



**Review technologies in the design and manufacturing of FO**

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## I. Introduction

Foot orthoses can be produced by employing manual physical processes, by using a range of digital tools and technology or a combination of both. The factors which influence the process of foot capture, orthoses design and orthotics manufacture vary across professional disciplines, industry, educational and research sectors. For many decades foot orthotics practice has typically used a “hands on” approach, this is despite the growth of digital technology for foot orthotic services. The challenge for health care professionals is to appraise whether traditional “hands on” approaches are required in contemporary practice, given the advances in digital technology for the foot orthotics industry. The use of digital technology in the orthotics industry may now see an increased use, especially in light of the challenges due the current COVID-19 pandemic, (Binedell, Subburaj, Wong, and Blessing, 2020). For example, during the pandemic, some health care practitioners have used digital technology to transform services to virtual consultations, in response to reducing physical contact with patients.

There are some debates in the literature comparing digitally driven and manual processes to illustrate levels of accuracy and repeatability when capturing foot shape and designing features of foot orthotics, (Parker, Nuttall, Bray, Hugill, Martinez-Santos, A., & Nester, C. 2019). In addition, digital tools appear to be used more frequently for high risk groups in the public sector to measure the effectiveness of offloading with custom-made designs, (Paton, Stenhouse, Bruce, Zahra, & Jones, 2012; Bus, Ulbrecht, and Cavanagh, 2004 and Zwaferink, Custers, Paardekooper, Berendsen, & Bus, 2020). Digital technology is used in the private sector and research domains to provide quantifiable measures of the intended orthotic effect on muscle, motion and biomechanical changes This results in a moderate amount of

evidence which tends to position the use of digital tools and technology with custom-made foot orthotic designs. Some of the problem areas for foot orthoses design relate to the differences in approaches between manual and digital methods, with variations in reported use of technology in foot capture, orthotic design and manufacture (Crabtree, Dhokia., Newman.and Ansell 2009). The possible design features for a foot orthotic are vast and prescription values or orthotic dose can vary between practitioners and be achieved with both digital and manual processes. This review will offer a discussion of the factors influencing engagement with digital tools and technology in the capture, design, manufacture and evaluation of foot orthoses.

Scoping of the literature was conducted, to allow an an overview of the available research evidence of a range of different study designs and methods in the diverse area of technology used the design and manufacture of foot orthoses.

The key aim of the review was to identify what technology and digital tools are used the design and manufacture of foot orthoses practice. Inclusion criteria applied as follows:

- 1) The period of 2000-2020
- 2) Studies published in English.
- 3) Qualitative and quantitative research designs and literature reviews
- 4) Studies with a focus on foot orthotics
- 5) Peer reviewed

The following were excluded: case study reports, foot prosthetic studies, surgical studies.

Multiple search terms were used in order to cover the topic of digital technology in the design and manufacture of foot orthoses. The search terms were \*digital skills and foot orthotics \*CAD/CAM and foot orthotics \*dosage and foot orthotics \*foot scan and foot orthotics

The following databases were searched ProQuest, Science Direct, PubMed, Medline and Cinhal and Web of Science.

Papers were filtered following retrieval from the data bases for duplication of titles and applicability to the inclusion and exclusion criteria. Papers were then organized to identify any common themes and approaches emerging from the literature. A number of key factors were evident which appeared to influence the use of digital technology in foot orthotic practice.

The key factors influencing use of digital tools for foot orthotic decision making are,

- Intended effect – plantar pressure and dosage response model (Telfer, Woodburn, Collier, and Cavanagh 2017; Parker et al 2019).
- Cost (Payne, 2007; Paton, et al 2012; Parker, et al 2019).
- Fit and footwear (Bus, Ulbrecht, and Cavanagh 2004; Demits, Coorevits, De Clercq, Elewaut, Woodburn, and Roosen 2012; and Price and Nester 2016).
- Shape of the foot (Price et al 2016; Owings, Woerner, Frampton, Cavanagh, and Botek 2008; Telfer et al, 2017; Billis, Katsakiori, Kapodistrias, and Kapreli 2007; Cornwall and McPoil, 2011 and Stankovic, Booth, Danckaers, Burg, Vermaelen, Duerinck, and Huysmans, 2018).
- Reliability and repeatability of design (Carroll, Annabell, & Rome 2011; Crabtree et al, 2009 and Telfer, Pallari, Munguia, Dalgarno, McGeough, & Woodburn, 2012; Farhan, Cheng, Burns, Wang, Zhanzi and Bray, P. 2021).
- High risk demographic groups (Bus, et al, 2004; Paton, et al, 2012; Santos, 2016; Parker et al, 2019; Telfer et al, 2017; DeMits et al, 2012 and Ahmed, Barwick,

Butterworth, and Nancarrow, 2020; Zwaferink, Custers, Paardekooper, Berendsen, & Bus, 2020).

- Knowledge and experience of foot health scientist (Carroll et al 2011; Nester, Graham, Martinez-Santos, Williams, McAdam, & Newton, 2017 and Nester, Graham, Martinez-Santos, Williams, McAdam & Newton, 2018).

## **II. Current perspectives from the scientific literature.**

Recent comparisons of manual and digital supply chains for foot orthoses show that digital processes demonstrate accuracy and reliability in capturing foot shape and size (Parker et al., 2019) (Carroll et al., 2011) (Price & Nester, 2016). However, whilst digital methods such as foot scanning demonstrate accuracy in measuring foot dimensions compared to conventional methods (Lee, Yu-Chi, Lin, & Wang, 2014), there is still potential for clinical error when interpreting data from digital capture methods due to differences in foot positioning (Cornwall and McPoil, 2011) and different factors affecting foot morphology (Stankovic et al, 2018). There variability in the choice of clinical measurements for foot orthotic practice means there is no agreement within the literature, whether a manual or digital pathway is the most appropriate choice for capture of foot posture and deformity (De Mits et al, 2010). The availability of new technologies, such as 3D printing, computer aided design and milling, means that they are now being incorporated into some foot orthotic practices. However, limited review of evidence on the use of digital technology in the design and manufacture of foot orthosis may go some way to explain the low levels of engagement with available technology in practice. Another barrier to the implementation of digital technology may relate to the initial cost outlay.

Nester et al (2017) provided a multi professional profile of foot orthosis provision in the UK which indicated that a range of health care professions are providing foot orthoses for various patient groups using a range of designs including computer aided design and manufacture.

The environment in which different professionals capture clinical information to inform foot orthoses practice, varies widely as does the type of data collected pre and post foot orthotic provision. As such, the manufacture of foot orthoses can involve skills employed in a physical workshop space with manual use of machinery. Other foot orthotics are generated by using

skills of Computer Aided Design (CAD) prior to manufacture of foot orthoses in specialist on site or off site Computer Aided Manufacture (CAM) facilities.

The use of digital technology and digital tools will now be explored around evidence themes and will be contextualised to foot orthotic practice.

### III. Foot orthotics - Intended effect and costs

Foot orthoses are commonly used for the management of foot pain and lower limb pathology. The use of foot orthoses is advocated within international guidelines, for example, the management of feet affected by diabetes [IWGDF 2019]. For people with diabetes, the intended effect of a foot orthotic is to offload plantar pressure from areas at risk of ulceration. This has been demonstrated in several studies by employing the use of technology and digital tools in the design, manufacture and evaluation process (Bus 2004; Telfer et al 2017; Paton et al, 2012; Santos, 2016; Parker, et al 2019).

That said, the intended effect of offloading for people at risk of foot ulceration has also been achieved by combining the use of digital tools to measure foot pressure with pre-fabricated foot orthoses (Paton et al, 2012). Evidence suggests that there are differences in cost and quality of foot orthoses when comparing manual processes versus digital tools and technology (Payne, 2009). Use of digital technology increases the cost of custom made orthotics (Owings et al, 2008) and Paton et al, (2012) says cost must be considered in clinical practice especially if there are good outcomes from pre-fabricated foot orthotics.

It is important to critically appraise the value of foot orthotic practice for different demographic groups and for different pathological conditions. Certain conditions appear to respond less favourably to foot orthoses than others and some literature on foot orthosis practice has questioned the value of custom made foot orthoses by comparing to sham devices Munteanu, Landorf, Bonanno, Pizzari, Cook, and Menz, (2011). However, the method of evaluation regarding intended effect of custom made orthotics and design features of sham orthoses is important when interpreting the results of these studies. This is illustrated by



McCormick et al (2013) who employed the use of Pedar to quantify the effect of custom and sham orthoses on plantar pressure. They concluded there was some evidence for a mechanical effect and credibility of sham orthoses, with certain shapes and materials showing reductions in plantar pressures.

Some studies have demonstrated how digital tools and technology can be used to quantify the biomechanical effect on the knee from dose adjusted laterally wedged foot orthotic designs (Tipinis, Anloague, Laubach, & Barrios, 2014)

Dose response of foot orthotics design does not feature highly within the literature but shows some promising findings. Telfer et al (2013) and Tipinis et al (2014) attempted to establish the effect of dose response for foot orthotics by adjusting the proportional prescription of foot orthoses. Each study used digital technology to quantify the effect of foot orthotics. Whilst Telfer et al (2013) was not able to show any significant change in EMG data to different doses of foot orthotics, there was a significant response in plantar pressure data. In addition, Tipinis et al, (2014) was able to demonstrate how dose response of lateral wedged foot orthotics resulted in biomechanical changes to knee adduction. Despite these interesting initial cases, there is a lack of consensus within the literature on orthotic prescription dosage for foot orthotics (De Mits et al 2010).

#### **IV. Fit, footwear and foot orthotics**

Measurements of the foot play an important role in precision for manufacturing of footwear and foot orthotics. Findings (Witana Xiong, Zhao, and Goonetilleke, 2006) suggest there are critical dimensions of the feet for footwear fitting to ensure good fit and comfort.

Measuring foot morphology can be accurately achieved using digital tools such as scanner technology. Price and Nester (2016) captured scanned data from a sample of 69 males and transformed these to a computed foot shape. Price and Nester (2016) concluded that consideration should be given to impact of high BMI on the dimension and shape of feet for footwear design to ensure comfort and fit.

The same considerations are likely to be true when taking measurements for good fit and comfort of foot orthotics. Achieving an accurate fit of a foot orthotic is an important factor in foot orthoses design and manufacture and requires some consideration to be given to reliability and repeatability of measures for capturing foot shape.

## **V. Shape of the foot and foot orthotics**

The physical measurements of the size and shape of the foot has implications for the design and manufacture of foot orthotics. A number of systems exist to digitally capture the surface shape of the foot, and foot shape and size can change between non-weightbearing and weightbearing positions. Research (Tsung, Ming, Yu Bo, and Boone, 2003.) suggests increasing the weightbearing positions of the foot will increase the contact area of the shape of the foot, which has implications when capturing measurements for foot size and shape. Price (2016) looked at the repeatability and validity of producing 3D models from a mobile application and a 3-D scanner to capture foot shape to get an accurate picture of foot size. The 3-d scanner demonstrated greater repeatability and the study recommended that caution be applied when using APP's to estimate foot size as there is a greater degree of observed error.

The literature suggests accuracy in capturing foot shape is a key driver for orthoses design. prfor capturing foot shape have remained unchanged for decades, they been shown to be error prone and less repeatable than 3D scanning. This may lead to problems in accuracy of orthotic fit, which might explain why practitioners frequently modify customised orthoses. However, whilst there is evidence that changes in the shape of an orthotic affects foot motion and pressure, there is no evidence that these adjustments result in proportional changes in clinical outcomes.

## **VI. Reliability and repeatability of technology**

Measurements of the foot can be done manually or by using digital tools such as scanners.

For manual measures, the skill level of the measurer and instrument is important in capturing accurate data. Limitations of manual measures are mainly due to errors and variations in foot measurement, due to poor inter-operator reliability.

To reduce errors in foot measurement, scanning technology can be used to capture foot shape to improve accuracy. Even with improved accuracy using digital tools, it is important to define foot parameters to be measured so they can be reproducible and repeatable.

Digital scanning also requires good skill from the measurer and also has room for error unless fully automated.

Carroll et al (2011) found the reliability of capturing foot parameters using manual suspension cast methods has a greater degree of variability when compared to digital scanning methods.

Telfer et al (2012) carried out a similar study but included foot capture methods using the Foam Impression which further demonstrated how different foot capture methods increased the variability of the foot parameters. This resulted in foot orthotics with different amounts of contact area with the plantar aspect of the foot. The implication of this are important when interpreting the reported values of in shoe plantar pressure.

These studies provides some evidence that high levels of intra and inter-rater reliability can be achieved using digital scanning methods compared to use of a manual suspension cast and foam impression boxes. Nevertheless, limitations and errors are not eradicated with use of digital scanning methods as there remain some challenges in standardizing the position and loading of the foot, making interpretation and comparison of studies difficult.

## **VII. High risk groups**

Use of CAD/CAM approaches are suited to the prescription of custom-made foot orthotics.

There appears to be favourability for custom made foot orthotics in the literature, especially for some high-risk patient groups (Bus et al 2004; Paton et al 2012; Telfer et al 2013, Santos 2016, Parker et al, 2019). In addition, the ability to accurately adapt and reliably reproduce the orthosis design to accommodate deformity (Billis et al, 2006, Cornwall and McPoil, 2011, Stankovic et al, 2018; Owings 2008; De Mits et al 2010 and, Price, 2016) is reported as a key reason for choosing customised foot orthotics.

Harnessing technology to improve effectiveness of custom insoles is best illustrated by the evidence from research undertaken on people with diabetes experiencing foot problems.

For example, (Owings et al., 2008) was able to compare the offloading ability of custom insoles designed from just foot shape with those from foot shape combined with plantar pressure data. The custom insoles designed from foot shape and plantar pressure enhanced the offloading efficacy of pressure under the forefoot.

Using digital tools to measure peak pressure is essential in foot orthotic design and evaluation, because for people with diabetes orthotics offer protection against ulcer recurrence. There are a number of digital tools to measure peak pressure as an outcome measure and this is evidenced in the work by Paton et al 2012 and Telfer et al 2017. Telfer et al, (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. The optimization models combined data from a surface 3-d scan which used ultrasound tissue thickness

measurements to produce a computer model of a foot. They found that the virtually optimized orthotics enhanced the offloading performance on the forefoot region.

Ki, Leung, & Li, (2008) used the Pedar system to compare plantar pressure distribution between total contact insoles produced by foam impression foot capture and insoles produced by a CAD-CAM system. Both similarly redistributed peak pressure from the heel to the midfoot area, but CAD-CAM designs performed better in reducing the pressure dosage over time in the mid forefoot regions, which is clinically important for managing risk of foot ulceration. This may be due to the way the foot was captured or the computer generated foot model. In conclusion, caution must be applied when comparing peak pressure findings between studies, as Price et al., (2016) suggests in shoe devices used to quantify plantar pressure vary in their response to loading. Pedar system appears to be the most accurate, repeatable and valid for both clinical and research settings.

### **VIII. Knowledge of foot health scientist.**

The factors which influence use of foot orthotics varies across professions, industry, educational and research sectors. Previous work regarding the provision of foot orthoses has identified there are differences in the levels of evidence informing practice, and this can depend on the type of business and service provided, (Nester, et al 2017; Nester, et al 2018).

The use of digital technology is important and relevant to foot healthcare practice where there is an increasing drive to provide flexible digital solutions to healthcare problems.

Manufacturing methods for foot orthotics has focused on foot shape and position for many years and there is a need for improved skills and training in the development and application of foot orthotic practice requiring the use of digital technologies. Supporting health professionals to use digital tools and technology in foot orthotic practice is especially important given the growth in clinical populations that demonstrate a positive clinical and cost-effective outcome from orthoses use (e.g. diabetes)

The differences between the manual physical process and the use of digital tools in foot orthoses prescription and manufacture, creates problems particularly in relation to the teaching of foot orthotic practice. Therefore, It is important to appraise the best available evidence for technology and digital tools for teaching orthotic practice, to help people teaching and working in foot health research and for clinical practice

## **IX. Conclusion**

Scoping of the literature aimed to connect foot health research and science to the use of foot orthoses in practice, within the context of digital skills and technologies. This has revealed there are some patterns of evidence from research studies demonstrating how technology and digital tools have been embraced in the assessment, design, manufacture and evaluation of foot orthotics.

Strengths of this review; that the literature search was conducted in scientific, international, and widely used databases, and their coverage of research in the field of health sciences is comprehensive. Limitations of this review; this relates to the type and design of the studies included, which were heterogeneous and conducted using different study designs, this variation creates some challenges in translation of the findings into foot orthotic practice.

In addition, the review findings are of a broad descriptive level, and future work may explore a narrower focus using studies of a similar design to provide more in-depth knowledge on the discrete aspects of digital technology namely;

Digital technology for the Assessment for foot orthotics,

Digital technology for the Design of foot orthotics,

Digital technology for the Manufacture of foot orthotics

Digital technology for the Evaluation of foot orthotics.

On a positive note, health care professionals who have successfully engaged with digital technology during the COVID pandemic during 2020-21, may now be ready to give more focus on digital technology, both in the clinical environment and in the context of teaching foot orthotic practice and research. The benefit of this is to acquire more comprehensive



and reliable foot health data to inform accurate foot orthotic designs with more successful outcomes for foot health practice.

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