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Lasers in the manufacturing of cardiovascular metallic stents: Subtractive and additive processes with a digital tool

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Abstract

Laser beams can be manipulated to achieve different types of interaction mechanisms with metals allowing them to heat, melt, vaporize, or ablate them. Today's laser sources are robust, fast-addressable optoelectronic devices, easily integrated into automation systems along with sophisticated CAD/CAM solutions. Being a photonic digital tool, the laser beam is a fundamental tool for Industry 4.0 and is already widely exploited in the manufacturing of metallic stents. The conventional manufacturing method of laser cutting employs a subtractive method to cut the stent mesh on tubular feedstock. On the other hand, laser beams can be exploited to melt metallic powders to produce stent geometries in a layer-by-layer fashion. The present work provides a short state of the art review concerning the works focusing on the two laser-based manufacturing processes underlining the evolution of the laser source types and used materials. The work provides insights into the future opportunities and challenges that should be faced by the manufacturing research communities in the light of improving the biomedical device performance by exploiting the possibilities provided by the digital tool.

Keywords: Laser cutting; laser powder bed fusion; laser microprocessing; pulsed lasers; biomedical device

1. Introduction

Cardiovascular diseases are amongst the major causes of death in Europe. Cardiovascular stents have become an essential device for resolving the narrowing of arteries with a minimally invasive surgery. Stents are commonly placed in the narrowed artery by means of a catheter and expanded to the final dimension either by means of a balloon or superelastic behaviour. The simple functioning principle of the cardiovascular stent requires a cage-like

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tubular geometry that maintains its shape for the duration required to remodel the artery. Since their introduction as a solution to cardiovascular pathologies, metallic stents have been widely produced via laser based manufacturing processes. Initially laser cutting of microtubes was the preferred method due to the high focusability of the laser beams to small spots able to produce the strut sizes in the range of 100 µm. As the laser technology developed further, several novel possibilities enhancing the functioning of the biomedical device emerged thanks to the flexible manufacturing platform allowed by the digital photonic tool. Today, lasers can provide the means for both subtractive manufacturing with small beams (typically 20-80 µm) through laser cutting and additive manufacturing through laser powder bed fusion for the metallic stents. The recent developments in the laser technology provides further opportunities for higher precision, higher productivity, and in-process monitoring solutions. Indeed laser systems have become a workhorse in industrial manufacturing with the leading applications in cutting and welding. The increased flexibility and adaptability of the laser based manufacturing systems result in a system revenue of up to 50 billion USD [1]. Similarly the metal additive manufacturing processes are widely driven by the pace of the laser based processes. While stent manufacturing is a highly specific application, the benefits of the laser based manufacturing processes by means of a digital tool have been exploited arguably since the inception of the device. Hence, this work provides an overall view of the two manufacturing routes and the related scientific literature with an outlook on the future challenges.

2. Subtractive and additive laser based manufacturing methods for stents

Laser cutting (LC) is the conventional manufacturing method used for producing metallic stents. Standard geometries are produced by cutting tubular precursors with typically 1-5 mm diameter and 0.05-0.20 mm thickness. The laser beam separates through closed incisions on the tubes. Laser powder bed fusion (LPBF) as an additive manufacturing process generates the stent geometry by layer-by-layer melting of powder precursors. Table 1 provides a basic comparison of the two manufacturing techniques. Fig. 1 shows example systems and the related components for the manufacturing of metallic stents. Fig. 2 Shows examples of stents produced by the two laser based manufacturing techniques with different materials, geometries and sizes.

Table 1. Basic comparison between the two laser based manufacturing solutions for producing metallic stents

Process	Laser cutting	Laser powder bed fusion
Feedstock	Standard minitubes	Powder
Geometry	Optimized for strength	Optimizable for patient requirements
Feature resolution	Very high (<10 µm)	Medium (>100 µm)
Toolpath programming	Conventional 2D CAM	Layer-by-layer scanning
Surface finish	Medium to high	Low to medium
Materials	Several certified alloys	Materials under development
Productivity	High	Potentially very high
Production scale	Serial, large scale, and centralized	Serial or on-demand and decentralized
Process monitoring	Highly feasible, underdeveloped	Highly feasible, progressively developing

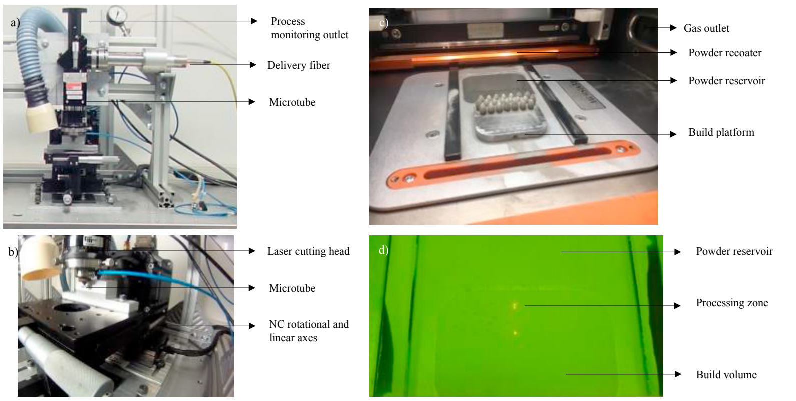

Fig. 1. Examples of laser based metallic stent manufacturing systems from Politecnico di Milano. a) General view and b) close up of the laser cutting system for microtubes. c) Internal view of the LPBF system with a reduced build platform and d) the system during the process.

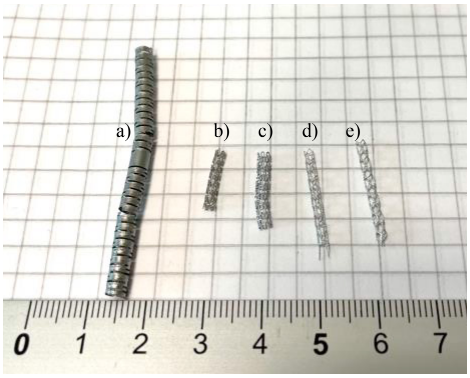

Fig. 2. Examples of biomedical devices manufactured using laser cutting (a,b,c) and laser powder bed fusion (d,e) with NiTi (a), AISI 316L (b), AZ31 Mg-alloy (c), and CoCr (d,e). The ruler shows numbers in cm.

3. State of the art in laser based manufacturing of metallic stents

The literature survey was carried out based on Scopus and sectorial conferences regarding laser based stent manufacturing (last access on 20 June 2022). The literature on metallic stent manufacturing is rather limited, although publications appear consistently. A total of 64 works were gathered and categorically analyzed between 1998 and 2022 (see Fig. 3). The first appearance of a scientific article by Kathuria describes the use of laser cutting of a metallic stent in 1998 [2]. Wessarges et al describe the use of laser powder bed fusion in 2014 [52]. To date, several types of materials have been investigated by different groups. The sparse behaviour of the number of publications per year can be related to the hardware intensive research requirements and the need to build up or work with specialized manufacturing equipment. However, several insights concerning the technological developments and future trends can be extracted from these works.

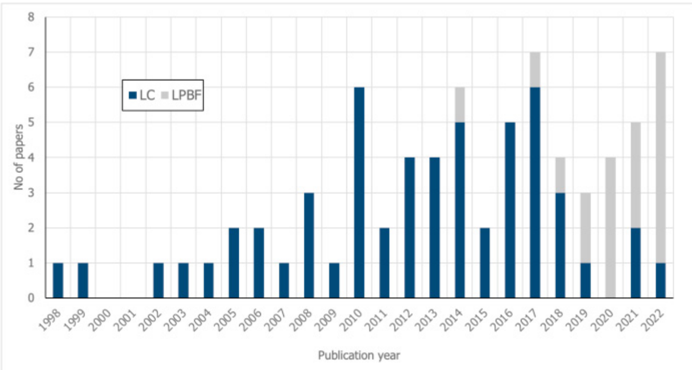

Fig. 3. Evolution of laser based metallic stent manufacturing articles over the years (LC: laser cutting, LPBF: laser powder bed fusion)

3.1. Laser cutting (LC) of metallic stents in the literature

Table 2 lists the laser cutting works in literature consisting of 51 works between 1998 and 2022. It can be seen that the research follows the certain developments in the laser technology over the years. Starting from the pulsed Nd:YAG lasers, the research converts to the use of fiber laser as early as 2002 by Keline et al [3].While being anticipated by Momma et al [2] in 1999, the use of ultrashort pulsed lasers becomes a matter of deeper discussion from 2010 as shown by Mielke et al [17] with the use of an Er:glass fiber optic chirped pulse amplification (CPA) system. Around 2010 also the long pulsed (µs to ms) and CW fiber lasers become mainstream as shown in Fig. 3.a and later dominate the types of laser sources employed as shown in Fig. 3.b. As the ultrafast ps- and fs-pulsed lasers become more widely available starting from 2010 their share in the analyzed laser cutting systems increases (Fig. 3.c). The different wavelengths are scarcely explored as visible and UV ranges have been explored in a total of 3 works, as the authors have employed the fundamental wavelengths of NIR lasers most commonly (Fig. 3.d). The vast majority of works analyzed AISI 316L as arguably the gold standard for stenting (Fig. 3.d). A considerable attention towards superelastic NiTi and biodegradable Mg and Zn-alloys has been observed since 2010.

Table 2. Laser cutting of stents in literature (t: feedstock thickness; λ: laser wavelength; na: not available; *:water cooled; +water jet guided; #submerged).

Reference	Year	Material	Feedstock	t (mm)	Geometry	Laser source	λ (nm)	Emission
Kathuria [2]	1998	AISI 316L	Microtube	0.10	Stent	Nd:YAG	1064	µs-pulsed
Momma et al [3]	1999	AISI 316L	Microtube	0.10	Stent	Nd:YAG	1064	µs-pulsed
Kleine et al [4]	2002	AISI 316L	Microtube	0.10	Stent	Fiber	1070	µs-pulsed
Gachon et al [5]	2003	AISI 316L	Microtube	0.10	Stent	na	na	na
Raval et al [6]	2004	AISI 316L	Microtube	0.11	Stent	Nd:YAG	1064	µs-pulsed
Liu et al [7]	2005	na	na	na	na	Fiber	1070	µs-pulsed
Kathuria [8]	2005	AISI 316L	Microtube	0.10	Stent	Nd:YAG	1064	µs-pulsed
Baumeister[9]	2006	AISI 316L	Thin sheet	0.10	Linear cuts	Fiber	1070	CW
Sudheer [10]	2006	AISI 316L	Microtube	0.11	Stent	Nd:YAG	1064	µs-pulsed
Kubota et al [11]	2007	AISI 316L	Microtube	0.11	Stent	Nd:YAG	1064	µs-pulsed*
Chen [12]	2008	CoCr	Thin sheet	0.08	Stent	Fiber	1070	CW
Meszlényi et al [13]	2008	AISI 304L	Microtube	0.12	Stent	Nd:YAG	1064	µs-pulsed
Sudheer [14]	2008	CoCr	Microtube	0.11	Stent	Nd:YAG	1064	µs-pulsed
Meng et al [15]	2009	AISI 316L	Microtube	0.11	Stent	Fiber	1070	µs-pulsed
Kovalenko et al [16]	2010	AISI 316L	Microtube	0.10	Stent	Nd:YAG	1064	µs-pulsed
Lesma et al [17]	2010	Mg-alloy	Thin sheet	0.40	Stent mesh	Fiber	1070	ns-pulsed
Mielke et al [18]	2010	NiTi	Microtube	0.25	Stent	Fiber optic CPA	1550	fs-pulsed
Muhammad et al [19]	2010	AISI 316L	Microtube	0.15	Stent	Fiber	1070	µs-pulsed*
Muhammad et al [20]	2010	NiTi	Microtube	0.28	Linear cuts	Disc	343	ps-pulsed
Pauchard et al [21]	2010	NiTi	Microtube	0.28	Stent	Nd:YAG	1064	µs-pulsed +
Haga et al [22]	2011	NiTi	Microtube	0.25	Stent	Ti:sapphire	775	fs-pulsed
Muhammad et al[23]	2011	Pt-alloy	Microtube	0.07	Stent	Disc	343	ps-pulsed
Chen et al [24]	2012	AISI 316L	Microtube	0.08	Stent	Fiber	1070	µs-pulsed
Demir et al [25]	2012	AISI 316L	Microtube	0.20	Stent	Fiber	1064	ns-pulsed
Demir et al [26]	2012	Mg-alloy	Microtube	0.20	Stent	Fiber	1064	ns-pulsed
Mohammad and Li [27]	2012	NiTi	Microtube	0.18	Linear cuts	Ti:sapphire	800	fs-pulsed #
Demir et al [28]	2013	Mg-alloy	Microtube	0.20	Stent	Fiber	1064	ns-pulsed
Qiang et al [29]	2013	Mg-alloy	Microtube	0.20	Stent	Fiber	1064	ns-pulsed
Muhammad et al [30]	2013	AISI 316L	Microtube	0.15	Linear cuts	Fiber	1070	µs-pulsed*
Nagy et al [31]	2013	NiTi	Microtube	0.10	Stent	Nd:YAG	1064	µs-pulsed
Bhullar [32]	2014	AISI 316L	Thin sheet	0.13	Flat stent	Ti:sapphire	800	fs-pulsed
Demir and Previtali [33]	2014	Mg-alloy	Thin sheet	0.40	Flat stent	Fiber	1070	CW
Demir and Previtali [33]	2014	Mg-alloy	Microtube	0.20	Stent	Fiber optic CPA	1550	CW
Demir et al [34]	2014	Mg-alloy	Microtube	0.20	Stent	Fiber	1064	ns-pulsed
Teixidor et al [35]	2014	AISI 316L	Thin sheet	0.10	Linear cuts	Fiber	1070	µs-pulsed
Amin et al [36]	2015	AISI 316L	Thin sheet	0.10	Linear cuts	Nd:YAG	1064	µs-pulsed
Fu et al [37]	2015	NiTi	Thin sheet	0.75	Linear cuts	Fiber	1070	µs-pulsed
Demir and Previtali [38]	2016	Mg-alloy	Thin sheet	0.25	Flat stent	Fiber	532	ns-pulsed#
García-López al [39]	2016	AISI 316L	Microtube	0.22	Linear cuts	Fiber	1070	ms-pulsed
Liu et al [40]	2016	NiTi	Microtube	0.24	Linear cuts	Fiber	1070	µs-pulsed *
Mostaed et al [41]	2016	Zn-alloy	Microtube	0.25	Linear cuts	Fiber	1064	ns-pulsed
Sealy et al [42]	2016	Mg-alloy	Thin sheet	0.70	Linear cuts	Fiber	1070	µs-pulsed
Biffi and Tuissi [43]	2017	NiTi	Thin sheet	0.10	Flat stent	Fiber optic CPA	1030	fs-pulsed
Biffi and Tuissi[43]	2017	NiTi	Thin sheet	0.13	Flat stent	Fiber	1070	CW
Catalano et al [44]	2017	AISI 316	Thin sheet	0.20	Flat stent	Fiber	1064	ns-pulsed
Catalano et al [45]	2017	Mg-alloy	Thin sheet	0.20	Flat stent	Fiber	1064	ns-pulsed
Liu et al [46]	2017	CoCr	Microtube	0.15	Linear cuts	Fiber	1070	µs-pulsed
Maudes et al	2017	AISI 316L	Microtube	1.00	Stent	Fiber	1070	ms-pulsed
Catalano et al [47]	2018	Zn-alloy	Thin sheet	0.12	Flat stent	Fiber	1064	ns-pulsed
García-López et al [48]	2018	Mg-alloy	Microtube	0.16	Linear cuts	Fiber	1070	µs-pulsed*
García-López et al [49]	2018	AISI 316L	Microtube	0.11	Linear cuts	Fiber	1070	µs-pulsed
Sun et al [50]	2019	AISI 316L	Microtube	0.20	Linear cuts	Fiber	1070	ms-pulsed*
Nuñez-Nava et al [51]	2021	Mg-alloy	Microtube	0.11	Linear cuts	Fiber	1070	µs-pulsed
Sun et al [52]	2021	NiTi	Microtube	0.20	Linear cuts	Fiber	1070	µs-pulsed
Cadena et al [53]	2022	NiTi	Microtube	0.23	Linear cuts	Fiber	1070	µs-pulsed

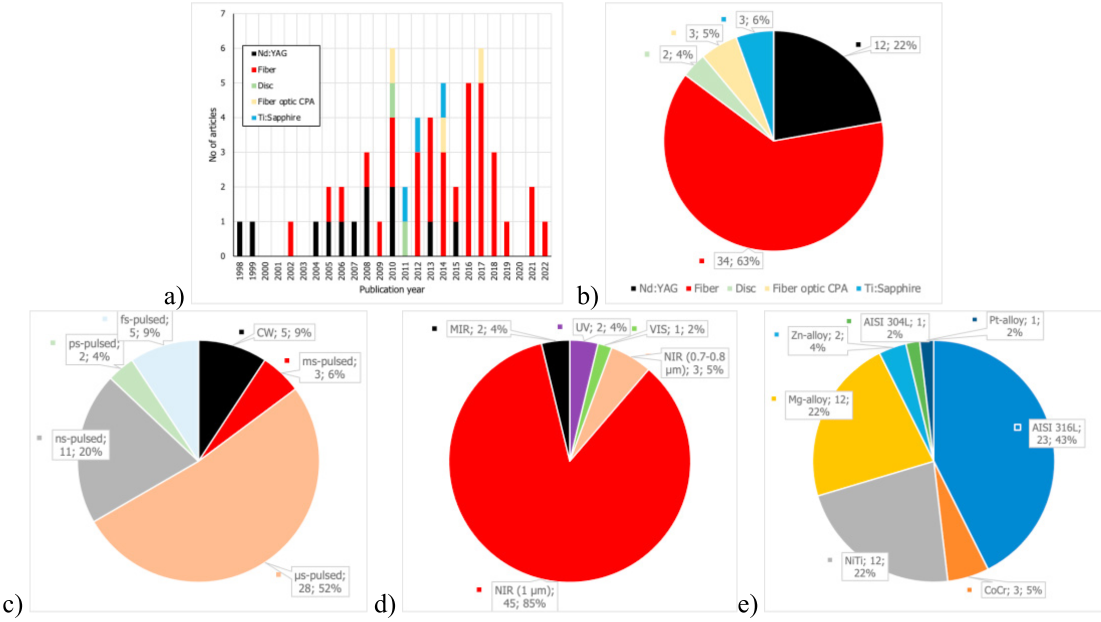

Fig. 4. The distribution of laser cutting of metallic stent works in literature a) in years and in terms of b) the used laser sources, c) the emission modes employed, and d) the corresponding emission wavelength ranges.

Amongst the different explored technologies the use of wet cutting [18], water jet guided cutting [20], and submerged cutting in different liquids (eg. water, alcohol, oil) [26] emerges. While the authors have demonstrated improvements in the cut quality, their use has been limited apparently due to the more complicated manufacturing systems. The rise of high power ultrashort-pulsed lasers in the last decade is also expected to contribute to the limited use of liquids in the laser cutting systems. Ultrashort-pulsed lasers with higher power levels (>10W) allow for high quality cuts with limited amount of dross and heat affected zones without compromising the productivity. An important aspect regarding the flexibility of laser cutting regards the employed feedstock geometry. While the conventional stents are made of microtubes cut to the stent shape, the use of flat and inflatable geometries have been demonstrated [31]. Such geometries take advantage of the small laser beam to cut through the flat material, which can be expanded to a 3D tubular form.

3.2. Laser powder bed fusion (LPBF) of metallic stents in the literature

While being widely used in the production of biomedical implants, the attention towards the use of LPBF for producing metallic stents is a relatively more recent. Wessarges et al [52] demonstrated the possibility of producing AISI 316L stents with simplified mesh geometries using a micro LBPF system and small sized powders (0-10 μm). The possibility of producing stent meshes in tubular geometries employing industrial LPBF machines and conventional powder sizes (typically in the range of 15-50 μm) was demonstrated later in in 2017 [53]. Several research groups later on started to focus on the LPBF of metallic stents. The main challenge in LPBF of metallic stents lies on the feature resolution of the conventional machines used. Therefore as reported in Table 3, the diameter and the strut size of the produced stents as well as the definition of the design rules are important factors of future feasibility. Within the limited amount of 17 works the main material of interest have been AISI 316L and CoCr, both of which are conventional stent materials and are processable stably by LPBF (Fig. 5.a). The interest over superelastic NiTi and biodegradable Fe and Zn alloys is also present in the case of LPBF. A main issue with LPBF regards the low surface quality of the as-built surfaces, while chemical and electrochemical polishing techniques are still under development (Fig. 5.b). The achieved strut thicknesses vary in a wide range between 0.05 to 0.5 mm, while the lower end of this distribution is more desirable for the final application (Fig. 5.c) .

Table 3. Laser powder bed fusion of metallic stents in literature (t: strut thickness; D: stent diameter; PP: post-processing; CE: chemical etching; EP: electrochemical polishing).

Reference	Year	Material	t (mm)	D (mm)	PP	Relevance
Wessarges et al [54]	2014	AISI 316L	0.05	2.0	None	Pioneering work with micro LPBF
Demir and Previtali [55]	2017	CoCr	0.30	2.0	CE	First journal publication, confirms feasibility of LPBF
Wen et al [56]	2018	Pure Zn	0.05	2.0	None	Shows suitability with biodegradable alloys
Finazzi et al [57]	2019	CoCr	0.02	2.0	CE	Design rules defines, bifurcated stents demonstrated
Langhi et al [58]	2019	AISI 316L	0.15	3.0	None	LPBF microstructure shown with tubular geometry
Finazzi et al [59]	2020	CoCr	0.07	2.0	EP	Functional stent design with balloon expandability
Hufenbach et al [60]	2020	FeMnCS	0.12	2.0	None	Biodegradation and expandability shown
Wiesent et al [61]	2020	AISI 316L	0.10	3.0	EP	Manufacturing irregularities analyzed by FEM
Omar et al [62]	2020	CoCr	0.30	13.0	None	Different geometries with very large diameters
Langhi et al [63]	2021	AISI 316L	0.50	2.0	None	LPBF metallurgy extensively analyzed with tubes
Maffia et al [64]	2021	NiTi	0.25	6.0 to 8.0	None	NiTi stent with variable diameter and open-cell
McGee et al [65]	2021	Ti6Al4V	0.25	10	CE	Chemical etching for removing supports for open-cell
Wiesent et al [66]	2022	AISI 316L	0.10	3.0	EP	FEM analyzing influence of geometrical irregularities
Langi et al [67]	2022	AISI 316L	0.40	4.0	EP	LPBF and commercial stents compared
Tseng et al [68]	2022	Ti6Al4V	1.20	12.8	None	Laser annealing studied on very large geometries
Yan et al [69]	2022	NiTi	0.45	12.0	None	Superelastic/biocompatible with very large geometries
Jamshidi et al [70]	2022	NiTi	0.30	8.0	CE	Superelastic behaviour observed upon heat treatment
Finazzi et al [71]	2022	NiTi	0.12	2.0 to 6.0	None	Patient specific design and superelastic behaviour

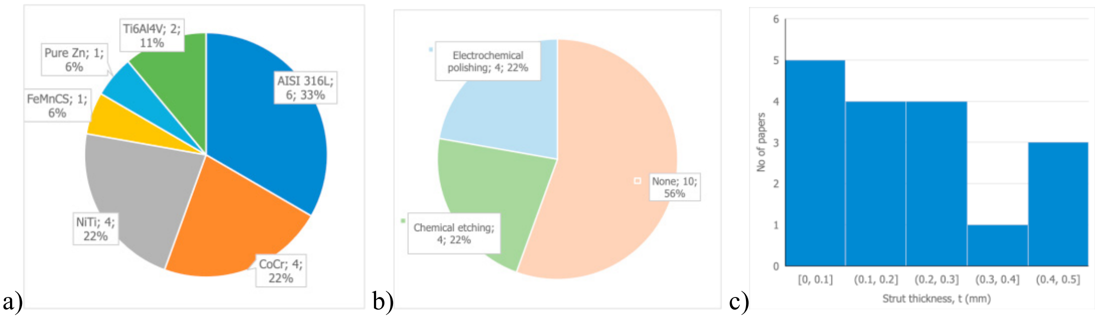

Fig. 5. The distribution of laser powder bed fusion of metal stent works in literature a) in terms of the processed materials, b) post-processing methods, and c) the resultant strut thicknesses (strut larger than 0.5 mm were excluded in the graph).

4. Opportunities and challenges of future

4.1. Geometrical opportunities

The literature survey indicates that the manufacturing solutions are not considered often with the geometrical opportunities. The recent studies on LPBF identified the need for assessing the design rules for the additive manufacturing of metallic stents, while for laser cutting such solutions are scarcely addressed. Flat stents, use of origami or kirigami approaches may be better exploited using LC and LPBF for actuation, deployment, and even for removal purposes. The achieved strut thicknesses at the end of the processing route is an important factor. While strut dimensions are related to material, geometry, and stent type the use ultrafine struts in the range of 50 µm is what is expected in the clinical use [72]. Evidently, the current production routes need to be pushed towards thinner struts in LPBF. Surface texturing for coating or drug insertion is another possibility provided by both of the technologies [73]. While surface texturing has been associated to laser cut stents, the 3D design of additively manufacturing stents with dedicated surface textures [74] can be envisaged for future with adequate feature resolution being achieved. The use of hollow sections or density variations is a possibility through LPBF that can provide benefits from the perspective of manipulating the stent properties locally.

4.2. Material challenges

Both of the laser based processes require further studies of new materials. In the case of laser cutting the attention is towards the novel biodegradable alloys, which require further understanding of the possible thermal alterations caused by the process on the biodegradation behaviour. On the other hand, the use of laser cutting of flat sheets can be a platform for producing prototype stents with novel materials. Such route would provide a more direct solution for producing implantable devices with a realistic mesh produced through a manufacturing cycle including all the main phases. The laser cutting system can be potentially used for modifying the material properties through a local heat treatment. The digital laser tool can be employed to change the material to behave in a more rigid or more elastic way enabling new opportunities in the insertion and deployment phases. Concerning LPBF, the process should be developed for standard stenting materials as well as novel ones. The rapid solidification process induced by LPBF generates very different material properties compared to the conventional ones used in laser cutting. Their mechanical and biological performances are still required to be studies. On the other hand, multimaterial processing in LPBF [75] is another new and interesting possibility that can regulate mechanical, biological, and biodegradation properties as desired providing a larger domain for the stent design [76].

4.3. Monitoring for in-process quality control

The process monitoring of LC and LPBF produced stents does not seem to be addressed in the literature. Although being an industrially employed process, the monitoring means for LC appear to have been neglected in the literature, while cutting issues related to nozzle clogging, focal point errors, geometrical deviations of the tubing should be better addressed. The LC process can benefit from methods and lessons learned in macro cutting operations and other laser micromachining processes [77][78]. In LPBF there is a vibrant literature on the process monitoring [79]. Such solutions can be investigated and adapted to the dimensional requirements of the metallic stents. Concerning the route for patient-specific devices the monitoring methods can provide the in-process or on-board quality control highly desirable for the one-of-a-kind devices.

5. Conclusions

This work showed an overview of the use of laser based manufacturing techniques for producing metallic stents. The laser beam has been shown to be a fundamental digital tool for producing the fine features of the stent geometry both in the subtractive laser cutting and the additive laser powder bed fusion methods. The work underlined the main outcomes of the literature works in a categorical manner, indicating possible future outcomes. An important aspect that remains crucial to the future research regards the communication between the clinicians and the engineers. Indeed a direct collaboration between the two parts will allow for improving the device performance and availability by a more efficient manufacturing route. The biomedical implant manufacturing field may take advantage of the identified future opportunities to for enhancing the collaborative efforts between the two sides.

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