading.

In turn, the reported values thus acquire a tangible manufacturing significance. On the one hand, the findings illustrate that the NiTi implantation is indeed feasible via various additive manufacturing methods. On the other hand, the figures provide specific justification for the respective routes by pointing out failure risks associated with each. The density data confirm the choice of LPBF, since this technique is characterized by high precision and low defects. Similarly, the measurements regarding porosity, Young's modulus, reversible strain, and tribocorrosion provide a solid rationale for DED. EPBF appears to be the best option only when contamination is controlled after phase and superelasticity assessments.

5. Conclusions

This paper responds to its research question by proving that route-class matching is necessary for additive manufacturing of NiTi implants, while universal process ranking cannot be applied to them. LPBF should be used for patient-specific fixation hardware, thin porous meshes, and anatomically fitted devices due to its capability of producing high-density implants with complicated architectural features, as well as translating complex geometrical models directly into implants. It can be applied if the major concern is geometry misfit or local stiffness control deficiency; however, this process depends on rigorous energy input, atmosphere, evaporation of nickel, hatch spacing, corrosion resistance, and post-processing control.

DED can be recommended as the best choice for porous load-bearing NiTi scaffolds aimed at achieving low modulus of elasticity, reversible deformations, and mechanically stable porous structure. Specific evidence about their porosity ranging from 12 to 36% and the ability to endure reversible deformations up to 2–4% with moduli of elasticity equal to 18 GPa confirms the route choice. The results of the comparison of tribocorrosive behavior of DED NiTi and DED Ti–6Al–4V implants indicate that DED is the best process for producing biomedical implants resistant to mechanically assisted corrosion. DED should nevertheless be validated using pore structure, fatigue, internal surface condition, corrosion, tribocorrosion, and nickel release tests.

The EPBF process is best viewed as an appropriate route to denser or contamination-sensitive NiTi implants. Reduced residual stress is one of the process benefits, but it does not alone ensure implant suitability. The selection of EPBF is only warranted if phase compositions, transformation temperatures, cyclic recoveries, corrosion resistance and surface chemistry have been demonstrated in the particular implant under consideration.

It should be considered practically beneficial that such criteria provide more consistent grounds for publishing the results of NiTi biomedical experiments by researchers and manufacturers. In other words, the justification of the route must follow from the necessity to implement a certain function of the implant. In addition, any claims of medical suitability need to contain details on the surface conditions for the tested components. It guarantees that geometry innovation, material performance and bioavailability remain connected through a single evidence base.

The most important finding is that surface treatments influence each of the processes. Thus, there can be no correlation between NiTi biomedical suitability, printed geometry and dense or porous nature of the structure. Any finishing treatments, oxide removal, electropolishing, nanotube fabrication, hydroxyapatite or polymer-brush coating have an impact on the corrosion, biological and osseointegrative characteristics and even nickel release. As such, a fully developed manufacturing specification for NiTi biomedical parts requires mentioning both routes – printing and surface treatment. The assignment is straightforward. LPBF will serve as a basis for personalized fine structures, DED will be utilized for porous load-bearing architectures, and EPBF will cover dense implants.

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