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Sustainability in Healthcare Sector: The Dental Aligners Case

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Abstract: The study conducts a comparative life cycle assessment (LCA) analysis to assess the environmental impact of two different manufacturing processes used to produce transparent dental aligners. The former method consists of thermoforming a polymeric disc over 3D printed, customized models, while the second, more innovative approach involves the direct printing of aligners using additive manufacturing (AM), specifically applying digital light processing (DLP) technology. The analysis results highlight how adopting direct printing through AM brings significant advantages in terms of environmental sustainability, thanks to the substantial reduction in raw materials and electricity consumption. These drops translate into decreased potential environmental impacts across all impact categories considered within the EF 3.1 method. Furthermore, lowering the amount of raw materials needed in the direct printing process contributes to a notable decrease in the overall volume of waste generated, emphasising the environmental benefits of this innovative technique.

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1. Introduction

Since the 20th century, the growing awareness of malocclusion and its related consequences have led to the development of various orthodontic approaches for repositioning teeth. Adolescent and adult patients who are aware of their malocclusion traits and are not satisfied with their dental appearance tend to suffer from psychosocial concerns. However, the treatment of malocclusion has historically been related to invasive appliances that severely affected the wearer's daily life. This has improved with the introduction of clear and removable aligners [1].

The standard manufacturing process of the aligners and the practice of companies producing an excess of orthodontic aligners is at odds with the environmental concerns. There is a growing demand from the orthodontist for minimizing the environmental impact associated with aligner production [2].

This study aims to analyze and compare two technologies for the production of clear aligners from a sustainability point of view, in quantitative terms; this is possible by applying LCA (Life Cycle Assessment), which is a methodology regulated by ISO 14040:2006 [3] and ISO 14044:2006 [4]; in fact, it allows a quantitative assessment of the potential environmental impact related to product manufacturing.

The two analyzed technologies are thermoforming of in-mould aligners and direct 3D printing. In particular, the DLP (Digital Light Processing) photopolymerization has been chosen among all AM technologies, with the primary data available.

1.1. State of the art

Historically, in the early 1900s, malocclusion was treated by positioning metal rings cemented to teeth to support wires for applying moving forces. This approach caused many dental caries: it was

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almost impossible to maintain correct dental hygiene because of the limited offering of tools in the market, the mechanical encumbrance of the rings, and subsequent dental plaque formation [5].

The following steps were the use in the 1960s of brackets to support wires made from stainless steel and in the 1970s of brackets made of transparent or translucent non-metallic material.

In 1997, a significant development occurred in orthodontics with the introduction of the first aligners designed for orthodontic treatment. This innovation was driven by patient demand for more comfortable and less obtrusive methods to improve their dental alignment. Unlike traditional braces, aligners do not cause discomfort to the lips and are aesthetically pleasing. Additionally, their transparent appearance and the ability to remove them while eating and maintaining oral hygiene are additional benefits [5,6].

However, clear aligner therapy consists of the change of position, angulation and rotation of teeth, improving all parameters needed for proper and healthy occlusion and articulation: it might treat mild non-extraction cases faster and with higher efficiency, but it requires more time than fixed appliance treatment for more complex patients [1,6].

It is important to emphasise that it makes sense to compare different technologies for the production of aligners, capable of acting on the same problems, and not between different orthodontic treatment techniques.

Nowadays, the most widespread technology for producing clear aligners is the manufacture of dental models that express the desired tooth movement. The traditional process involves five steps: acquisition of the original dental anatomy, development of teeth movements model, 3D printing of the model, thermoforming, and cutting of the aligners [7,8].

The thermoforming equipment is shown in Figure 1.

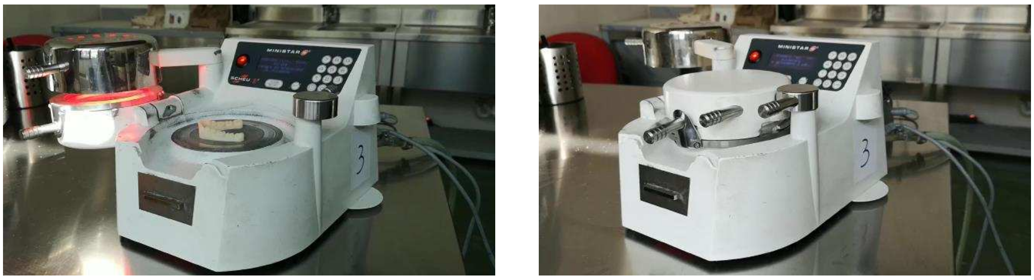

Figure 1. Thermoforming equipment.

3D printing, also called additive manufacturing, is a set of technologies based on adding materials, usually layer upon layer, through different techniques (material extrusion, material jetting, powder bed fusion, vat photo-polymerization, etc.), and this production process might be impractical for large-scale production. Still, it can be especially applicable for all those applications requiring a high level of individual customization, such as dental aligners [7–9].

Recent techniques have enabled clinicians to print the aligners directly, eliminating the thermoforming step. Direct additive manufacturing technique increases efficiency and reduces waste, eliminating inaccuracies associated with the 3D printing of models and thermoforming processes. Moreover, several advantages over conventional fabrication are present: digitally designed borders, smooth edges, no need for undercuts, higher precision without errors introduced by model moulding and thermoforming and customizable intra-aligner thickness.

However, in the current context, there is a low diffusion of this methodology of manufacturing aligners, mainly related to some limitations of the technologies and materials involved [5,7,8].

This study will consist of a comparison, from the sustainability point of view, of these two technologies for producing clear aligners and could be a burst for the aligners companies to invest in the research and development in additive manufacturing approach.

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2. Materials and Methods

Direct 3D printing of aligners is a technology with many plus points but, being less established as a process, it has some limiting factors. The choice of material to be used is one of them. Indeed, the material should be biocompatible and transparent, with low stiffness and good elasticity, resilient and resistant to its use in human saliva [1]. Moreover, these materials have to be selected among the classified as Class IIa long-term biocompatible resins and conform to the essential requirements and provisions of the Council Directive 93/42/EEC and Medical Device Directive 2007/47/EC [10].

The biocompatibility of aligners is one of the most discussed issues because patient safety has to be assured. When dealing with additive manufacturing of photosensitive resins (e.g., through technologies like Material Jetting and VAT photopolymerization), the toxicity of 3D printed materials decreases as they undergo post-polymerization. Therefore, post-curing is essential to eliminate the toxicity levels, removing any uncured resin and making the printed material safer for intraoral usage [11]. The recommended protocol suggests UV curing and subsequent washing; these steps guarantee increased mechanical properties and reduced cytotoxicity [12].

With traditional technology, different polymers are used to produce the 3D-printed model and the thermoforming of aligners. The material used for the model comprises acrylic monomers and oligomers, and the supports are made of a mixture of acrylic oligomers, glycols and glycerine. Differently, PETG copolyester is the chosen material for thermoforming the aligners.

Additive manufactured aligners can reduce the variety of materials used as it is no longer necessary to have a model on which the plastic disc is thermoformed.

Various additive manufacturing technologies can be used to print clear aligners directly: fused deposition modelling, selective laser sintering, selective laser melting, direct pellets fused deposition, stereolithography, multi-jet photo-cured polymer process, or continuous liquid interface production technology [8,13].

However, among AM technologies, VAT photo-polymerization is currently the most appropriate choice due to its exceptional resolution and accuracy. Additionally, its ability to achieve high transparency in 3D printed components makes it a viable option and is in part already used in orthodontics. Moreover, in the case of DLP technology, the material used for the support is the same as the one used for the aligners and could contribute to the goal of reduction of material variety.

Digital Light Processing is part of the VAT photopolymerization family, in which a liquid photopolymer is put in a resin tank and is selectively cured by light-activated polymerization to create a solid polymer. In particular, in DLP-based approaches, light exposure is carried out by projecting a single digital image (mask), polymerizing every single layer simultaneously, reducing the printing time compared to other technologies [5,8].

This study consists of a comparative life cycle analysis between two processes for the production of dental aligners, one more familiar and one innovative. The software OpenLCA and the database Ecoinvent v3.9.1 were used to perform the numerical calculations. An attributional approach was adopted for the study, with the choice of database processes built according to the allocation cut-off method.

2.1. Goal and Scope definition

In the International Standard ISO 14040 [3] are indicated the mandatory information that should be declared: the goal and the scope of the study, the functional unit and the target audience.

The goal of this study is the quantification of the environmental burdens associated with the manufacturing of dental aligners in order to allow a comparison of the potential impacts associated with the two production technologies.

The chosen functional unit is 40 dental masks, which constitute an average complete set needed for treatment, with their packaging. Each pair of aligners is used for two to three weeks and, after this time, replaced with the next one for continued treatment.

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The analyzed system includes the production of precursors from raw materials, logistics, and the aligners' manufacturing: this is a cradle-to-gate study. Since primary data on the use and disposal of aligners are unavailable, it is impossible to include the use and disposal steps. In the production processes many steps are considered, from the cast production to the finishing and packaging, and the difference between the materials used is considerable: in fact, the polymer used for thermoforming can not be used for direct 3D printing of the aligner. The System boundaries are reported in Figure 2 and in Figure 3 for the thermoforming and the additive manufacturing techniques, respectively.

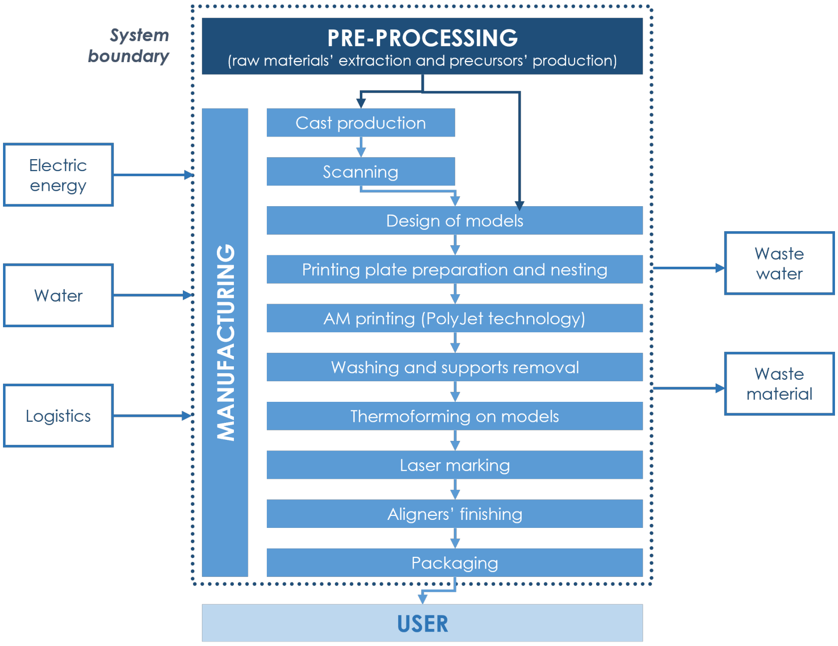

Figure 2. System boundary of the process which uses the thermoforming technology.

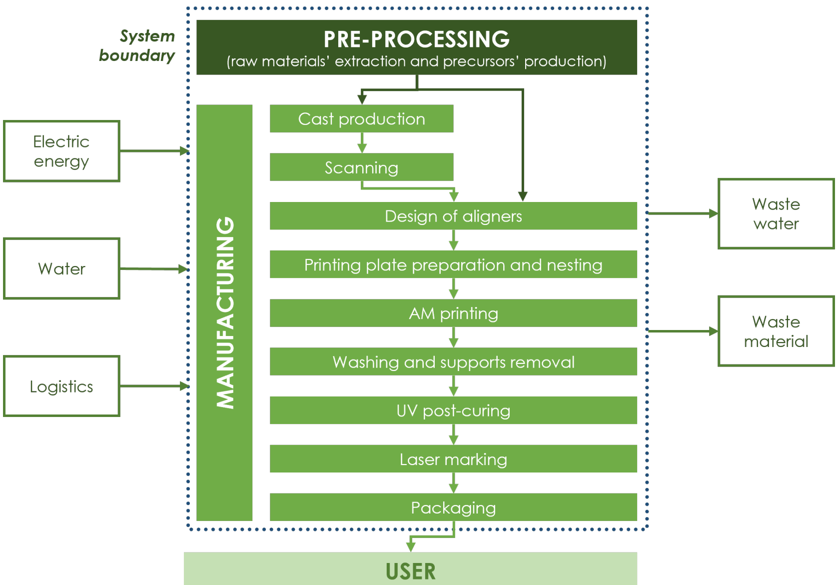

Figure 3. System boundary of the process which uses the additive manufacturing technology.

The target audience of this study consists of healthcare professionals, especially dentists and orthodontists, researchers, LCA practitioners, and additive manufacturing operators.

In almost all cases, primary data, measured directly in the field, were used for all technologies analyzed. In fact, support was received from AirNivol Srl, an italian company specialized in the design and production of dental aligners, which provided a substantial portion of its primary production data. However, some modelling was necessary for the polymers present in the process and was carried out starting from the scientific literature and the procedures already present in the Ecoinvent database.

2.2. Inventory characterization

Being a cradle-to-gate analysis, the starting point is extracting raw materials and producing precursors and materials used in manufacturing. This phase is similar for all three technologies, obviously with the difference relating to the materials.

The data used are primary in quantities, but processes already present in the database were used for modelling. Since no chemicals were available, ad hoc processes were created in some cases, exploiting the technical information in the literature, such as the most widespread synthesis method, and the process flows already present within Ecoinvent.

The first steps of manufacturing are the production of the plaster cast and its scanning; these are not always performed in the system considered because, in about 80% of cases, a digital scan is provided by the dentist, and therefore, it is not necessary to produce the cast starting from the impression. Thus, a mass allocation was performed in the modelling: only 20% of the material and energy consumption related to these two steps was counted.

From this point forward, thermoforming and 3D printing technology modelling differ significantly and will be described individually in the following subsections.

2.2.1. Thermoforming

Once the scan of the patient's dental arches has been obtained, technicians proceed to the models' design on which plastic discs will be thermoformed.

The next steps are the preparation of the printer, in particular the cleaning of the printing plate and the nesting, and the 3D printing with PolyJet technology of the models required for the entire treatment. PolyJet technology belongs to Material Jetting additive manufacturing method. It uses multiple print heads to deposit ultra-thin layers of liquid material onto a build platform, which are then cured instantly with UV light. It is known for producing high-resolution, multi-material, and full-color 3D printed objects. Two different polymeric materials are needed to print the models: one for the models and one for the supports. A fraction of both these materials is considered to be discarded during the purging process of the 3D printer.

After printing, the supports are removed by washing with high-pressure water jets; the resulting wastewater, polluted with the media material, is sent to the water treatment plant.

Following the cleaning of the models, thermoforming is performed: a disc of thermoplastic material, specifically a PETG (polyethylene terephthalate glycol) copolymer, is heated and molded over the model to obtain the dental aligner. The result of the thermoforming application is shown in Figure 4.

The next stages are laser marking, cutting of aligners, where excess material is removed with a milling machine, and packing. The packaging includes the plastic bags in which the aligners are inserted in pairs, a rigid plastic case, a cardboard box and the information material.

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Figure 4. Results of the thermoforming process: aligner thermoformed on the printed model.

2.2.2. Additive Manufacturing

The same starting point as the thermoforming procedure is assumed for direct printing. Having the scan of the dental arches of the patient, the design of the aligners can begin. Then, after computer modelling, the printer can be prepared and nested, and the aligners' direct printing can occur.

The main difference between this technology and thermoforming is the absence, in this case, of the models to be printed; in fact, the aligners are printed directly, reducing waste and material use and eliminating inaccuracies associated with the 3D printing of models and the thermoforming process. Printing result is shown in Figure 5.

The DLP is part of the vat photopolymerization (VPP) family and consists of selective curing of a liquid photopolymer: the light exposure is performed by projecting a single mask in order to polymerize every single layer simultaneously [5,8].

The composition of the material used for the direct printing of aligners is described by [14] as an aliphatic vinyl ester-urethane polymer, possibly cross-linked with methacrylate functionalization.

Figure 5. Result of direct printing DLP technology: the clear aligner with supports.

After printing, the supports necessary for this step are removed manually, followed by a 30-minute water wash, to eliminate residuals of resin which were not polymerized and part of remained supports. Then, UV post-curing is essential in producing dental aligners because it guarantees increased mechanical properties and reduced cytotoxicity of the materials used. In the present study, a UV post-curing duration of 30 minutes was considered.

After laser marking the set of dental aligners is packed using plastic bags, in which the pairs of aligners are inserted; the rigid plastic case and the information material are added to the cardboard box of the user package.

2.2.3. Materials

The modelling of the polymeric materials, used both for the production of the model, in the case of thermoforming, and for the production of the aligners, was carried out from the existing sheets in the Ecoinvent database. As the materials used were not available in the database, the precise composition of which was obtained from the safety material data sheets, modelling of the most common synthesis routes was used, taking information from the literature regarding the operating conditions and energy required for production. Proceeding in this manner, an attempt was made to remain as faithful as possible to the materials used, avoiding generic data sheets.

For plastic packaging materials, such as bags and aligners' rigid case, the starting points are data sheets of the database of the corresponding plastic material to which the manufacturing processes, extrusion and injection moulding processes, respectively, were added.

2.2.4. Energy and Logistics

Concerning modelling the electricity used, the only energy source in the system boundary considered, the Italian residual mix (*electricity, low voltage, residual mix | electricity, low voltage | Cutoff, U (IT)*) was used as it is taken from the national grid, and there are no certificates on the energy purchased.

The system boundary chosen also includes the transport phase of all the raw materials to the manufacturing step. For most of the materials, data sheets have been selected from the market-type database, mainly at a European level, which already considers an average transport, as more detailed information is not available. Instead, as regards the transport of the packaging, for which the distances are known, expressed in km, but not the specific means of transportation, the data sheet *"market for transport, freight, lorry, unspecified |transport, freight, lorry, unspecified | Cutoff, U (RER)"* was chosen.

3. Results

In this section, the life cycle assessment analysis results will be presented, both in terms of the main drivers for each technology presented and in terms of comparative analysis between thermoforming and the additive manufacturing application considered. Moreover, the hypotheses and the sensitivity analysis results will be discussed.

The method chosen for the assessment of potential environmental impacts is EF 3.1, which provides results on 25 impact categories.

The results will be presented for the main categories, and there will be a special focus on four of them; in fact, even in the field of additive manufacturing, different impact assessment methods and different categories are used but in accordance with what is reported in the literature, it was chosen to delve deeper into these categories: climate change, energy resources, acidification and eutrophication [15,16].

3.1. Comparative analysis

According to ISO 14044 [4], in a comparative study, the systems must be evaluated with the same functional unit and equivalent methodological considerations, such as performance, system boundary, and data quality.

The chosen functional unit is a complete set, consisting of 40 aligners, capable of performing orthodontic treatment consisting of several cycles. This study is cradle-to-gate, i.e. it starts with the extraction of raw materials, their processing to obtain intermediate products, the actual production of the aligners, by thermoforming or direct printing, and their packaging. Thus, the considered functional unit is exactly the same for both the technologies and the system boundaries are perfectly comparable.

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The results of this comparative study, referring to a functional unit, are shown in Figure 6 in terms of potential environmental impacts for the main impact categories of the EF 3.1 method.

When analysing the overall results over the whole system, it can be seen that thermoforming has a higher potential impact for all impact categories considered with respect to the direct 3D printing. The smallest gap occurs in the "Land use" category with a 31% change and the largest gap occurs in the "Ozone depletion" category with a 98% reduction in impact.

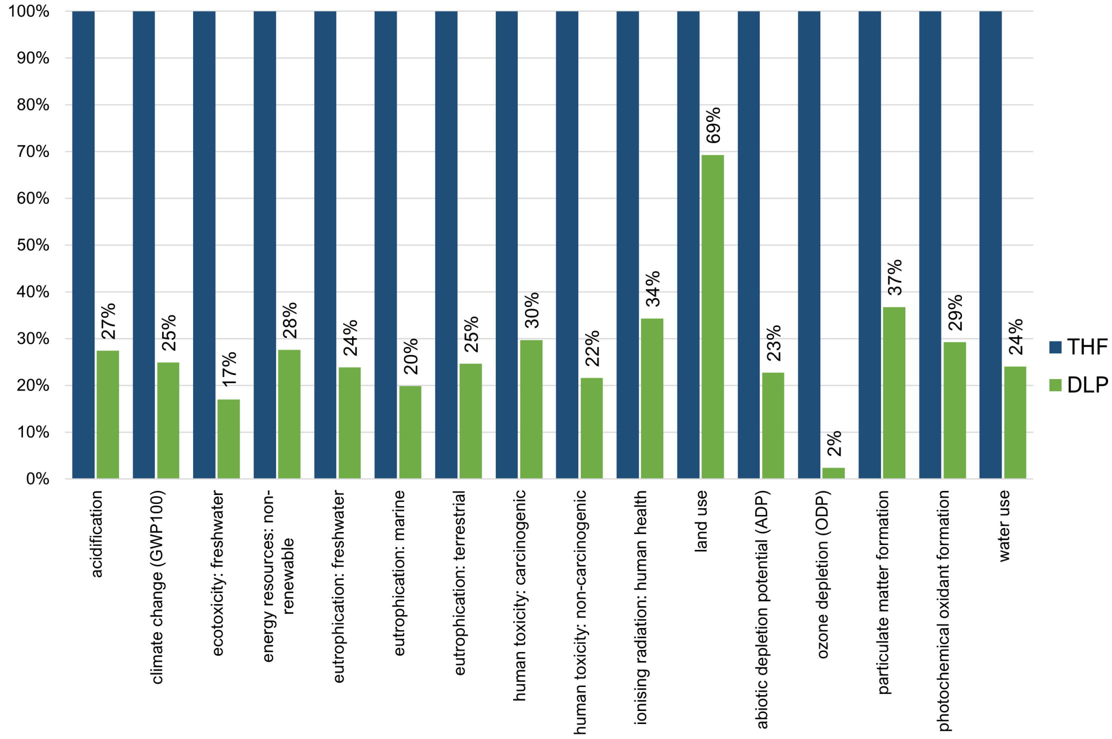

Figure 6. Results of the comparative LCA calculation performed with EF 3.1 impact method.

To investigate in more detail the reasons that lead to such clear-cut results, an in-depth analysis was carried out investigating the main vectors between the categories of materials, wastes, energy, transport and packaging.

The impact categories investigated are Acidification, Climate change, Energy resources and Eutrophication, freshwater, marine and terrestrial, and the detailed results are shown in Figure 7 and in Figure 8.

Analyzing in detail the comparison of the impacts represented in Figure 7 and Figure 8, it can be seen that for thermoforming the main impact is given, for almost all impact categories, by the raw materials used. Another significant portion of the impact is given by energy and waste, depending on the category considered.

It is necessary to highlight the substantial decrease in the impact for direct printing using DLP technology due to the material, energy and waste contribution; instead, since the packaging is the same for the two technologies, there is an impact with the same absolute value but a much greater relative value in the case of 3D printing.

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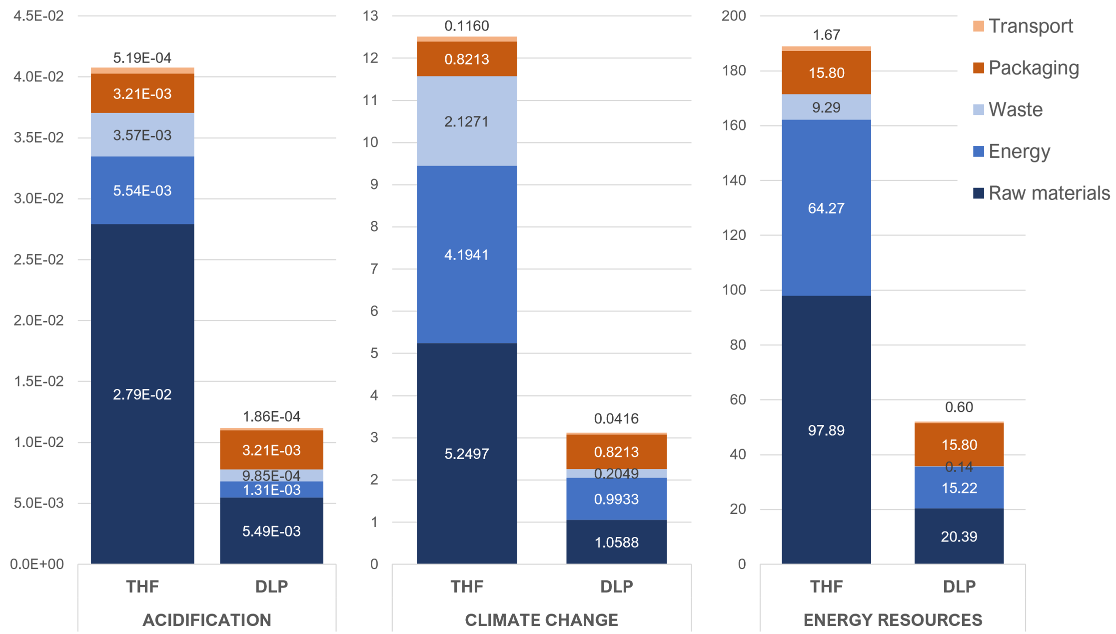

Figure 7. Impacts per FU for acidification, climate change and energy resources impact categories.

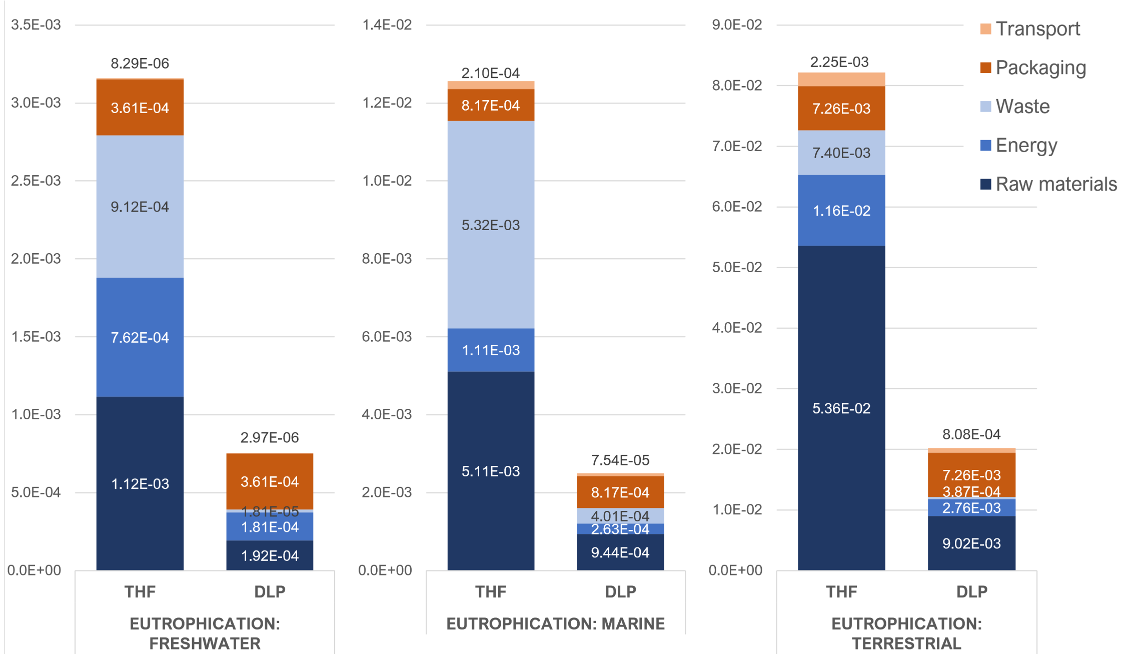

Figure 8. Impacts per FU for the eutrophication impact category.

3.2. Interpretation and Discussion

The consistent reduction in environmental impact, for all impact categories considered, for additive technology compared to thermoforming is substantially due to the decrease in the quantity of material and energy used, depicted in Figure 9.

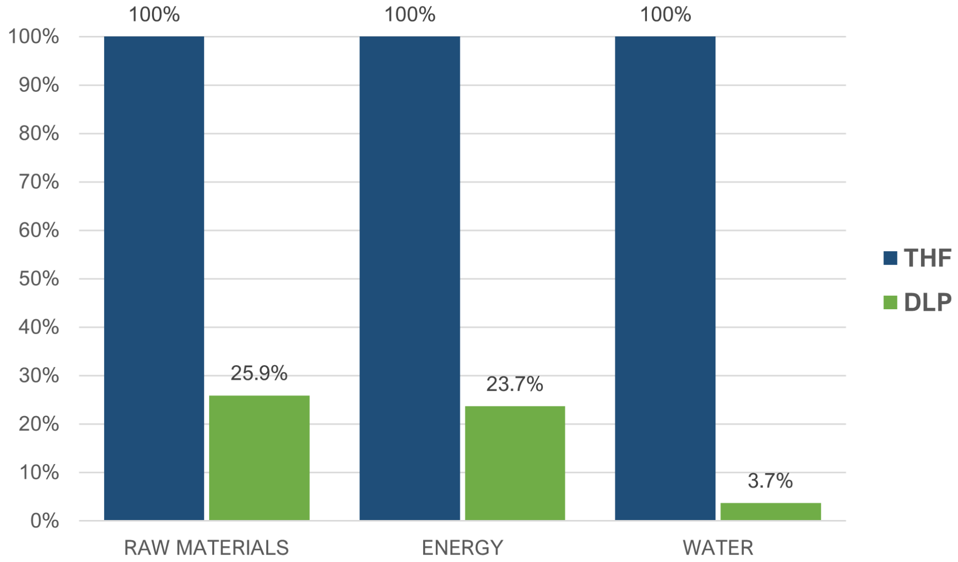

Figure 9. Percentage reduction in energy and material consumption between technologies.

In fact, by using direct printing technology, there is no longer the consumption of material and electricity linked to printing the model; therefore, waste material and water use will also be lower.

Furthermore, the significant difference in the quantity of water used is due to the washing of the soluble supports after printing the models in the case of thermoforming, using special equipment; on the contrary, for the direct printing, only a small amount of water is needed to remove residuals of resin which was not polymerized.

3.3. Limitations of the study

The study's main limitation is linked to the materials used for the production of the models, for thermoforming and for direct printing. In fact, the material safety data sheets, when available, report only the families to which the mixture's components belong and not the specific compound. Within the particular case of the material used for direct printing, not even the safety data sheet is available as it has a patented composition; therefore, the modelling of such material is based on information available in the literature.

Furthermore, only a few chemical compounds are available in the Ecoinvent database, and a simulation of a realistic synthesis route and its operating conditions is therefore necessary.

4. Conclusions and Future research

In this comparative LCA study, the environmental impacts associated with two production processes of dental aligners have been evaluated: thermoforming and direct 3D printing through digital light processing (DLP). This analysis aimed to provide insights into the sustainability of these processes considering a cradle-to-gate perspective, encompassing all life cycle stages, from raw material extraction to aligner fabrication.

In conclusion, the results of this study suggest that direct printing of dental aligners has a lower environmental impact than thermoforming. This advantage is primarily attributed to the efficient use of materials, reduced energy consumption, and minimized waste generation associated with DLP.

An holistic assessment that considers both environmental and economic aspects could be interesting as future perspective for making informed decisions in the dental aligner production industry, aligning with the broader goals of sustainability and responsible manufacturing practices.

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