Introduction

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1 Theoretical content

1.1 FO evolution/Heritage of FO

Orthoses were used during much of recorded history[1,2]. Paintings from the fifth Egyptian Dynasty from 2750 to 2625 Before Common Era depict men wearing orthoses and during the 4th century Before Common Era, various braces and splints have been attributed to Hyppocrates[1,2]. Orthoses have evolved over the centuries and in 1781 Petrus Camper stimulated interest in placing arch-supporting orthoses into shoes for children's flatfoot[3]. Then, in 1845, Lewis Durlacher developed a leather foot orthosis (FO) [3] and in 1912, Percy W. Roberts developed a metal FO[3].

The development of the thermoforming process in the 1930s [3] significantly influenced innovation in the FO field [4–9]. Early thermoforming processes consisted of heating a sheet which was drawn under vacuum pressure to take the shape of a cooled mould [10]. This process was introduced in the foot orthotics industry by heating a sheet which is then positioned on a foot model, and applying vacuum pressure in order for the sheet to take the shape of the model [10]. After the thermal moulding is completed, the plastic has to cool down and solidify before being removed, trimmed and polished [10]. In 1958, Root was one of first to experiment the vacuum forming techniques with thermoplastics [4] and his Root Functional orthoses theory has been followed by other FOs such as the UC-BL [5], the Blake Inverted Orthosis [6–8] and the medial heel skive[9].

In the 1980's, the subtractive manufacturing technique was introduced in the FO field [11], approximately 30 years after the first commercial numerical-control programming system had been developed [12]. Once more, the development of a manufacturing technique significantly influenced the innovation in the FO field [12]. To date, the most recent manufacturing method which has been implemented in the FO field is the additive manufacturing (AM)[13–21].

It is recognised that the digital manufacturing process provides a lot of opportunities such as a potentially increased accuracy of the product manufactured[22–24], the ability to better embrace the concept of dosage response modelling [25,26,35,27–34] and it allows to increase the knowledge and insight into complex phenomena [36]. However, the potential of the digital manufacturing process has not yet been sufficiently explored in the field of orthotics [37]. Through many years, orthoses had no apparent innovation and as already shown, the collaboration with experts in the domain of CAD/CAM such as designers, engineers and manufacturing specialists permits enhanced orthotic designs with a high degree of customisation [38]. Aside from these opportunities, there are also different barriers to implement the digital manufacturing process in the field of FO:

- Firstly, CAD/CAM is considered to raise **significant training issues** in the manufacturing industry [39]. As suggested by Barnes & al., the training in the domain of CAD/CAM should be done in a context which seems real for the learners and which promote the development of technological awareness and capability[36]. Note that different solutions are offered in the orthotic industry ranging from complete office-based solutions to factory-based manufacturing [39].
- Secondly, the **price of this technology** can be a drawback even if it has progressively decreased over time[37] and thus is becoming available to a wider range of foot health practitioners [40].
- Finally, there are also some **regulatory issues** [41].

1.2 FO customisation

Most of the FOs previously described are considered as customised in the current literature due to the fact that they are manufactured for a specific person based on a 3D model of that person's foot [42]. Contrary to customised FOs, the prefabricated FOs are designed to fit a range of patients and are mass-produced based on a generic foot shape [42,43]. The business model for mass production is primarily cost-oriented rather than value-oriented [23]. In this context, some studies have evaluated an intervention based on its value for the patient and on its underlying costs [44] and the merit of customised FO has been challenged suggesting that they have limited or no added value for patients despite their cost compared to prefabricated FO [45–47]. This can justify the fact that the tendency to prescribe customised or prefabricated FO is varying depending on the country of practice, the working sector, and the condition targeted [42].

While the benefits of customised FOs have been questioned several times [45–47], the manufacturing process should absolutely be considered in this debate since it directly impacts the cost [23]. As an example, One of the major advantages of the additive manufacturing method is that it allows to reach higher degrees of customisation than traditional manufacturing and this with no additional costs (« Customisation is free ») [23](Fig. 1). Thus additive manufacturing is likely to be more competitive than other manufacturing techniques when it comes to fabricating FOs with higher levels of customisation [23].

While it has become evident that digital technologies has the power to improve the clinical effectiveness of FO, there are a number of barriers which should be overcome if one pursues an optimal integration of it in FO practice. In this perspective, it should be recognized that the community lacks a conceptual model in which this could be integrated in a straighforward manner. In the next chapter we aimed at describing such a conceptual model on one hand and directly illustrate the digital component simultaneously.

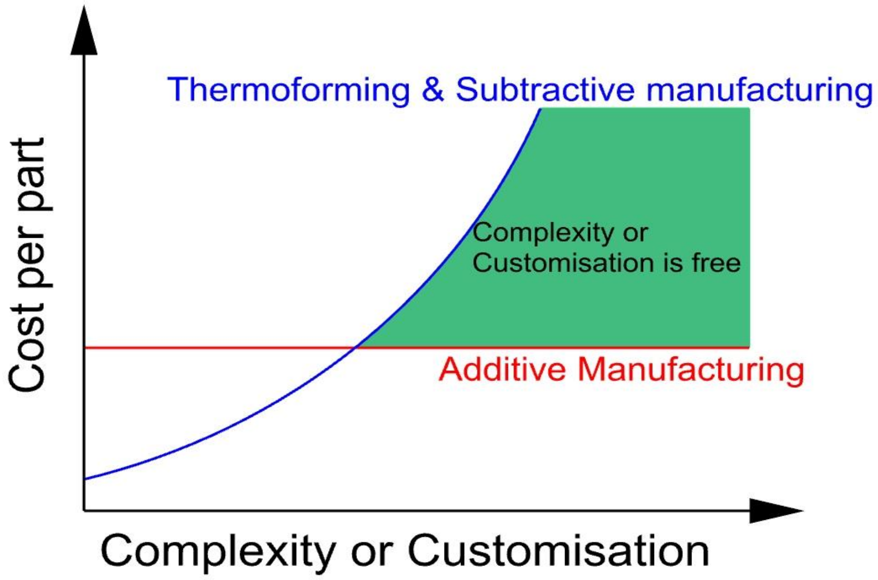

Fig. 1: Complexity and customization are free with additive manufacturing[23].

2 Task

Telfer (2017) compared three designs (standard milled orthotic, virtually optimized milled orthotic and a 3-D printed orthotic) to test whether virtually optimized orthotics would provide greater reductions in plantar pressure to a standard approach[48].

- Could you describe the optimization models used in this paper?

- Is there an orthotic which provide greater reductions in plantar pressure?

3 Reference

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