BANDAGIST
JAN NIELSEN A/S
ORTOPÆDITEKNIK

Comparative Life Cycle Assessment (LCA)

Comparison between a laminated and a 3D-printed transtibial prosthesis

Summary Report

June 2021

Summary report

This summary report compiles the main findings of the LCA Background Report. The LCA Background Report is available from Bandagist Jan Nielsen Management upon request.

Bandagist Jan Nielsen (BJN) is a Danish company that manufactures prosthetic limbs. In addition to conventional laminated prosthetic limbs, BJN also offers prostheses made using additive manufacturing technology (3D printing). Processes associated with 3D-printed prostheses are more efficient and are associated with a substantial decrease in waste generation.

BJN has commissioned a comparative life cycle assessment (LCA) study to compare the environmental impacts of a conventional, laminated transtibial (TT) prosthesis with the same prosthesis produced using 3D printing technology. The purpose is to communicate the environmental savings to BJN's stakeholders (end users, staff and organisations paying for the prostheses, such as Danish municipalities) with a specific focus on GHG emissions and water consumption.

The LCA Background Report has been compiled in accordance with the International Reference Life Cycle Data System (ILCD) Handbook and in alignment with ISO 14040 and 14044 Environmental Management – Lifecycle Assessment, except that no critical review has been performed by another third-party assurance provider, and that no uncertainty analysis has been performed.

The comparisons are carried out based on the main function of the products, which is the replacement, to the extent possible, of a biological transtibial limb for everyday functions (walking, climbing stairs, standing and sitting support) for the maximum duration of time that the amputee's anatomic evolution allows (shifting muscle mass and tissues are the major determinants of a prosthesis' useful life). The analysis focuses on the cradle-to-gate life cycle stages, stopping at BJN's production facility gate. All data is received from BJN, since the company produces both types of prostheses.

The reference flow is the entire design and fabrication process of a TT prosthesis, from the patient's measurement to the delivery of a prosthesis ready to be worn.

As for system boundaries, the analysis focuses on the cradle-to-gate life cycle stages, stopping at BJN's production facility gate. We assume that the use and end-of-life stages are the same for both the 3D-printed and the laminated prostheses, and we therefore leave these two stages out of the LCA.

Evidence seems to suggest that the useful life of the two prostheses is indeed equivalent in the case where the laminated prosthesis is fitted with a boa (which is modelled here). At the end-of-life stage, the 3D-printed prosthesis will be easier to recycle due to its clean fractions of polymers than the mixture of composite fibres and binding agents used for laminated prostheses. Therefore, it is reasonable to believe that the 3D-printed TT prosthesis would represent even larger savings, had we also considered the end-of-life phase.

Figure 1 depicts the system boundaries. Raw materials and their upstream processes are included in our analysis, as well as energy. However, we leave out capital goods, equipment and BJN's own infrastructure.

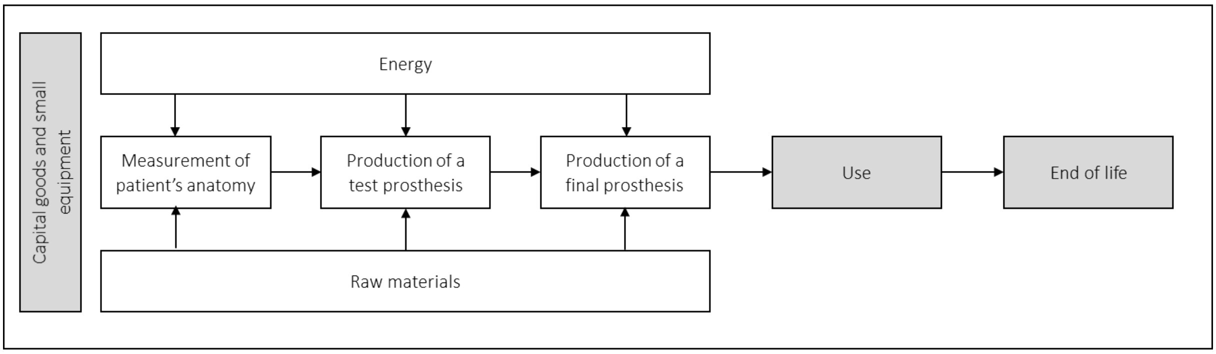

Figure 1: System boundary of a TT prosthesis (greyed out processes are out of boundary)

Table 1 and Table 2 show the LCA environmental impacts of a conventional laminated TT prosthesis and a 3D-printed TT prosthesis. Table 3 compares the impacts of the two prostheses, provides the savings associated with the 3D printing process and expresses them as a percentage of the impacts observed for the laminated prosthesis (decimal mismatches due to rounding). These comparisons are also displayed in Figures 2 and 3.

Table 1: Impacts of a laminated prosthesis

Impacts	Total	Measurement	Test	Liner	Final
GHG emissions in kg CO_2 eq.	81.7	26.8	35.4	0.5	19.0
Water in m^3	2.1	1.326	0.437	0.006	0.320

Table 2: Impacts of a 3D-printed prosthesis

Impacts	Total	Measurement	Test	Liner	Final
GHG emissions in kg CO_2 eq.	40.2	0.3	18.3	5.8	15.8
Water in m^3	1.4	0.014	0.546	0.193	0.634

Table 3: Comparison of the impacts of a 3D-printed TT prosthesis and a laminated 3D prosthesis

Impacts	3D-printed	Laminated	Absolute savings	Relative savings
GHG emissions in kg CO_2 eq.	40.2	81.7	41.4	51%
Water in m^3	1.4	2.1	0.7	34%

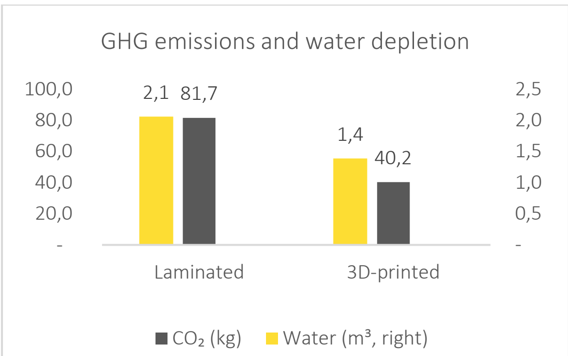

Figure 2: Impacts of a laminated prosthesis and a 3D-printed prosthesis

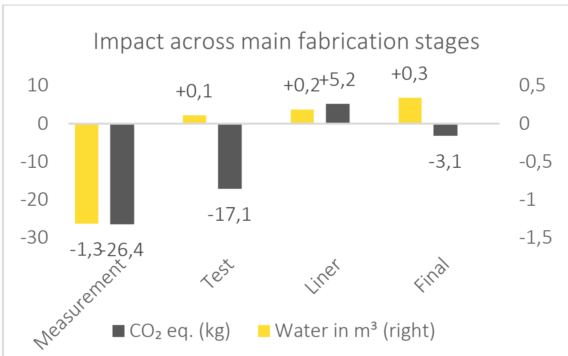

Figure 3: Impacts across production stages

Switching to a 3D printing process translates into savings of 41.4 kg of CO_2 eq. and 0.7 m^3 of water. This indicates that a 3D-printed TT prosthesis is always a more environmentally friendly choice for the two selected impact indicators (GHG emissions and water consumption).

Table 4 and Table 5 show the distribution of materials by weight for a laminated TT prosthesis and a 3D-printed prosthesis, respectively. 10.7 kg of materials are required to produce a laminated prosthesis, while 2.9 kg. are needed to produce a 3D-printed prosthesis (73% less than a laminated prosthesis).

Table 4: Bill of materials for a laminated TT prosthesis

Process	Material	Weight	Factored weight
Casting of two plaster casts (moulds)			**632.8**
	PE stretch film	10 gr.	10.0
	"Gypsona S" plaster of Paris bandages	615 gr.	615.0
	Tap water	4 litres	4.0
	PE foil 0,08mm	3.8 gr.	3.8
Filling (making the positive)			**1,453.5**
	Plaster of Paris	800 gr.	800.0
	Tap water	3 - 4 litres	3.5
	½" steel pipe (water pipe)	650 gr.	650.0
Modelling			**150.6**
	Plaster of Paris	150 gr.	150.0
	Tap water	0.6 litres	0.6
Moulding of test socket (x2.5)			**6,000.0**
	Ringmaster 16 x 13 mm (PETG)	2,400 gr.	6,000.0
Finishing of test socket (x2.5)			**639.0**
	Aluminium pipe Ø30/25 x 134 mm	75/3= 25 gr.	62.5
	Cast and machined titanium	85/5 gr. = 17 gr.	42.5
	Cast and machined stainless Steel	110 gr.	275.0
	Scotchweld DP601	50 gr.	125.0
	PE moulded Mixing nozzle	5 gr.	12.5
	Flexible PVC tubing, Ø6/4mm	24 gr.	60.0
	Injection moulded PA6	8 gr.	20.0
	Ethylcyanoacrylate glue	15 gr.	37.5
	Dyneema cord Ø1,5mm	1.6 gr.	4.0
Refilling of test socket (x0.3			**439.4**
	Plaster of Paris	**800 gr.**	**240.0**
	Tap water	3 - 4 litres	1.1
	Gaffer tape	11 gr.	3.3
	½" steel pipe (water pipe)	650 gr.	195.0
Using existing positive (x0.7)			**511.2**
	Plaster of Paris	80 gr.	56.0
	Tap water	0.3 litres	0.2
	½" steel pipe (water pipe)	650 gr.	455.0
Prostethic liner			**160.0**

	Multiform 5mm (Polyethylene foam)	150 gr.	150.0
	Renia Vulkofest 96	10 gr.	10.0
Final socket			**704.1**
	PVA (PolyVinyl Alcohol)	60 gr.	60.0
	Copacryl Resin "Carbon"	350 gr.	350.0
	Sipacryl Activator	9 gr.	9.0
	Unknown type of thermoplastic fabric	50 gr.	50.0
	E-Glass fibre	80 gr.	80.0
	E-Glass fibre	40 gr.	40.0
	Aluminium pipe Ø30/25 x 150 mm	84 gr.	84.0
	BOA, Nylon monofilament Ø2.0	5 gr.	5.0
	BOA, PTFE tubing Ø4	14.5 gr.	14.5
	BOA, Channel glueing	10 gr.	10.0
	Dyneema cord Ø1,5mm	1.6 gr.	1.6
Total materials			**10,690.6**

Table 5: Bill of materials for a 3D-printed TT prosthesis

Process	Material	Weight	Factored weight
Test socket preparation (3.5)			**7.0**
	Glue stick	2 gr.	7.0
Test socket printing (x3.5)			**1,930.6**
	PCTG	550 g.	1,925.0
	Dyneema cord Ø1,5mm	1,6 gr.	5.6
Final socket preparation			**2.0**
	Glue stick	2 gr.	2.0
Final socket printing			**651.6**
	PLA+	650 g.	650.0
	Dyneema cord Ø1,5mm	1.6 gr.	1.6
Liner preparation			**2.0**
	Glue stick	2 gr.	2.0
Liner printing			**350.0**
	Varioshore	350 gr.	350.0
Total materials			**2,939.2**

In addition to having a much lower footprint, the 3D-printed prostheses are also quicker to produce. This can be of great value to the patient, who may spend less time without a prosthesis, making the recovery process easier. So there is a possibility that BJN might simply produce more prostheses for the same patient – this would counteract some of the savings made by shifting to 3D printing from the laminated process for the benefit of patient life quality.

Another way of saying this is that some of the savings achieved by shifting to 3D printing could be used to enhance patient life quality instead of lowering resource consumption.

Statement by Management

Bandagist Jan Nielsen A/S Management has today considered and approved the comparative Life Cycle Assessment (LCA) Summary Report, which compares the environmental impact of a laminated transtibial prosthesis to a 3D-printed transtibial prosthesis.

The LCA Background Report has been prepared in accordance with the International Reference Life Cycle Data System (ILCD) Handbook and in alignment with ISO 14040 and 14044, except that no critical review has been performed by another third-party assurance provider, and that no uncertainty analysis has been performed.

This report is an accurate summary of the main results of the LCA Background Report.

In my opinion, the LCA Background Report is compliant with the International Reference Life Cycle Data System (ILCD) Handbook and in alignment with ISO 14040 and 14044, with the exception noted above, and is free from material misstatement and omissions, whether due to fraud or error, including the accuracy and completeness of the data, sources and assumptions used.

Copenhagen, 9 July 2021

Management

Lisbeth Staxen
CEO

Independent auditor's compilation report on the LCA Summary Report

To Management and other stakeholders of Bandagist Jan Nielsen A/S

We have been asked to compile the Comparative Life Cycle Assessment (LCA) Summary Report for the environmental impacts of a 3D-printed transtibial prosthesis produced by Bandagist Jan Nielsen compared to a conventional, laminated transtibial prosthesis produced by Bandagist Jan Nielsen. The LCA Summary Report has been compiled based on the information we have received from Bandagist Jan Nielsen A/S Management and is a summary of the LCA Background Report. The LCA Summary Report may be used for the purpose of general market communication.

We performed this compilation engagement in accordance with ISRE 4410, Compilation Engagements.

We have applied our expertise in non-financial reporting to assist Management in the preparation and presentation of the LCA Background Report in accordance with the International Reference Life Cycle Data System (ILCD) Handbook and in alignment with ISO 14040 and 14044, except that no critical review has been performed by another third-party assurance provider, and that no uncertainty analysis has been performed. We have complied with relevant provisions of the Danish Public Accountants Act and FSR – danske revisorer's Code of Conduct for professional accountants, including the principles of integrity, objectivity, professional competence and due care.

The LCA Summary Report is a summary of the LCA Background Report, and the accuracy and completeness of the information used to compile the LCA Summary Report and the LCA Background Report are Management's responsibility.

Since a compilation engagement is not an assurance engagement, we are not required to verify the accuracy or completeness of the information Management provided to us to compile the LCA Summary Report and the LCA Background Report. Accordingly, we do not express an audit opinion or a review conclusion on the LCA Summary Report or the LCA Background Report.

Our Compilation Report is solely for the purpose set forth in the first paragraph above and for your information and is not to be used for any other purpose.

Copenhagen, 9 July 2021

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Helena Tara Barton
Partner
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