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Title: Environmental sustainability of orthopaedic devices produced with powder bed fusion

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Abstract:

Additive manufacturing consists in melting metallic powders to produce objects from 3D data, layer upon layer. Its industrial applications range from automotive, biomedical (e.g. prosthetic implants for dentistry and orthopedics), aeronautics and others.

This study evaluates the possible improvement in environmental performance of laser-based powder bed fusion additive manufacturing systems on prosthetic device production through Life Cycle Assessment (LCA) methodology. Environmental impacts due to manufacturing, use and end of life of the designed solution were assessed. In addition, two powder production technologies, gas atomization (GA) and plasma atomization (PA), were compared in order to establish the most sustainable one. Production via traditional subtractive technologies and the additive manufacturing production were also compared.

3D building was found to have a significant environmental advantage compared to the traditional technology. The powder production process considerably influences on a damage point of view the additive manufacturing process, however its impact can be mitigated if GA powders are employed.

1 Introduction

Additive manufacturing (AM) is a 3D building technology that is rapidly increasing among manufacturing processes, in which the building process involves layering materials. Its strengths are its ability to create objects with a high geometrical complexity, which are not possible to obtain in traditional manufacturing, and the flexibility in meeting customer's requests in terms of design, without increasing the productive costs.

Its aims are perfectly in line with the European Union Industry 4.0 plan (European Parliament Research Service, 2015), which is built on the model of the high-tech strategy of the German government, and whose main objectives are an increased flexibility and productivity in manufacturing, mass customization and better quality.

In order to achieve these ambitious goals a new vision, named the "smart factory", is needed, including the integration of IT services, such as the digitisation of information and big data analysis, and of cyber-physical systems, such as embedded sensors, intelligent robots and additive manufacturing devices.

Additive manufacturing has been designated by the Boston Consulting Group, the worldwide multinational company in management consulting, as one of the five enabling technologies due to increased efficiency in material use (Sirkin, Zinser & Rose, 2015).

Powder bed fusion (PBF) is one of the latest terminologies for the designation of an AM process in which a metal powder layer is laid out over a bed and sintered by a high-energy beam, often a laser (Gibson, Rosen & Stucker, 2015).

This technology can be applied to a wide range of materials, but is most suited to metals. The opportunity to build metal objects with a complex geometry and high customization potential, which is impossible in traditional manufacturing, is one of the most interesting features from a technological, as well as a business perspective.

Selective laser melting (SLM) is one of the commonly used techniques, in which metallic powder is fully melted in high-density and 3D structures (Gibson et al., 2015) rather than sintered, thus giving greater control over material properties such as porosity and crystal structures.

Although the technical achievements of AM processes are widely acknowledged, they still need a Life Cycle Assessment (LCA), in order to evaluate the strengths and weaknesses from a sustainability perspective, in comparison with traditional manufacturing. A literature analysis was therefore conducted and the main findings are reported below.

1.1 Literature analysis

As reported by Kellens et al. (2017), regarding AM processes as self-sufficient technologies is not accurate, as post-processes are often required to reduce surface stresses due to the anisotropy of AM parts.

The same authors provided a wide overview of AM processes compared to the corresponding traditional manufacturing processes.

For example, Serres, Tidu, Sankare and Hkawka (2011), applied the Eco-Indicator 99 methodology (Goedkoop & Spriensma, 2001) to the production of a mechanical component in Ti_6Al_4V alloy, and analyzed the incidence on total damage caused by upstream processes, such as powder production and ingot production, on additive and traditional manufacturing. The authors showed that the AM involves much lower damage compared to traditional manufacturing, however the two technologies are comparable if larger parts are produced with the AM, due to the considerable amount of metal powder needed to build the component.

Peng et al. (2017) applied a system expansion approach to the AM process to model the by-product derived from unmelted loose powder at the end of the productive process. They considered five environmental indicators, global warming potential, acidification potential, Chinese resource depletion potential, eutrophication potential, and respiratory inorganics. They found that an impeller made with titanium alloy totally produced with AM has a higher impact compared to that produced with traditional manufacturing. This environmental damage is mainly due to powder production and electricity consumption. AM may only have environmental advantages if the impeller is partially produced with traditional manufacturing.

Priarone, Ingarao, Di Lorenzo and Settineri (2016) studied both productive processes (traditional and additive manufacturing) from a cradle-to-grave perspective in terms of CO_2 emissions, computed using the carbon emission signature (CES) method proposed by Jeswiet and Kara (2008), and the energy demand by applying the system expansion with substitution LCI model. They found that the environmental loads are influenced by the material removal rate - AM is the most favourable technology when a significant amount of material can be saved, although there is a higher energy consumption compared to traditional manufacturing when small quantities of material need to be removed.

Huang et al. (2015) found that AM has a considerable advantage over traditional manufacturing when different case-studies (EOS, 2013; Krailling & Novi, 2014; Munsch, Wycisk, Kranz, Seyda & Claus, 2012; the SAVING project, 2009; Tomlin & Meyer, 2011) related to the production of components for transportation vehicles, are considered and analyzed in order to outline a common profile.

The use phase plays an important role in damage assessment. Considering a period from 2014 to 2050, AM parts are preferable to the traditional manufactured ones in terms of energy savings, thanks to a significant mass reduction in the components, which entails a lower fuel consumption. Moreover, lower buy-to-fly ratios of AM parts, which were assumed to be 1.5 for all AM processes, in the cradle-to-gate LCI model resulted in lower primary energy use and GHG emissions compared to traditional manufacturing.

In the medical devices production field, the following studies have been published, however none of them involve a comparison with traditional manufacturing. Baumers, Tuck, Bourell, Sreenivasan and Hague (2011) analyzed the energy consumptions of two laser sintering platforms (Sinterstation HiQ+HS and EOSINT P 390) for building two prosthetic parts and found that most energy is employed for heating and cooling.

Sreenivasan, Goel and Bourell (2010) calculated the energy consumption for producing prosthetic parts using polymeric material by defining an energy indicator which enables different selective laser sintering processes to be compared.

1.2 Scope of the LCA study

In this study LCA methodology was used to analyse the different levels of impact on the environment of manufacturing hip prostheses using AM and traditional manufacturing processes. In particular, femoral stems produced with Ti_6Al_4V alloy by Powder Bed Fusion technology and by traditional manufacturing, over the whole life cycle, were considered.

Due to the relevance of metal powder production in terms of the total damage, gas atomization (GA) and plasma atomization (PA) were compared, in order to evaluate the most sustainable production method.

The advantages of AM compared to traditional manufacturing were also assessed through a social indicator during the impact assessment stage which expresses the acquired utility of the part produced with AM from a social perspective. In this study, the interest in the environmental performance of the product is predominant over its technical performance, although this was taken into account in the environmental analysis in order to provide a result as complete as possible.

2 Life cycle of a femoral stem produced with PBF

A hip implant is the only effective cure for coxitis, which is a degenerative disease in which the cartilage surrounding the two extremities of the joint, femoral head and the acetabulum, deteriorates.

In its primitive form, coxitis occurs in people over 60, while it can affect younger people due to congenital illness, such as dysplasia (Gruppo Biompianti, 2017). In Europe more than 600,000 hip replacement procedures were performed in 2005 (Kiefer, 2007).

The entire life cycle of femoral stems produced with AM was considered taking into account Ti_6Al_4V alloy powder production, femoral stem production, use and end of life phases. The titanium alloy production, titanium alloy powder (40 μm) production with atomization and the production phase with an EOS M290 machine were included. Waste material disposal, such as waste metal recycling and exhausted argon treatment, were also included.

During the production process, indoor emissions were taken into account, considering PPE (personal protective equipment). The main steps in the life cycle of femoral stem production with AM are described in Figure 1.

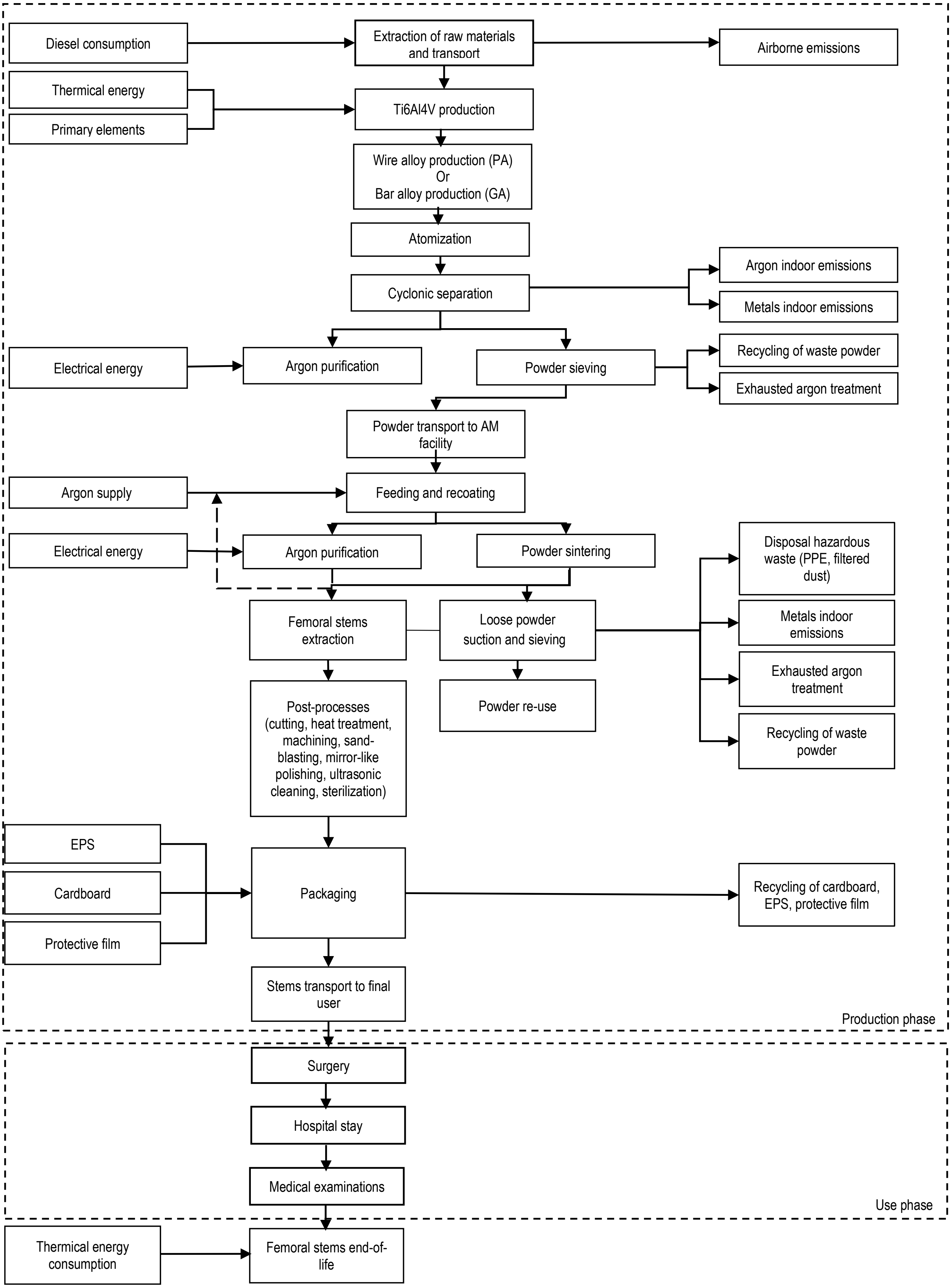

Figure 1 System boundaries of femoral stem life cycle with AM

2.1 Ti_6Al_4V powder production

Ti_6Al_4V powder production is described first considering the GA technology and then the PA. The main differences between these production processes consist in alloy feeding and atomization technology.

The PA process uses a Ti_6Al_4V wire feedstock, which is straightened and positioned at the apex of three plasma torches. Each plasma torch provides about 30 kW (Pyrogenesis, 2017) and is fed with argon. Cooling water is fed to each torch and to the atomization tower in order to ensure accurate temperature control. The plasma flow melts the wire, whose droplets solidify into spherical particles when they fall down the atomization tower.

The GA process uses a Ti_6Al_4V bar feedstock that is rotated and, at the same time, lowered into an inductive coil which melts the bar without making contact with it. The melt is then atomized by high-pressure argon jets.

Another important difference between the two technologies is the morphologic atomization efficiency. Morphologic atomization efficiency is the capacity to produce high purity and high sphericity of particles and it is mathematically defined as the ratio of perfectly spherical and pure particles over the total amount of target powder.

PA technology is characterized by nearly 99% morphologic atomization efficiency, while, GA technology has about 90% morphologic atomization efficiency. These efficiencies are estimated on the basis of SEM images reported in Popovich, Sufiiarov and Grigoriev (2017).

The outgoing argon and powder flows, for both PA and GA technologies, are then separated by the following steps:

- cyclonic separation of Ti_6Al_4V powder from argon;
- sieving of Ti_6Al_4V powder in order to accurately separate powder particles with the correct particle size distribution and morphology for AM from oversized powder, which is supposed to be sold to coating manufactures, and from undersized powder, which is supposed to be sent to metal recycling process;

- baghouse filtration which purifies exhausted argon;
- argon recirculation in the atomization process.

The powder produced by PA technologies presents a tap density of 2810 kg/m^3 (Advanced Powder and Coatings Inc., 2017), while powder produced by the GA process has a tap density of 2710 kg/m^3 (Venkatesh et al., 2016).

Both atomization processes work 16 hours/day (EOS, 2017) and are characterized by indoor and local emissions of argon and metals.

2.2 Femoral stem production

Femoral stem production takes place in an EOS M290 machine, where fusion is performed by a 400 W laser. The production lasts 61 hours and 21 minutes with a production capacity of 20 femoral stems (Poly-Shape, 2017) per job. After a set-up phase, in which argon is injected in order to minimize the oxygen level, powder is fed by the dispenser system. A 40 μm thick layer is then extended on a titanium plate with a recoater. Laser fusion involves the selective melting of cross-sections, previously defined by the CAD model. After each layer has been completely melted, the plate is lowered for a new layer deposition which, in turn, will also be melted.

During the build phase, the argon flow is insufflated in the process chamber in order to prevent the development of an explosive atmosphere due to increase in powder particles and to control the N/O pick-up. An air recirculating filtering system works continuously in order to guarantee the right level of argon purification.

After the job has been completed, the parts are extracted by workers, who wear protective equipment. Extraction involves the separation by sieving solidified parts from the remaining loose powder, which are then reused for the following job. After extraction, the parts are heat treated for two hours at 840° C, cut from the plate with a wire erosion machine and, then, finished with sand-blasting and mirror-like polishing. As the parts produced have no internal cavities, depowderization with compressed-air is not considered. Indoor metal emissions are considered, which occur during the part extraction, machine cleaning and cutting of the stems from the building platform. Waste metal powders resulting from machine cleaning and caught by protective equipment are rendered inert first and then buried in a residual landfill.

2.3 Use phase

The use phase takes into account the surgical stem implantation, a hospital stay for two weeks and medical examinations over the patient's lifetime. The average lifetime of the prosthesis is calculated to be 14.5 years. This value was obtained with a weighted average of current hip joint survivals, which range between 92% at 11 years and 86% at 22 years, as reported by Wyatt, Hooper, Frampton and Rothwell (2014). It is assumed that the first medical examination occurs in the initial weeks after the stem implantation with the second examination occurring in the same year. In normal conditions patients undergo subsequent medical examinations every five years. The medical check-up consists in X-ray examinations, which take 30 minutes, in order to evaluate the effects of wear and tear on the prosthesis. If the patient lives beyond the lifetime of the prosthesis, a surgical removal was considered. Deceases before the stem removal were defined as being equal to 25% of total implantations (rate of decease within 10 years from the stem’s implantation, Wainwright, Theis, Garneti & Melloh, 2011).

If death occurs before removal, the prosthesis is not removed from the patient, in order to preserve the integrity of the person.

2.4 End of life

Femoral stem end of life was defined following direct interviews with technicians from an Italian hospital, the Rizzoli Orthopaedic Institute. These technicians reported that prostheses are surgically removed, sterilized and then archived. No material recycling or prosthesis reuse is performed, according to practices adopted by interviewed technicians.

3 Methods: Life cycle assessment

3.1 Goal and scope definition

The goal of the study was to assess the environmental impacts of Ti_6Al_4V alloy based femoral stems produced with AM over their entire life cycle in order to identify the environmental hotspots of the system in line with UNI EN ISO 14040-14044 regulations and to propose improvements for impact mitigation.

3.2 System, functional unit and function of the system

The system studied is a bed fusion of Ti_6Al_4V alloy powder. AM is used for the application of biomedical devices, such as femoral stems. Twenty femoral stems produced with AM were analyzed.

3.3 System boundaries

The system boundaries cover the entire life cycle of the analyzed system ranging from the Ti_6Al_4V alloy feedstock and Ti_6Al_4V powder productions to the manufacture, use and end of life stages of the femoral stems (Figure 1). The system boundaries of the femoral stem production using traditional manufacturing are shown in Figure 2.

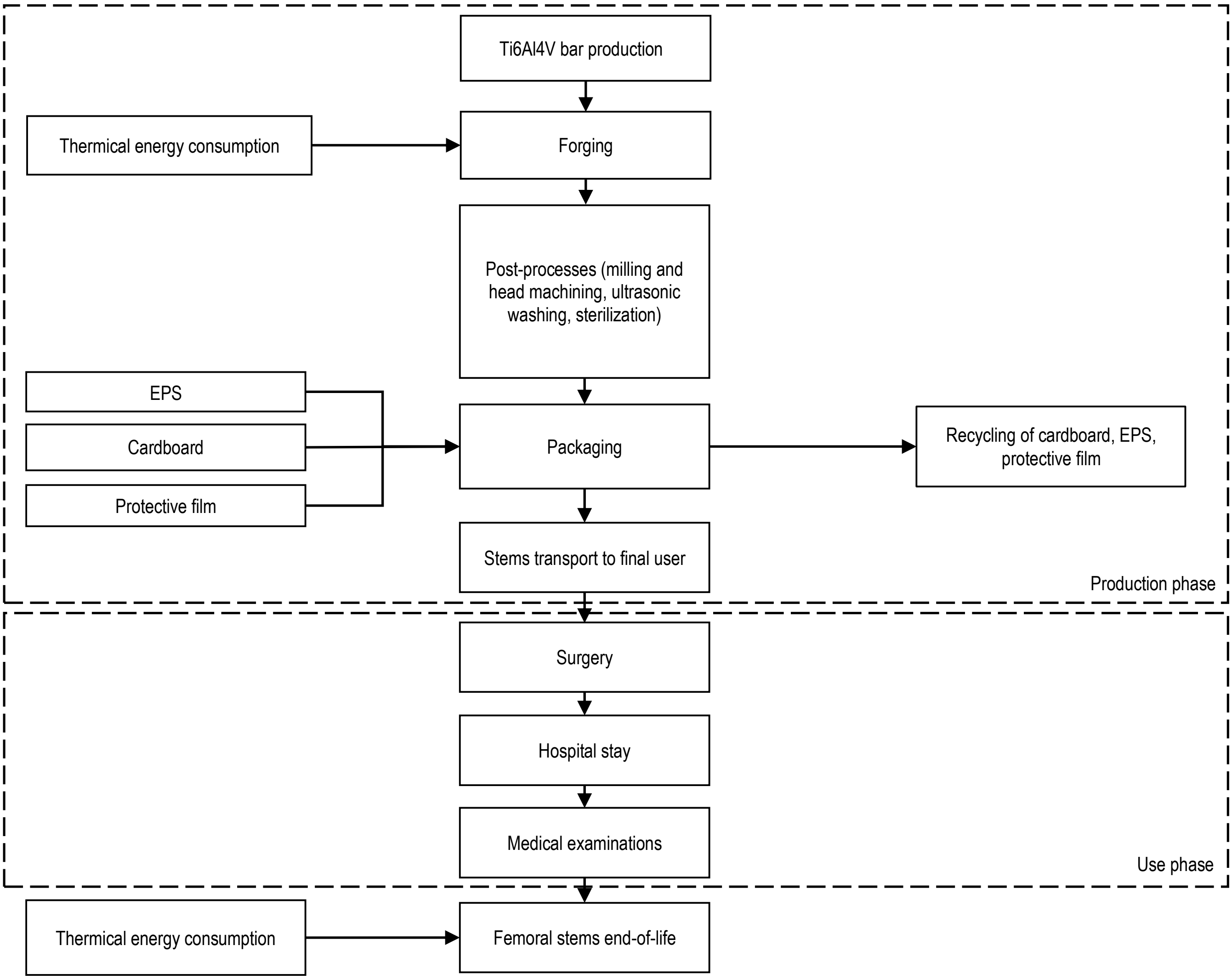

Figure 2 System boundaries of femoral stems life cycle with traditional manufacturing

The production, maintenance and disposal of facilities as well as other auxiliary materials were also included in the present study. Air and indoor emissions as well as solid and liquid waste produced in each step were considered and quantified. The following assumptions were also made:

- Transport of raw materials, facilities, systems and machines are considered for an average distance of 100 km from the producer to the user, as required by the environmental product declaration (EPD) certification, when primary data about distances are not available;
- Distance of transport of femoral stems from the producer to the final customer is fixed at 100 km: 40% by rail and 60% by road;
- Electricity energy production is assumed to be the European mix electricity energy proposed by Ecoinvent database (Ecoinvent Centre, 2018);

- Installation of 99.97% efficiency HEPA air filter during femoral stem production and powder production steps;
- Use of 99.95% efficiency personal protective equipment (filter category P3) during EOS M290 machine cleaning, cutting, powder production and exhausted argon treatment steps (EOS, 2016).

3.4 Data quality

Primary data related to the raw materials and to the AM process, the machine characteristics, the consumables needed for the stem production (such as the amount of argon, while the amount of powder is calculated on the basis of other primary data), the post-production treatments were directly collected from a market leader in AM production in Europe.

Another market leader in Europe in prostheses produced by traditional manufacturing was also interviewed. Use and end of life phases were modeled with secondary data from the literature.

The inventory analysis was modelled in SimaPro 8.5.0 (Pré, 2017) and with vers. 3.4 of the Ecoinvent database (Ecoinvent Centre, 2018).

The LCI model *attributional, partitioning*, in terms the presence of the co-product represented by loose powder remaining at the end of the production process, is considered as the most appropriate to best satisfy the assessment requirements (Pini, Neri & Ferrari, 2018). The use of *substitution* in the attributional data modelling is not considered adequate, as the co-product is not assumed identical, due to additional processes to which it has been subjected, to virgin powder, even if they perform the same function.

The allocation is based on energy criterion, in particular non-renewable and renewable energy consumption is taken into account. Energy allocation is preferred because, from a methodological point of view, it is more representative of the studied system, as it takes into account all the stages in the production of stems, from an energy point of view.

The weight allocation is declined because it would attribute almost all the damage to the co-product, according to the respective masses involved, neglecting the purpose of the process, that is the production of prostheses. Moreover, this kind of allocation would erroneously equalize the products from an importance point of view. Allocation based on economic value is not performed due to the lack of primary data.

3.5 Impact assessment methodology

The environmental analysis were carried out by the IMPACT 2002+ method, modified in accordance with Pini, Ferrari, Gamberini, Neri and Rimini (2014). Since the IMPACT 2002+ method does not taken into account local and indoor emissions, characterization factors for argon and metal emissions were obtained by adopting a preliminary method (Ferrari et al., 2019) in order to calculate indoor and local human effects. These indicators were introduced in the Life Cycle Impact Assessment (LCIA) method.

The following were thus added to the above mentioned evaluation in order to consider a wider and more representative scenario of the considered system:

- New Carcinogens categories were introduced, Carcinogens indoor and Carcinogens local, in particular, new substances are added in the new categories, namely Metals, unspecified indoor and Metals, unspecified local with defined characterization factors calculated with the method mentioned above.

  In particular, the characterization factor for indoor and local Metals, unspecified result in 1642.011 kgC_2H_3Cl eq./kg and 1255.66 kgC_2H_3Cl eq./kg. These values are obtained considering for both factors the damage factor reported in Eco-indicator 99 (EI99) of the analysed substance (6.969E-4 DALY/kg), the fate factor and the population density (namely, 3.13E-5 m^2y/m^3 and 1.17E-4 pers/m^2, both the fate factor and population density belong to Lindane, the substance that in Annex v. 3 of EI99 has a damage factor near to Metals, unspecified), local and indoor fate factors (namely, 7.39E-5 m^2y/m^3 and 1.087E-5 m^2y/m^3, calculated by Eco-indicator 99 formula considering for local emission an emitting area of 4E8 m^2 and local concentration calculated by Gaussian Plume (Zannetti, 1990), a stationary model used to simulate the air pollutants dispersion into air emitted from a chimney, for indoor emission an emitting area of 25 m^2) and local and indoor population density (considering, namely, 100000 inhabitants for the local area and 2 workers in the shed).

- A new Non carcinogens category was introduced, Non carcinogens indoor, including Argon with the calculated damage factor. The limit of argon concentration in a working space, considered to be 500 m^3, is equal to 0.18 kg/m^3 and is calculated considering the increased percentage of argon (up to 10%) in air. Considering a breath rate of 2.5 m^3/h and 8 working hours per day, the indoor argon limit of emission was calculated as 3.57 kg. Referring to Europe (with a population density of 386 million, Goedkoop & Spriensma, 2001) and considering an average lifetime of 80 years and a 50 year old man exposed to emissions, the damage factor on human health is 2,18E-6 DALY/kg and the resulting characterization factor is 0.78 kgC_2H_3Cl eq./kg.

Social category	Social issues	CF	DAF	NF	WF
Industrial product function utility	Medical devices	1	-1	1	0.001
	Suction systems	1			
	Cooling systems	0.5			
	Heating systems	0.6			
	Mechanical processings	0.9			
	Agricultural machines	0.8			
	Electronic devices production	0.6			
	Movement transmission	0.8			
Product performance	Geometry complexity	0.8	-1	1/(0.8+0.8) = 0.625	0.001
	Biocompatibility	0.8			

Table 1 Impact/damage categories added in IMPACT 2002+, with each substance, characterization factor (CF), damage assessment factor (DAF), normalization factor (NF) and weighting factor (WF)

The benefits associated with AM compared to traditional manufacturing were also assessed. The aim was to consider the benefits of an AM product that are not considered by LCIA methods. Two social categories were created: Industrial product function utility and Product performance. The first indicator identifies the field of employment of the stem and the second indicator highlights the technical improvement of the stem produced with AM.

Both consider several new issues that express, from a subjective point of view, positive aspects, and which were introduced in the method with calculated characterization factors. For each social category, characterization factors (CFs), normalization factors (NFs) and weighting factors (WFs) are reported in Table 1.

The CF value ranges from 0 to 1, based on shared values with the stakeholders. DAF was set to a value of -1, in order to consider the benefit provided by AM. The NF of the Industrial product function utility is equal to the maximum value of the characterization factors. On the other hand, for Product Performance, the normalization factor is the reverse of the sum of the characterization factors of its social issues, because the issues can all coexist. WF has a value that is three orders of magnitude lower than the WF of IMPACT 2002+, in order to prevent an excessive influence on the environmental results. Only social issues that are representative of the case study are considered in the AM process, which are Medical devices, Geometry complexity and Biocompatibility. A higher biocompatibility of the stem produced with AM is possible because of the trabecular structure of the surface. This particular geometry, that has been validated from a technical-medical point of view by the stakeholders (Castagnini et al., 2018), mimics cellular structures of the bone and is not achievable with other manufacturing processes, and leads to an improved osseointegration of the prosthesis.

3.6 Life cycle inventory

The most representative data used in the Life Cycle Inventory of 20 femoral stems production with the EOS M290 machine with GA powder are reported in Table 2.

Input	**Value**	**Unit**
Materials		
Flooding argon	3.03	kg
Building phase argon	25.94	kg
Ti_6Al_4V powder	20.83	kg
Energy		
Electricity	147.26	kWh
Transport		
Road	6.72	tkm
Output	**Value**	**Unit**
Main product		
20 femoral stems	1.77	kg
Co-product		
Loose powder	18.99	kg
Indoor emissions		
Metals, unspecified indoor	5.95E-9	kg
Argon, indoor	1.2E-7	kg
Local emissions		
Metals, unspecified local	1.9E-3	kg
Emissions to air		
Metals, unspecified	1.71E-2	kg
Argon	2.89E-4	kg
Waste to treatment		
Metal recycling	1.9E-2	kg
Disposal to residual landfill of metals captured by filter	2.08E-2	kg

Table 2 Inventory input data for the AM process of 20 femoral stems with EOS M290

The percentages resulting from the energy allocation between the main product and the co-product were derived from equations (1) and (2):

$$20\ stems = \frac{n\ Stems\ x\ (NR\ energy_{1\ stem} + R\ energy_{1\ stem})}{(n\ Stems\ x\ (NR\ energy_{1\ stem} + R\ energy_{1\ stem})) + (n\ kg\ x\ (NR\ energy_{1\ kg} + R\ energy_{1\ kg}))}\ x\ 100 = 58.32\% \qquad (1)$$

$$Loose\ powder = \frac{(n\ kg\ x\ (NR\ energy_{1\ kg} + R\ energy_{1\ kg}))}{(n\ Stems\ x\ (NR\ energy_{1\ stem} + R\ energy_{1\ stem})) + (n\ kg\ x\ (NR\ energy_{1\ kg} + R\ energy_{1\ kg}))}\ x\ 100 = 41.68\% \qquad (2)$$

where:

- $NRenergy_{1stem}$ is the amount of non-renewable energy, expressed in MJ, required for producing one femoral stem;
- $Renergy_{1stem}$ is the amount of renewable energy, expressed in MJ, required for producing one femoral stem;
- $NRenergy_{1kg}$ is the amount of non-renewable energy, expressed in MJ, required for producing 1 kg of metallic powder;
- $Renergy_{1kg}$ is the amount of renewable energy, expressed in MJ, required for producing 1 kg of metallic powder;
- n Stems are the number of stems produced in one job;
- n kg are the number of kilograms of loose powder remaining at the end of the job.

4 Results: Impact assessment

An environmental analysis of the life cycle of one femoral stem produced with GA powder was performed. The single score damage was equal to 2.36E-2 Pt[1] for GA powder usage. The results of the analysis at the mid-point level for GA powder employment are reported in Table 3.

Figure S-1 highlights that the most significant contribution to the total damage is due to the Respiratory inorganics impact category (36.34%), which, in turn, is primarily affected by Particulates, <2.5 μm (49.94%) due to the production phase (82.72% on total damage of the specific category), in particular for electric energy consumption. Subsequently, the second largest contribution to the total damage is generated by the Non-renewable energy impact category (24.78%), mainly due to Coal, hard (29.42% on total damage of the specific category). This is used in the productive process (78.74% on total damage of the specific substance), especially for energy consumption in primary titanium production, used for the alloy production. In terms of Global warming (24.10%) the main damage is due by Carbon, dioxide fossil (93.02% on total damage of the specific category), especially in the production (68.2% on total damage of the specific

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[1] Pt is the abbreviation of “points”.

substance) and use phases (31.77% on total damage of the specific substance), in particular for the incineration of hazardous surgery waste.

The human health is affected by the release of Hydrocarbons, aromatic (80.71%) which influence Carcinogens (outdoor environment, 5.7% on total damage of the specific category), especially in the use phase (85.96% on total damage of the specific substance) for the production of surgery towels in PET.

The other impact categories provide less than 5% of the total damage.

Impact category	Unit	Total	Production phase	Use phase	End of life
Carcinogens	kg C2H3Cl eq	3.41E+00	9.46E-01	2.46E+00	5.64E-04
Non-carcinogens	kg C2H3Cl eq	1.14E+00	8.04E-01	3.33E-01	5.37E-04
Respiratory inorganics	kg PM2.5 eq	8.70E-02	6.92E-02	1.78E-02	2.92E-05
Ionizing radiation	Bq C-14 eq	9.81E+02	6.37E+02	3.43E+02	2.69E-01
Ozone layer depletion	kg CFC-11 eq	5.14E-06	3.75E-06	1.38E-06	2.02E-09
Respiratory organics	kg C2H4 eq	1.69E-02	1.16E-02	5.32E-03	8.43E-06
Aquatic ecotoxicity	kg TEG water	5.55E+03	3.15E+03	2.40E+03	2.61E+00
Terrestrial ecotoxicity	kg TEG soil	9.94E+02	6.52E+02	3.41E+02	6.65E-01
Terrestrial acid/nutri	kg SO2 eq	8.19E-01	5.99E-01	2.20E-01	3.27E-04
Land occupation	m2org.arable	5.87E+00	4.31E+00	1.56E+00	1.17E-03
Aquatic acidification	kg SO2 eq	2.51E-01	1.83E-01	6.80E-02	9.68E-05
Aquatic eutrophication	kg PO4 P-lim	1.56E-02	1.11E-02	4.55E-03	1.68E-05
Global warming	kg CO2 eq	5.64E+01	3.88E+01	1.76E+01	1.75E-02
Non-renewable energy	MJ primary	8.90E+02	5.74E+02	3.16E+02	2.82E-01
Mineral extraction	MJ surplus	8.93E+01	6.39E+01	2.53E+01	1.39E-01
Energia rinnovabile	MJ	9.89E+01	6.93E+01	2.95E+01	5.56E-02
Non-carcinogens, indoor	kg C2H3Cl eq	1.69E-05	1.69E-05	0.00E+00	0.00E+00
Respiratory organics, indoor	kg C2H4 eq	0.00E+00	0.00E+00	0.00E+00	0.00E+00
Respiratory inorganics, indoor	kg PM2.5 eq	0.00E+00	0.00E+00	0.00E+00	0.00E+00

Table 3 Characterized LCIA results at mid-point level of 1 femoral stem life cycle with GA powder

The endpoint analysis highlights (Table 4) that the phases of the life cycle with the highest environmental burdens are the production (69.32%) and the use phase (30.65%), followed by end of life (0.035%). Moreover, 44.07% of the total damage affects Human Health, 27.26% affects Resources, 24.10% affects Climate Change, 4.75% the Ecosystem Quality, 3.22E-2% the Human health, local and for 3.76E-5% the Human health, indoor. The categories Product performance and Industrial product function utility provide an advantage of -9.85E-2% and -1.23E-1%, respectively.

Damage category	Unit	Total	Production phase	Use phase	End of life
Total	Pt	2.36E-02	1.64E-02	7.25E-03	8.37E-06
Human health	Pt	1.04E-02	7.54E-03	2.88E-03	3.32E-06
Resources	Pt	6.45E-03	4.20E-03	2.24E-03	2.77E-06
Climate change	Pt	5.70E-03	3.92E-03	1.78E-03	1.76E-06
Ecosystem quality	Pt	1.12E-03	7.77E-04	3.47E-04	5.11E-07
Human health, local	Pt	7.61E-06	7.61E-06	0.00E+00	0.00E+00
Human health, indoor	Pt	8.89E-09	8.89E-09	0.00E+00	0.00E+00
Product performance	Pt	-2.33E-05	-2.33E-05	0.00E+00	0.00E+00
Industrial product function utility	Pt	-2.91E-05	-2.91E-05	0.00E+00	0.00E+00

Table 4 LCIA results at end-point level of 1 femoral stem life cycle with GA powder

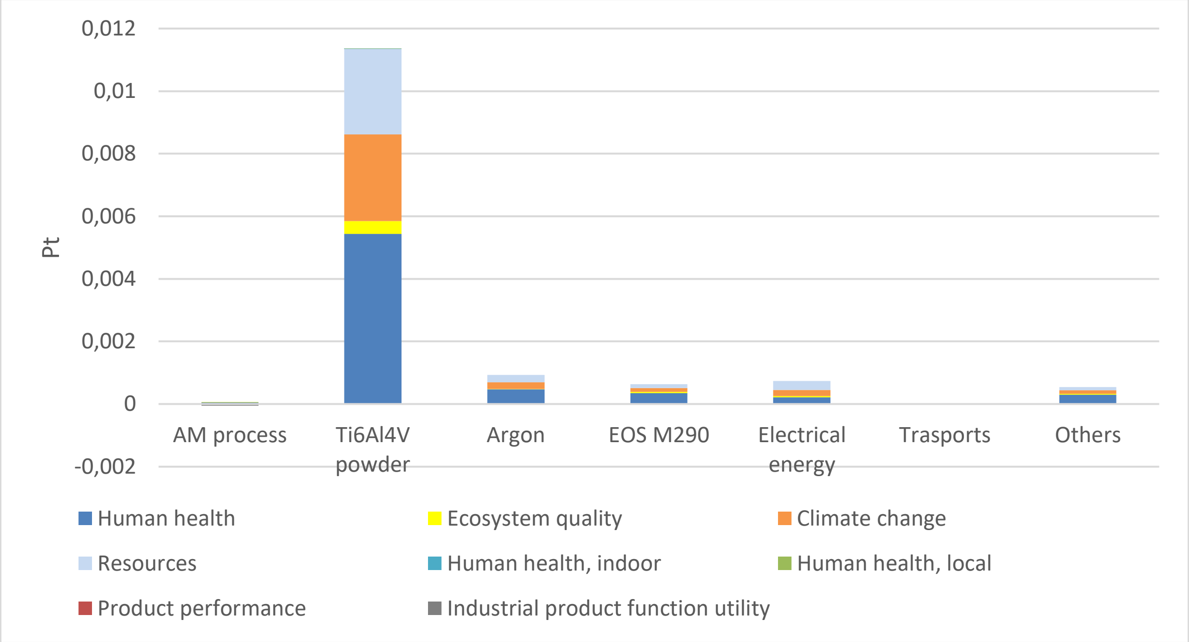

Figure 3 LCIA results at end-point level of 1 femoral stem AM process with GA powder. Underlying data used to create this figure can be found in supporting information S-2 on the Web

End-point analysis of one femoral stem production phase is 1.64E-2 Pt, where the AM process (86.79%) has the highest environmental load, and post-production treatments (6.46%) and other processes (6.73%) contribute to a lesser extent.

The analysis of the end-point analysis of the AM process (Figure 3) shows that the total damage (1.42E-2 Pt) is: 79.88% for Ti_6Al_4V powder production with GA, 6.55% for argon consumption and 5.18% for electrical energy consumption.

The damage assessment analysis shows that damage to the Human health accounts for 47.95% of the total damage, in particular with the substance Particulates, <2.5 μm (air) (49.08%, divided into 82.54% for powder production and 7.9% for argon consumption).

The Resources category provides 24.61% of the total damage, mainly for the substance Coal, hard (35.84%, due especially to the energy production for primary titanium used in alloy powder). The damage to Climate change (24%) is caused almost entirely by the substance Carbon dioxide, fossil (93.51%), 81% emitted for during gas atomization and 6.39% for argon consumption.

Aluminium in air affects the category Ecosystem quality (3.75% of the total damage) and is linked to the blasting process for hard coal extraction, used to produce energy, necessary for Ti_6Al_4V bar production process.

Human health, local accounts for 5.24E-2% due almost entirely (99.99%) to Metal, unspecified, local emitted during parts extraction and machine cleaning.

The Human health, indoor category contributes to the total damage with 6.24E-5% due, mainly, to indoor argon emissions during exhausted argon treatment and Ti_6Al_4V powder production, and then to indoor metal emissions occurring while treating exhausted argon, Ti_6Al_4V powder production and femoral stem production processes.

Finally, Industrial product function utility and Product performance provide environmental advantages, of -2E-1% and -1.64E-1% respectively.

4.1.1 Comparison of atomization processings

As Ti_6Al_4V powder production causes most of the total damage, a further atomization technology, PA, was investigated in order to assess the most sustainable one. The comparison between 1 kg of Ti_6Al_4V powder produced with GA and PA highlights the higher damage (+12.31%) of PA (2.1E-2 Pt) compared to GA (1.87E-2 Pt). In fact, Ti_6Al_4V powder production with PA provides a higher contribution to the total damage compared to GA because of the greater use of argon (2.56 kg of argon to produce 1 kg of powder) compared to GA (0.007 kg for 1 kg of powder), as EOS reported in direct interview (2017), and because of the lower atomization productivity of this technology (80 kg of powder produced in 16 hours) compared to GA productivity (500 kg in the same cycle) (EOS, 2017).

The damage category with the highest increase is Human health, indoor) which is two orders of magnitude higher, due to a higher amount of argon sent to treatment, followed by Resources (+18.38%), Climate change (+11.15%), Human health (+10.6%) and Ecosystem quality (+1.46%). Moreover, if higher argon consumptions for GA are considered (0.5 kg argon and 2 kg argon for 1 kg of powder), the comparison between the two production technologies provides as result higher damage for PA (namely, +10.8% and +6.3%).

Therefore, as compared with PA, GA, was shown to be the most sustainable option, it was chosen for further investigations.

4.1.2 Comparison of femoral stem production lines (traditional versus AM)

A comparison between femoral stem production with GA powder and traditional manufacturing is reported below.

The production phase of 1 femoral stem with traditional manufacturing has a higher impact (2.03E-2 Pt), +24.08% compared to the AM process, caused by the higher rate of metal scraps (15.4 kg) that are sent for recycling. Waste powder resulting at the end of the AM process (0.019 kg) and metal scrap resulting from stem's head machining (0.117 kg) are sent to recycling, too.

The co-product of AM (about 19 kg of loose powder), in fact, provides a damage reduction to the function. Traditional manufactured parts benefit only from the advantage of the Industrial product function utility. In particular, the indicator Product performance adds to the production of the AM stem an advantage (-0,14%) precluded to traditional technology thanks to the novel geometry imprinted by AM, while the benefit derived from Industrial product function utility, considered for traditional production as well, is more limited in the case of additive production (-0.18%) compared to subtractive production (-0.25%) due to allocation of the co-product. As a consequence of the changed geometry, the stem produced with AM, 82.8 g, is lighter (-21%) compared to the one produced with traditional manufacturing, 104.6 g.

A comparison between the complete life cycle damage of the part produced with traditional manufacturing and AM (with GA powder) is provided (Figure 4). 2.76E-2 Pt is the total damage of the life cycle of one femoral stem produced with traditional manufacturing which exceeds AM by 16.94% of total damage (2.36E-2 Pt).

The traditional production of 1 femoral stem equals to the share of 73.6% of overall life cycle impact. The use and end of life phases of the traditional stems were found to be equal to the AM stems.

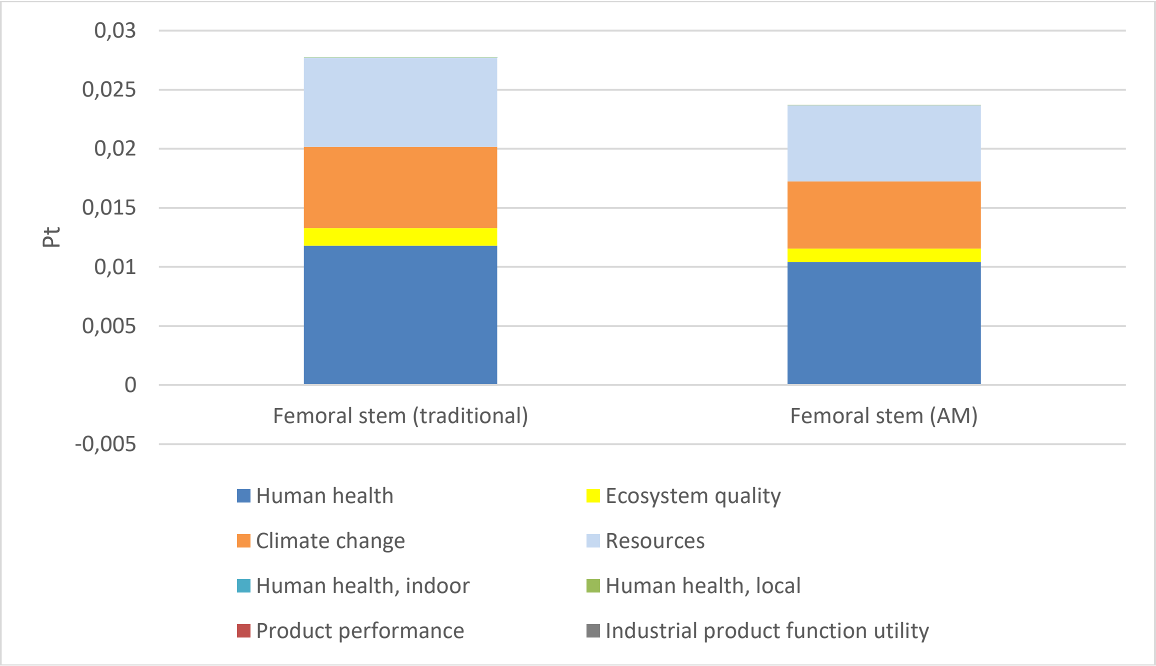

Figure 4 Environmental comparison between life cycle of 1 femoral stem produced with traditional manufacturing and with AM. Underlying data used to create this figure can be found in supporting information S-3 on the Web

4.1.3 Sensitivity analysis

Let us now make a final comparison between the life cycle of one stem made with traditional manufacturing and the life cycle of one reference stem made with additive manufacturing.

The reference femoral stem is defined as the stem with the average impact from among 160 stems produced in eight jobs.

Researchers estimate that loose powder can be reused eight times (Faludi, Baumers, Maskery & Hague, 2016), thus eight jobs, each producing 20 stems, are considered. The first job employes 20.83 kg of virgin powder, however the subsequent jobs use the remaining powder from the previous one, adding a small quantity of virgin powder to compensate for the powder lost with waste and printed parts.

Damage, in fact, is not constant from one job to another, as the amount of virgin powder introduced into the machine changes and the loose powder coproduct retrieved in each job has a variable impact. In particular, damage decreases until the 7th job, but increases at the 8th job, due to the higher amount of metal powder waste that could not be reused and is sent to recycling.

The results of the analysis (Figure S-4) shows that the stem produced traditionally has higher damage compared to the reference stem made with AM (1.81E-2 Pt) of 52.38% which this is due mainly to the reduction of damage associated with the virgin powder introduced in the machine.

The LCI modelling of the eight processes (i.e. the eight jobs) is performed once again with attributional, partitioning with energy allocation because loose powder is subjected to further processings, job after job, that could not be adequately expressed with other allocation criterions.

5 Conclusions

In this work, the environmental sustainability of orthopaedic devices with AM was evaluated with the life cycle assessment methodology.

A cradle to grave LCA was applied for one femoral stem produced using AM and GA powder and, as a result, the highest environmental burden was found to be the production phase, followed by the use and end of life phases.

The analysis of results highlighted that the main environmental load in the production phase is due to titanium alloy powder production. The same influence of titanium alloy powder production on total damage was found by Serres et al. (2011) and Peng et al. (2017). In this study two different titanium alloy powder production technologies (GA and PA) were therefore compared in order to highlight the most appropriate option for minimizing environmental loads and protecting human health.

The analysis of results illustrates that the most sustainable choice for powder production is GA.

An analysis of the benefits derived from the AM process compared to traditional manufacturing was also conducted, taking into account socially positive aspects (never considered before in E-LCA studies on additive manufacturing) related to the part produced with AM and concerning the increased biocompatibility and more complex geometry of prostheses. In particular, the indicator Product performance adds to the life cycle of the AM product an advantage (-0,098%) precluded to traditional technology, while the benefit derived from Industrial product function utility, considered for traditional production as well, is more limited in the case of additive production (-0,12%) compared to subtractive production (-0,18%) due to allocation of the co-product.

These aspects provide an insight into the high level of innovation introduced by this technology, which is aimed at meeting customer's needs.

Local and indoor emissions were included in the study and their incidence on total damage (namely 3.22E-2% and 3,76E-5%) was found to be very limited, thanks to the high filtration efficiency of HEPA filters and filter mask category P3.

The comparison showed that the AM process (in the GA powder usage hypothesis) is the most sustainable option. This is due to the presence of the co-product, represented by loose powder recovered at the end of the productive process, which reduces the damage to the function, choosing energy input as allocation criterion.

A further damage reduction compared to the traditional stem was highlighted when a reference stem, obtained by averaging the impact of 160 stems produced in 8 jobs, is considered. This final analysis highlights the extent of the benefits of additive manufacturing represented by the possibility of reusing loose powder, which is very difficult to investigate without considering all the jobs in which loose powder is employed.

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Supporting information

Supporting information 1: This supporting information provides data about the weighted results by impact categories of 1 femoral stem life cycle produced with AM and with GA powder. Underlying data used to create this figure can be found in supporting information S-5 on the Web

Supporting information 2: This supporting information provides data plotted in figure 3 of the main text.

Supporting information 3: This supporting information provides the data used in figure 4 of the main text.

Supporting information 4: This supporting information provides data about the comparison between endpoint results of 1-cycle-approach (comparison between one traditional stem and one AM stem, top histogram) and 8-jobs-approach (comparison between one traditional stem and one reference stem (AM), bottom histogram). Underlying data used to create this figure can be found in supporting information S-6 (top histogram) and S-3 (bottom histogram)

Supporting information 5: This supporting information provides data plotted in figure S-1 of the Supporting information.

Supporting information 6: This supporting information provides data about the underlying data used for the comparison between results of 1-cycle-approach (top histogram of figure S-4)

Figure Legends

Figure 1: System boundaries of femoral stem life cycle with AM

Figure 2: System boundaries of femoral stems life cycle with traditional manufacturing

Figure 3: LCIA results at end-point level of 1 femoral stem AM process with GA powder. Underlying data used to create this figure can be found in supporting information S-2 on the Web

Figure 4: Environmental comparison between life cycle of 1 femoral stem produced with traditional manufacturing and with AM. Underlying data used to create this figure can be found in supporting information S-3 on the Web