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Original Research Article

Sinter-based additive manufacturing for metallic implant applications: challenges and opportunities

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Abstract: Patient-individualised metallic implants manufactured via additive manufacturing (AM) are gaining increasing clinical relevance, with powder bed fusion using laser or electron beam (PBF-LB/M, PBF-EB/M) currently representing the commercially established standard. While these processes enable controllable lattice structures for osseointegration, high density, and good dimensional accuracy within a high technology readiness level, sinter-based AM (SBAM) processes may offer technical or economic advantages for specific applications in the future. This review examines the current challenges and opportunities of SBAM processes for metallic, in particular titanium implant applications. Key technical hurdles include geometric accuracy due to sintering shrinkage, chemical composition control (particularly oxygen and carbon limits for titanium alloys), and mechanical properties with emphasis on fatigue performance. However, economic analysis suggests that while AM printing costs may be competitive and comparable, extensive post-processing requirements can diminish printing cost advantages. Thus, significant opportunities for SBAM, such as superior as-sintered surface quality beneficial for internal lattice structures, higher resolution enabling fine surface texturing without post-processing, and as-sintered microstructure control, exist. Furthermore, sinter-based processes enable processing of alternative materials including metastable beta-titanium alloys and biodegradable metals such as magnesium, which are challenging to process via PBF-LB/M.

I. Introduction

Patient-individualised metallic implants are gaining increasing attention in orthopedic and maxillofacial surgery and are already being used commercially. Companies such as KLS Martin or implantcast demonstrate the clinical viability of AM titanium implants for cranial reconstruction and facial trauma [1] and hip cups [2], respectively. Currently, PBF-LB/M and PBF-EB/M represent the methods of choice, as they enable the fabrication of controllable pore and lattice structures for osseointegration, achieve high relative densities exceeding 99 %, and provide good dimensional accuracy [3, 4].

A key advantage of AM over conventional manufacturing is the inherent design freedom, which enables patient-specific geometries derived from computed tomography (CT) or magnetic resonance imaging (MRI) data without the need for patient-specific tooling [5]. Additionally, the ability to incorporate graded lattice structures addresses the persistent clinical challenge of stress shielding - a phenomenon caused by elastic modulus mismatch between implant material and surrounding bone that remains a primary cause of implant loosening and failure [3]. According to the Gibson-Ashby model, the effective elastic modulus of porous structures can be tailored through porosity control, enabling better load transfer to surrounding bone tissue as well as bone ingrowth [6, 7]. However, strength and fatigue strength decline highly dependable on chosen design [8], where Triply Periodic Minimal Surfaces (TPMS) appear to have best fatigue endurance ratios around 0.2 [7, 9] but only after post-processing such as hot isostatic pressing (HIP) and polishing.

Despite these advantages, PBF-LB/M faces limitations including high equipment and operating costs, limited feature size, high surface roughness, challenges within complex internal geometries, and difficulties processing certain material classes such as highly reactive or low-boiling-point metals. For such niche applications, SBAM processes - including binder jetting (BJT, see Figure 1), Cold-Metal-Fusion (CMF), lithography-based metal manufacturing (LMM), MoldJet (MJT) or even sinter-based material extrusion (MEX) - could offer distinct technical or economic advantages. These processes decouple the shaping step from densification, potentially enabling superior surface qualities, finer feature resolution and access to a broad range of materials.

Figure 1: BJT-processed and polished finger joint implant for the proximal phalanx (left) and metacarpal bone (right), courtesy Fraunhofer IAPT

This review summarises the current technical challenges and emerging opportunities for SBAM in metallic implant manufacturing, with particular focus on titanium alloys as the predominant implant material class due to their high biocompatibility, corrosion resistance and strength-to-weight-ratio [10, 11].

II. Technical challenges

For titanium and especially Ti-6Al-4V as frequently used implant materials, significant hurdles exist for commercial application of SBAM processes in medical technology. For titanium powder metallurgy in general, Hidalgo et al. [12] identified the acceleration of the sintering process, impurity control, and microstructure control as the main challenges. For AM specifically, process stability regarding density and dimensional accuracy presents additional concerns.

II.I. Geometric accuracy and shrinkage

SBAM processes require a densification step during which significant volumetric shrinkage occurs, typically ranging from 15-20 % linear shrinkage. Local density variations in green parts, especially vertical (z-direction), arising from the printing process are amplified by uneven shrinkage during sintering, leading to geometric distortion and dimensional inaccuracies [13].

Material extrusion processes are particularly susceptible to such defects due to the nature of extrusion paths, which can create systematic density gradients between infill regions and perimeter walls [14]. While general design guidelines exist for sinter-based processes borrowed from metal injection molding (MIM) experience, component-specific iterations remain necessary for complex implant geometries.

Sintering simulations offer potential for predicting and compensating shrinkage behaviour, though validation for AM-specific green part characteristics is ongoing [15].

II.II. Chemical composition control

While chemical requirements for stainless steels such as 316L or 17-4PH can be routinely achieved with SBAM, titanium and its alloys pose significant challenges due to their high affinity for oxygen and carbon. The ductility of titanium is critically impaired at oxygen contents above approximately 0.33 wt%, with a steep decline in elongation at fracture [12]. Consequently, ASTM F2885 and ISO 5832-3 specify maximum oxygen content of 0.20 wt% and carbon content of 0.08 wt% for Ti-6Al-4V surgical implants.

As Janzen et al. [16] demonstrated for BJT of Ti-6Al-4V, the fine particle size distributions required for adequate green density (<40 µm) result in high specific surface areas that readily absorb oxygen during the process chain. This leaves little margin for meeting specification limits when starting powders already contain close to 0.2 wt% oxygen. Table 1 summarises the chemical composition compliance of Ti-6Al-4V parts produced by different SBAM processes based on published literature except for LMM. While carbon limits are generally achievable for thermoplastic binder systems - particularly with recent advances in low-residue binder systems - oxygen limits remain problematic across all processes examined.

Table 1: Chemical composition compliance of Ti-6Al-4V for different SBAM processes.

Process	C < 0.08 wt%	O < 0.20 wt%	Ref.
CMF	✓	✗	[17]
BJT	✓	✗	[18, 19]
MJT	✓	✗	[20]
LMM	(✗)	(✗)	-

To the best of knowledge, for LMM, both carbon and oxygen limits are still frequently exceeded to date, attributed to the newly developed thermoset photopolymer binder systems employed. However, significant progress has been made through binder development in recent years, and ongoing research aims to address these limitations.

II.III. Mechanical properties

SBAM processes generally achieve lower relative densities than MIM or PBF-LB/M, typically ranging from 95-98 % compared to >99 % for optimised PBF-LB/M. While tensile strength is mostly acceptable - and often elevated due to interstitial strengthening - fatigue performance is significantly compromised and barely examined.

Additionally, sintering of titanium alloys in the beta-phase region (above ~995°C for Ti-6Al-4V) leads to substantial grain coarsening during densification, with prior beta grain sizes frequently exceeding 300 µm.

This coarse microstructure negatively affects fatigue crack initiation and propagation resistance. Table 2 summarises the mechanical properties of Ti-6Al-4V parts produced by selected sinter-based AM processes compared to desired and commercially achieved properties.

Table 2: Summarised mechanical properties of Ti-6Al-4V parts from selected SBAM methods.

Process	Density in %	UTS in MPa	A in %	Fatigue ratio f
general	≥ 99	≈ 1000	≥ 10	≥ 0.5 [3]
CMF [17]	95.5-98	1019	9.6	≈ 0.13*
BJT [18, 21]	≥ 96	≥ 900	9-13	0.15**
MJT [20]	97	960	14	No data
LMM [22]	97-98.5	1040	18-20	No data

*Fatique endurance ratio estimated using Basquin equation with values from [23] and UTS from [17]
** n= 10^6 cycles

Surface roughness and near-surface defects are identified as primary causes for the reduced fatigue performance in additively manufactured parts [24] (see Figure 2). In the study by Kaschube et al. [23], where CMF-manufactured surface roughness values of S_a = 7-11 µm were achieved through ceramic stone tumbling, the surface was still identified as the dominant crack initiation site in the high-cycle fatigue regime. Residual porosity of 1.8-2.3 % observed in metallographic cross-sections was also considered detrimental to consistent fatigue performance.

Whilst the fatigue properties achieved via SBAM are generally not sufficient, the limited published fatigue data for SBAM processes further complicates qualification efforts and regulatory approval pathways for medical devices to date.

III. Opportunities and solutions

Despite the challenges outlined above, SBAM processes offer unique advantages that may prove decisive for specific implant applications.

III.I. Surface quality

Fundamentally, as-sintered surfaces from sinter-based processes exhibit superior quality compared to as-built PBF-LB/M surfaces which are characterised by partially melted powder particles and comparably high roughness. For example, Melentiev et al. reported a R_a of 1.6 µm for LMM whereas PBF-LB/M typically exhibits R_a > 10 µm [25].

This advantage is particularly relevant for internal surfaces within complex lattice structures such as the graded TPMS structures that cannot be accessed for mechanical post-processing, but generally useful to reduce post-processing.

As reported by Oosterbeek et al. [26], the Hirtisation® electrochemical surface treatment enabled to reduce internal surface roughness of PBF-LB/M graded structures from S_a = 12 µm to 6 µm, improving the fatigue endurance ratio by approximately 80 %. For sinter-based processes, the inherently smoother internal surfaces could reduce or eliminate the need for such post-treatments, simplifying the process chain for lattice-containing implants.

Pre-sinter surface treatments represent another emerging opportunity of SBAM. For CMF, Headmade Materials together with AM Solutions has proposed a green-state surface smoothing approach that leverages the comparably easy to blast polymer of the green part for mechanical treatment before final densification, achieving surface roughness up to R_a = 1 µm after sintering and tumbling [27].

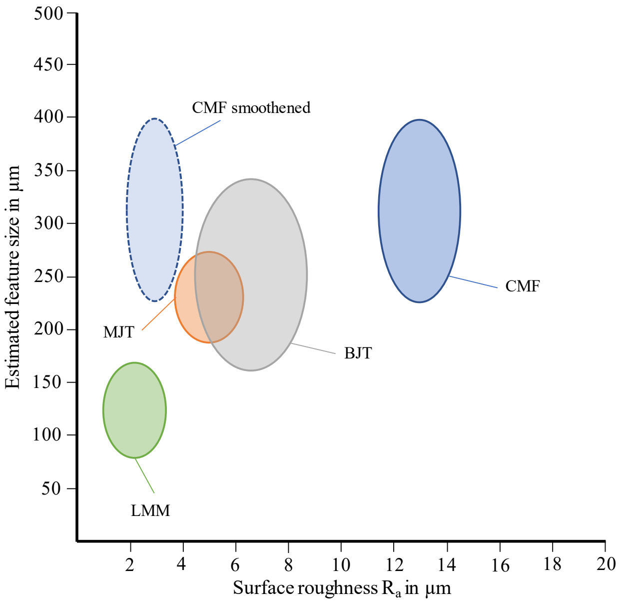

Figure 2: Estimated possible minimum feature sizes and surface roughness of selected SBAM processes, adapted data from [25, 27–32]

III.II. Feature resolution

SBAM processes, especially LMM, offer very high resolutions, enabling fabrication of features like fine surface textures that may promote osseointegration without requiring post-processing. While PBF-LB/M is fundamentally capable of producing distinct osseo-integrative structures, these face limits in design freedom and may not reach full potential.

This led to the ongoing iraSME research project “LitEndo”, where a hip cup together with its open, highly freestanding tripod surface, shown in Figure 3 is developed to be manufactured via LMM. The spike-like structures can hardly be manufactured by other AM processes, making the traditional casting manufacturing process necessary.

Furthermore, high resolution SBAM, in particular LMM, possess the ability to create controlled surface porosity through exposure pattern design - rather than incorporating macroscopic lattice structures - which could provide osseointegration benefits while maintaining structural integrity in thin-walled implant regions

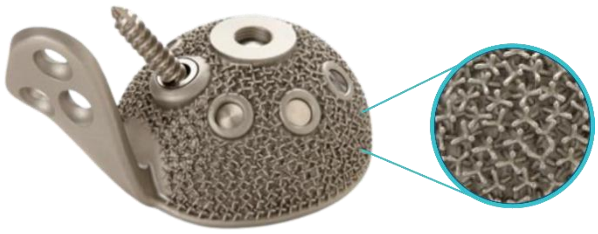

Figure 3: Casted commercial REVISIO® cup system (with kind permission) with osseointegrative tripod structure out of CoCrMo as sample for LitEndo project (LMM-printed hip cup)

III.III. As-sintered microstructure control

As discussed in section II.III., the coarse as-sintered microstructure of Ti-6Al-4V because of densification in beta phase is a major issue for achieving wrought-like properties. As thermomechanical post-processing isn't possible for near net-shape geometries, alternate pathways have already been developed.

Element22´s patented (EP 3 231 536 B1) "Selective Bead Sintering" (SBS) process uses fine powder ≤ 25 µm, which is also common in SBAM processes, to leverage the high sinter activity and reduce sinter temperature close to β-transus [33]. The remaining α Phase prevents unimpeded beta grain growth and the formation of typical lamellar structure after cooling below beta transus, which results in a globular microstructure favourable for ductility and fatigue [34]. Grain sizes remain below 30 µm, which indicates barley grain growth. Thus, a reproducible, fine globular microstructure can be attained without any post-processing, promising for medical applications.

A potentially transformative opportunity for sinter-based AM of titanium alloys is the hydrogen sintering phase transformation (HSPT) process, developed and patented (US 9816157B2) by researchers at the University of Utah [35]. This process addresses the need for microstructure control without requiring thermomechanical processing, being incompatible with near-net-shape manufacturing. The HSPT process utilises a hydrogen-containing furnace atmosphere to temporarily hydride α+β titanium alloys in the beta-phase region. Upon cooling, an aluminium-rich α_2 phase forms first, followed by titanium hydride (δ phase) at lower temperatures [36, 37]. Subsequent annealing at moderate temperatures reduces the hydrogen, leaving behind an extremely refined microstructure below 1 µm that dramatically reduces the length of alpha lamellae - the primary path for fatigue crack propagation in lamellar titanium microstructures [38]. Further annealing can achieve both bimodal and globular microstructures out of the as-sintered state, showing similarities to conventional annealing after mechanical treatment. Therefore, wrought-like microstructures of near net-shape geometries can be attained within a single furnace process including densification and microstructure modification.

Importantly, the HSPT process also benefits sintered density. Dehydrogenation during subsequent vacuum annealing creates new lattice defects that stimulate further densification, enhanced by the improved self-diffusion coefficient of titanium containing dissolved hydrogen [39]. Through the HSPT process, as-sintered Ti-6Al-4V can achieve fatigue strengths up to 500 MPa with fatigue endurance ratios of 0.4-0.5, approaching wrought material performance [38, 40]. This represents an improvement of approximately 150 MPa in fatigue strength compared to conventionally sintered material at similar density, even more compared to SBAM, rooting from the significantly finer microstructure.

However, Paramore et al. [38] hypothesised that besides extreme-sized pores, relatively large α grains formed at prior beta grain boundaries during high-temperature sintering - which are not refined by the HSPT treatment - may limit fatigue performance. Consequently, controlling beta grain growth during densification through reduced sintering temperatures (1050-1100 °C) can further improve fatigue life [41]. Possibly, the addition of rare earth elements such as Boron [42] or Yttrium [43, 44], which have shown to be beneficial for pinning grain growth, scavenging oxygen and mechanical properties such as fatigue strength, may amplify the impact of HSPT cycle for fatigue performance even further.

III.IV. Alternative and biodegradable materials

Sinter-based processes enable the use of materials that are challenging to process via PBF processes, opening opportunities for next-generation implant materials. Moreover, difficulties in impurity control, especially oxygen, may be overcome by selecting more suitable materials.

For one-to-one replacement of Ti-6Al-4V, metastable beta-titanium alloys such as Ti-15Mo or Ti-13Nb-13Zr, could be an alternative, offering significantly lower elastic modulus (55-85 GPa) compared to Ti-6Al-4V (110 GPa), potentially reducing stress shielding without requiring extensive lattice structuring [45]. The lower beta-transus temperatures of these alloys may also reduce grain coarsening during sintering. Moreover, the alloys may form α" martensite, which reduces elastic modulus [46] and may lead to a grain refinement when recrystallised.

These alloys such as Ti-Nb-Zr are also able to tolerate higher levels of oxygen, allowing the use as a cheap strengthener [47] and overcoming poor ductility when exceeding 0.3 wt% limit. Although their carbon solubility is even lower when compared to Ti-6Al-4V, there is already researched a possibility of carbide control [48]. Cobalt-chromium-molybdenum (CoCrMo) alloys are considerably less susceptible to carbon and oxygen pickup than titanium, and carbon content can even be reduced during hydrogen sintering through carbothermal reactions.

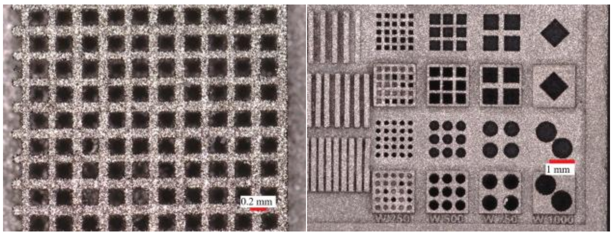

Figure 4: Filigree features of sintered CoCrMo sample, green parts printed with LMM by Incus GmbH

This makes CoCrMo an attractive candidate for sinter-based AM of articulating implant components. For LMM, first trials have shown good geometric accuracies with cross section densities >99.5 % with carbon content control being challenging but crucial for liquid phase sintering to high densities (see Figure 4). Biodegradable metals such as magnesium and molybdenum represent a particularly promising application domain for sinter-based AM, making an additional operation obsolete.

Magnesium alloys, to date already commercially available [49], are of high interest for temporary fracture fixation devices, as they can be fully resorbed by the body, eliminating the need for second implant removal surgery [50]. The degradation rate has shown to be highly dependent of alloying elements and testing method, ranging from <20 µm/year up to 25 mm/year [51]. Mainstream technologies of magnesium AM are PBF-LB/M and wire arc AM (WAAM) [52]. However, magnesium powders are highly reactive and potentially explosive and exhibit low laser absorption, making PBF-LB/M [53] processing extremely challenging from safety and process control perspectives [54].

Binder-based processes enable magnesium processing under controlled atmospheres with significantly reduced risk, as the powder is bound immediately upon feedstock production. Moreover, extrusion processes such as piston-based material extrusion enable hollow structures, defined via extrusion infill strategies, which can lead to graded degradation behaviour [55].

An example is given in Figure 5. As there is no AM-specific biomedical magnesium alloy developed yet, both AM pathways still face several challenges [51]. For SBAM, Azadi et al. generally report a low research maturity, where further research is required, particularly with respect to binder development and debinding, sintering and cycle time, fatigue properties as well as degradation control.

Molybdenum, a refractory metal with excellent biocompatibility [45], demonstrates controllable corrosion rates of uniformly few to benchmarked 20 µm per year, combined with high strength [56], which sums up to a mechanical stability of appr. 6 months, suitable for temporary implant applications in oral and maxillofacial surgery where large-volume degradation is not required [57].

Figure 5: piston-based extruded Mg4.5Gd alloy, courtesy Fraunhofer IAPT

The extremely high melting point (>2600 °C) makes molybdenum challenging but manufacturable for PBF-LB/M [58, 59] but also processable via sinter-based routes with appropriate high-temperature sintering equipment. The use of BJT for patient-individual maxillofacial applications is lately being researched in MOLY-Impact project, funded by Carl-Zeiss-Stiftung [60].

IV. Economic considerations

A comprehensive economic comparison between SBAM processes as well as PBF-LB/M is challenging due to the high variability in equipment costs and application-specific requirements such as part handling and depowdering. However, based on own cost calculations considering Fraunhofer IAPT equipment (e.g. Markforged DMP2500 for BJT), labour cost, as well as data from Wohlers Reports 2022-24 and a Fraunhofer IAPT case study comparing CMF to PBF-LB [61], several general observations can be made (Figure 6). Processes accounting for ≥5 % of total costs are labelled with their corresponding percentage.

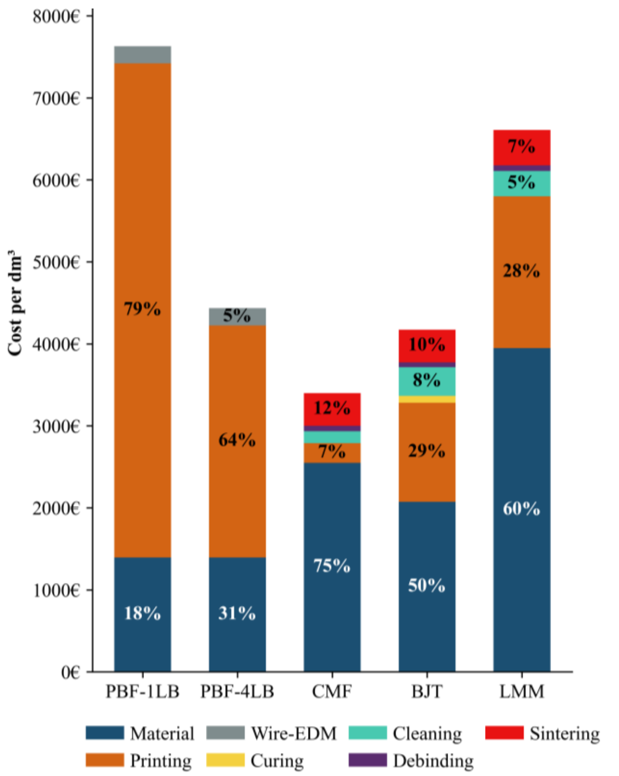

Figure 6: Estimated cost per manufactured dm³ Ti-6Al-4V of selected AM processes, based on estimated machine hour rates and 50 % printing productivity; post-processing excluded.

Estimated machine hourly rates have shown to be comparable to a SBAM AMPOWER report [62]. The cost structure of additively manufactured titanium parts is predominantly influenced by material costs (especially for SBAM) and printing productivity. While single-laser PBF-LB/M systems exhibit the highest overall cost, CMF and BJT demonstrate significantly lower production costs. This cost advantage is primarily attributed to printing productivity. Although SBAM processes require additional debinding and sintering steps, these contribute less than 25 % to total costs while eliminating the need for wire-EDM separation from build plates. Other than expected, manual part cleaning, being particularly problematic for filigree and lattice structures and often increasing labour costs [21], are not a main cost driver when assuming moderate manual work of 4-8 h/dm^3 and 35 €/h labour cost. However, for filigree parts, manual workload such as cleaning and part handling may multiply throughout the process chain and become a major cost driver.

Furthermore, the cost structure of PBF-LB/M extends beyond the printing process itself to include stress relief heat treatment, HIP for pore closure, support structure removal and surface finishing. For SBAM, post-processing of functional surfaces and, in particular, HIP may also be necessary. Thus, the reduction of post-processing remains a critical factor for AM economic viability, where recent SBAM improvements appear promising due to their combination of high resolution, superior surface quality, in-process annealing and competitive productivity.

V. Conclusions and outlook

SBAM processes face significant technical challenges for prosthesis applications, particularly regarding geometric accuracy, chemical composition control and fatigue performance of titanium alloys. Current state-of-the-art sinter-based processes achieve fatigue endurance ratios of only 0.10-0.15 for Ti-6Al-4V, compared to 0.5-0.6 for wrought material - a gap that must be addressed for load-bearing applications.

However, several benefits suggest a growing role for SBAM in medical device manufacturing. Important tools for achieving acceptable material properties are already available, and ongoing research in binder development and cost reduction, sintering optimisation, and process simulation continues to narrow the gap with established PBF technology. For specific applications, particularly components requiring fine surface features and biodegradable temporary fixation devices, SBAM may emerge as the preferred manufacturing route. Moreover, alternative materials in development, including metastable beta-titanium alloys, CoCrMo, and biodegradable metals, have shown to be more suitable material choices for SBAM.

Future work should focus on generating comprehensive fatigue data for sinter-based AM materials, qualifying SBAM-specific alloys, developing application-specific design guidelines accounting for distortion compensation, and establishing regulatory pathways building on existing MIM precedents.

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Author Contributions

M.H.: Conceptualisation, Methodology, Investigation, Writing, Original Draft; L.W.: Funding & Resources, Review & Editing, Supervision

Author's statement

Authors state no conflict of interest. Informed consent: Informed consent has been obtained from all individuals included in this study.

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