FutureFeet

3.Foot Orthoses manufacturing

Co-funded by the
Erasmus+ Programme
of the European Union

1 Theoretical content

In the last century, the development of new manufacturing process has significantly influenced the way FO are manufactured [1–7]. As a matter of fact, it can be estimated that 20 to 30 years separate the invention of the thermoforming technique from the first resource that describes its use in the field of FO [1–5] and the same statement can be done for the subtractive manufacturing technique [6,7]. In addition to the latency separating the invention of these techniques and their first use in the FO field, it obviously took time before their use spread within the profession [8]. A survey has highlighted that in 2016 in the United Kingdom, the vast majority of clinicians use either the vacuum forming technique or the subtractive manufacturing technique for the manufacture of their "customized FO" [8]. However, it has been reported that the additive manufacturing is rarely used [8] and this is not surprising since it is the most recent manufacturing method which has been implemented in the FO field [9–17]. While the additive manufacturing brings a lot of opportunities there are also some challenges to its implementation and this is probably one of the reason why this technique is little used at the moment [18–22].

As it has been highlighted by the World Health Organization in its Standards for Prosthetics and Orthotics more than one manufacturing technique may be appropriate for the manufacture of orthoses as long as it is requested, paid for and does not restrict access to services [23]. However, this section will focus on the manufacturing techniques used in the domain of FO and which are assisted with a computer. This encompasses the subtractive manufacturing technique, the Fused-Deposition Modelling technique and the Selective Laser Sintering technique [9,10,13–16,24–29]. Since these manufacturing techniques are quite different, their comparison would be difficult [30] and this is why this section rather aims to illustrate the value that can potentially be created with these different manufacturing techniques in the domain of FO. By doing so, this section aims to illustrate that one technique may be more appropriate than another depending on its application [30].

I. Subtractive manufacturing

The subtractive manufacturing refers to the use of a computer-controlled milling machine to manufacture parts [31]. The CNC milling machine works by removing material from a block with a rotating cutting tool [31]. In the case of a 3-axis CNC milling machine, the rotating tool is guided in the three directions of the Cartesian coordinate system : X (length), Y (width) and Z (height) axes [31]. But other axes can be added to the machine which will result in a 4-axis CNC milling machine, 5-axis CNC milling machine and so forth [31].

The major advantages of this manufacturing technique lies in its ability to produce objects with a good accuracy, reliability, surface finish and ideal mechanical properties [32]. From an economic point of view, the costs per pair of FO manufactured with subtractive manufacturing highly depends on the number of pairs manufactured [14]. In other words, the more FO are manufactured, the more this manufacturing technique will be cost-effective [14,33]. This can be mainly explained by the fact that the initial capital investment in tooling and machinery should be amortized [33].

From an ecological point of view, there will automatically be a waste of material when adopting this manufacturing technique since this process creates a FO by removing material [34]. In addition, the material generally used with the subtractive manufacturing technique is a polymer and more specifically Ethyl Vynil Acetate foam [26,35] which have a low recycling rate of Ethyl Vynil Acetate [36,37]. However, in recent years some research have investigated some potential recycling applications for this material [36,37]. This seems to be a good opportunity to improve the ecological value of orthotics manufactured with a CNC milling machine. In addition, it seems evident that the ecological value could be further improved by decreasing the waste of material, increasing the recycling rate and developing more environmentally responsible material.

II. Additive manufacturing

The additive manufacturing (AM), also referred to as 3D printing, is a manufacturing process in which a part is produced via the depot of material layer-by-layer [38]. This technology was first introduced in the early 1980's with the stereolitography and since then other techniques have emerged [19]. Recently, the Additive Manufacturing Technology Standards International have classified these technologies into 7 categories: material extrusion, powder bed fusion, vat photopolymerization, material jetting, binder jetting, sheet lamination, and directed energy deposition [39]. These technologies which are in constant progress in terms of processes and materials, are revolutionizing the production of parts [22,30,40,41].

The biomedical market of which the orthotics are part is one of the areas that could potentially benefit most from additive manufacturing [22,38,42,43]. While this market represented 11% of the total AM market in 2018 it is expected to grow and to be one of the leaders of the AM development in the future [22,38,42,43]. However, the introduction of additive manufacturing into the biomedical market remains relatively new and there are therefore challenges which still need to be addressed [19,30]. Thus, it is important to acknowledge what has already been achieved without expecting that this technology will revolutionize the field of FO overnight [19]. Among other things, we can emphasize that:

A) the toxicological hazards of AM materials are still not fully understood [43]
B) that the 3D printed FO must comply with complex regulations [30] [22]
C) that it remains difficult to have a consistency in the quality of the orthosis manufactured with additive manufacturing [22,44]

In the field of FO manufacturing two technologies have been used in the literature : the material extrusion [14,15,24,27,29] and the powder bed fusion [9,25,27]. While the manufacture of FO with the material extrusion process consists of extruding molten thermoplastic material layer by layer [45–49], the powder bed fusion uses laser to selectively melt Nylon powder layer by layer [18,27].

Since the additive manufacturing process relies on the depot of material layer-by-layer, it offers a great opportunity to reduce waste [38,41]. However, it cannot be categorically stated that 3D printing is more environment-friendly than subtractive manufacturing since its environmental impact has not been fully investigated yet [43,50]. Infact, a low utilization of a 3D printer might result in a negative environmental impact and this is why its utilization should be maximized by sharing it in order to reduce the number of machines used [50]. However, when comparing the different additive manufacturing techniques, even when the material extrusion printer is not frequently used it has a lower environmental impact than the other additive manufacturing techniques in maximal utilization [50]. Thus, from an environmental point of view, the material extrusion 3D printer might be the most appropriate for the manufacture of FO but this it is only hypothetical until we have quantified all the major environmental impacts of specific FO [50]. In general, from an environmental point of view, additive manufacturing can be considered as a good alternative for producing parts with a high degree of customisation or geometrical complexity [43,51] and this is why healthcare is one of the rare domains in which additive manufacturing could have an environmental added value [43].

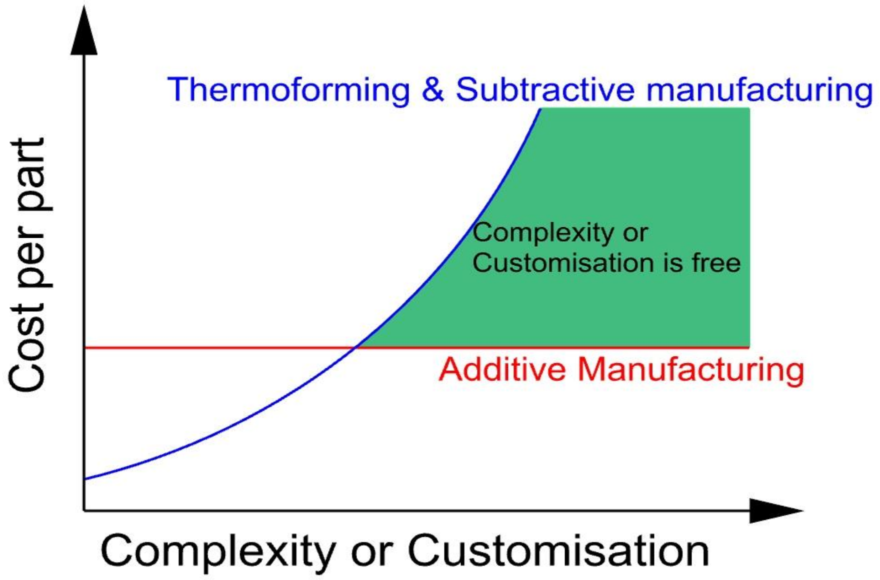

Fig. 1: Complexity and customization are free with additive manufacturing[23].

From an economical perspective, additive manufacturing is also likely to be more competitive than other techniques when it comes to fabricating parts with high levels of customisation or geometrical complexity [38]. This could be explained by the fact that, unlike other manufacturing techniques, the level of customisation and geometrical complexity of a part does not affect its price when it is manufactured with an additive manufacturing technique [22,38]. This could be one of the reasons why the material extrusion and the powder bed fusion techniques have both already been considered as cost-effective for the manufacturing of FO [14,27,33]

From an experience point of view, the merit of foot orthoses with higher degrees of customization is currently challenged in the literature due to the fact that FO with higher degrees of customization might not have added value for the patient [52]. Nevertheless, this debate may take a different turn in the future since it is believed that the added value of 3D printing lies in its ability to manufacture FOs with a higher degree of customisation and geometric complexity compared to the manufacturing technique used in the studies mentioned above [9,38,53]. However, while a geometric complexity factor has already been developed, it is unfortunately not the case for the level of customisation which is currently evaluated with discrete levels [38]. This limitation in the evaluation of the level of customisation of a product might give rise to the inability to differentiate some FO based on their degree of customisation which makes it difficult to put forward the potential added value of 3D printed FO [38]. We therefore support the statement made by Conner & al. in 2014 : “Future work could explore the development of continuous scales customisation” [38].

To put forward the potential added value of 3D printed FO, it is also suggested that this field should be better explored [38,54,55]. Over many years, orthoses had no apparent innovation and as already shown, the collaboration with experts such as designers, engineers and manufacturing specialists can allow to create an enhanced orthotic with a high degree of customisation [56]. Innovation in the manufacturing of FO through the use of additive manufacturing could allow to revisit its function. For instance, the ability of additive manufacturing to incorporate an antimicrobial compound into a FO might transform it into a device which prevents infection [14]. In addition, allowing the incorporation of pressure sensors into the FO would transform it into a device capable of processing biofeedback

[57] which could be very valuable in the management of diabetic patients [58–60]. Additive manufacturing can also optimise the mechanical function of FO by giving more possibilities to adapt the mechanical properties of parts thanks to its ability to produce parts with multiple materials and complex geometries [14,18,29,30,61–65]. Finally, the combination of different manufacturing processes to overcome the limitations associated with individual processes [30] is also a promising opportunity to improve FO value in the future [56,57,66–68].

2 Task

- Based on this text, how could you classify/categorise the value provided by a FO intervention

- In which circumstances is the additive manufacturing likely to be more competitive than other techniques?

- Why does the debate on the merit of foot orthoses with higher degrees of customization could take a different turn in the future?

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