Leveraging Digital Technology to overcome barriers in the Prosthetic and Orthotic Industry: an evaluation of its applicability and use during the COVID-19 pandemic.

Trevor Binedell, Karupppasamy Subburaj, Yoko Wong, Lucienne T M Blessing

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Trevor Binedell[1, 2, 3] MSc; Karupppasamy Subburaj[1, 2] PhD; Yoko Wong[4] PhD; Lucienne T M Blessing[1, 2] PhD

[1]SUTD-MIT International Design Centre Singapore University of Technology and Design Singapore SG
[2]Engineering Product Development Pillar Singapore University of Technology and Design Singapore SG
[3]Footcare and Limb Design Centre Tan Tock Seng Hospital Singapore SG
[4]Consortium for Clinical Research and Innovation Singapore Singapore Clinical Research Institutes Singapore SG

Abstract

Background: The prosthetic and orthotic (P&O) industry typically provides an artisan "hands-on" approach to assessment and fitting of orthopedic devices. Despite growing interest in digital technology for P&O service provision, little is known of the quantum of use and the extent to which the current pandemic has accelerated the adoption.

Objective: This study's objective is to assess the use of digital technology in P&O and whether its use can help overcome challenges posed by the current COVID-19 pandemic.

Methods: A Web-based survey of working Prosthetists/Orthotists and lower limb patients was conducted between June-July 2020 and divided into three sections: Lower limb amputees, Prosthetist/Orthotist currently using digital technologies in their practice and Prosthetist/Orthotist not using any digital technology. The input was sought from industry and academia experts for the development of the survey. Descriptive analyses were performed for both qualitative (open-ended questions) and quantitative data.

Results: In total, 113 individuals responded to the Web-based survey. 83 surveys were included in the analysis (patients: 15%; prosthetists/orthotists: 85%). 30 surveys were excluded because less than 10% of the questions were answered. 44% of the prosthetist/orthotists utilizes digital technologies. 3D scanning and imaging were the leading digital technologies being used, primarily for footwear, AFOs, transtibial and transfemoral sockets. Digital technology is particularly suitable for scanning of prosthetics during COVID-19. The use of virtual care was reported by the prosthetists/orthotists to be beneficial. However, the technology could not overcome inherent barriers such as the lack of details normally obtained during a physical assessment. Virtual care could be useful for education, monitoring, or triaging purposes or in rural settings.

Conclusions: Digital technology is transforming healthcare. The current pandemic highlights its usefulness, but digital technology must be implemented thoughtfully and designed to address issues that are barriers to current adoption. Technology advancements utilizing virtual platforms, digitalization methods, and improved connectivity will continue to change the future healthcare delivery. The prosthetic and orthotic industry should keep an open mind and move towards creating the required infrastructure to support this digital transformation, even if the world returns to pre-COVID-19 days.

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Binedell T[124], Subburaj K[1], Wong Y[3], Blessing LTM[4]

[1] Singapore University of Technology and Design, Engineering Product Development

[2] Tan Tock Seng Hospital

[3] Singapore Clinical Research Institutes, Consortium for Clinical Research and Innovation Singapore, Singapore

[4] Singapore University of Technology and Design, SUTD-MIT International Design Centre

ABSTRACT

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open mind and move towards creating the required infrastructure to support this digital transformation, even if the world returns to pre-COVID-19 days.

BACKGROUND

Currently, the prosthetic and orthotic industry designs devices to restore, replace, correct, protect, or immobilize a body part, through hand-crafted artisan approaches. These devices are highly patient-specific and are a result from the specialized skills and experience of the individual prosthetist/orthotist (P&O) (1). The provision of these prostheses and orthoses is time-consuming and wasteful, and not completely customized (2), with production costs a significant burden (3). They require on-going maintenance, monitoring and repeated visits to a clinic to ensure optimal fit and function throughout their use.

The introduction of digital technologies aims to improve these inefficiencies. **Digital technology** in this article refers to 3D scanners, tablets, computers, computer software programs, and computer-aided design and manufacturing (CADCAM). **Virtual care** refers to the use of telehealth, telerehabilitation, virtual assessments, and fittings. Digital technology and virtual care have successfully provided assistive devices assessment (4,5), therapy services (6), and diagnostic evaluations (7). They have also eliminated distance obstacles from health care (8).

Digitalization of the Prosthetic/Orthotic Design and Manufacturing process

3D scanning provides high accuracy (9), reduces product waste and improves quality (10,11). It has a high capability to capture 3D measurement without physical contact (12,13) and minimize the need for messy plaster of Paris casting. Digital libraries of files are created, manipulated, and personalized to fit a patient's unique needs with greater precision and ease (14). These files can be either be outsourced for central fabrication via CADCAM technologies or printed using Additive Manufacturing systems.

The use of **CADCAM** in the prosthetic and orthotic applications has been rapidly developing as a technology since the mid-1980s (15). Although considered expensive to use due to the high infrastructure and equipment costs, the technology has shown great potential (16). This technology's benefits includes shorter delivery times, design consistency, repeatability, quantifiable modification, and modern manufacturing (17,18). CADCAM has become an enabler for central fabrication, which can reduce the need for the additional workforce or technical workshop but requires users with significant CAD experience (19). With an overwhelming need for prosthetic and orthotic services in developing countries, it may be possible to digitize many residual limbs in satellite clinics, then send the data to a central location where facilities can quickly produce the prosthetic limbs or orthoses (16).

Additive Manufacturing (AM) systems reduce unnecessary waste of the traditional subtractive manufacturing methodologies and produce almost any geometric form, independent of its complexity (3). It is considered the newest healthcare-enabling concept with its technology capable of transforming current prosthetic and orthotic designs. 3D printed devices can have comparable biomechanical properties to traditionally manufactured devices, with potential for fine control over these properties (20). It will likely become an invaluable tool in constructing bespoke orthoses, prostheses, and exoskeletons (21,22). 3D scanning and printing are currently used in applications across a spectrum of devices that include ankle-foot orthoses (23,24), helmets (25,26), and prostheses (27–29).

Digitalizing Assessment and Care

Despite its benefits to improve outcomes and utilize the contactless process of scanning to reduce cross-contamination (12,13), the use of digital technology is not without challenges to routine clinical care. There are often high capital costs in equipment, training, and concerns over the return of investment. Researchers still debate the ideal way to "digitize" the residual limb, whether it is better to cast and scan the negative mold, whether medical imaging (CT/MRI/X-Ray) is more suitable (30,31), whether scanning should be done while weight-bearing (15), or not. An “expert” P&O has little to gain in the short run by adopting computerized methods (16). A significant amount of retraining is required, and current virtual technology has not overcome typical physical characteristics of an assessment such as palpation.

Virtual care offers a unique capacity for remote screening, triage, and treatment. It could be a powerful tool for reducing transmission of contagious diseases such as COVID-19 to and among health care workers and patients who are not infected (32). With patients using the internet to access healthcare increasing each year, the quality of any service provided by this means should be evidenced-based and necessary (33). Any assessment administered online needs to be followed by automated reports with scans or images, objective and subjective assessment (34,35), patient expectations, prescription, expected outcomes and timelines. Virtual assessment can overcome many of the pitfalls of physical assessment while greatly expanding the potential pool of patients who may be unable or unwilling to attend a physical clinic. Due to the current pandemic crisis, the British Association of Prosthetics and Orthotics (BAPO) recommends the use of virtual care for triage, advise, assessment, reviewing on-going care, the provision of off-the-shelf (OTF) orthoses, and to review all patients undertaking virtual assessments once normal working conditions resume (36).

Several barriers exist in virtual care implementation, including the lack of reimbursement (37,38), patient privacy and confidentiality, medicolegal concerns, practical workflow concerns, and physicians' fears of being overwhelmed by online messages (39). Furthermore, virtual assessments lack the vital elements of palpation, dynamic testing, and real-time feedback. Some patients may also find virtual assessments are quite impersonal and may feel more comfortable seeing someone in person to get the care they need. There remains the on-going issue of internet connectivity in some regions, the high cost of hardware and software, and the patient's ability to use information technology (IT). Quality of service for live streaming audio/video applications must be improved to provide sustained bandwidth and low latency (8).

Prosthetic and Orthotic care under COVID-19

Virtual care can address several aspects of assessment and care that do not require the time and effort necessary to travel to the P&O or allows care when such travel is not possible or puts patients at risk, such as during a pandemic. The current COVID-19 situation necessitates that we utilize available resources to optimize patient quality and outcome of the virtual visit (19).

COVID-19 is one of the most significant challenges faced by the world in this century. Its ease of transmission and potentially life-threatening effects have led governments worldwide to introduce new norms like social distancing and stay-at-home orders to save lives and reduce the strain on healthcare systems. With many hospitals stretched to support operations to contain the spread of the virus, new measures are needed to maintain patient care. Health care professionals of all types that manage patients are affected, including P&Os (40). The result of this pandemic has propelled virtual care adoption and transformed healthcare delivery (32).

The International Society of Prosthetics and Orthotics has recommended continuing services for the industry during this pandemic. In prosthetic and orthotic facilities, there is a need for a combination of care and technical expertise. Prosthetic and orthotic services are generally delivered face to face with a high amount of physical contact. As a result, the pandemic provides unique challenges that can be difficult to overcome. The delivery care model will need to change as a result of COVID-19. There may be a “new normal” that is very different from traditional practice, including the increased use of digital technologies. Digital technologies can potentially lead to different and more efficient designs, provide greater access to care, and limit physical contact. However, digital technology must be implemented thoughtfully and designed to address issues that are barriers to current adoption.

This paper presents the results of a study aimed at assessing the applicability and barriers of digital technology use in prosthetics and orthotics and whether this technology can help overcome challenges posed by the current COVID 19 pandemic on the industry.

METHODS

An online survey was designed and used to survey P&Os currently practicing and lower limb amputees using a prosthesis. The survey was administered between June and July

2020. This study was approved by the Institutional Review Board (IRB) at SUTD Participants were recruited via IRB-approved social media platforms like LinkedIn, WhatsApp, and social chat groups. Interested participants agreed to a preceding statement of consent, and a participant information sheet link was provided. Participants were asked for their email only if they were agreeable for a follow-up interview. This information was stored separately from the responses to maintain confidentiality. Participants were able to review and change their answers before submission.

The 68-items of qualitative and quantitative survey was divided into three sections, with the survey logic routing the participant to questions based on previous responses. The first section of the survey gathered Lower Limb Amputees (**LLA**) experiences and preferences. This included questions relating to prosthetic use, barriers to care, and opinions on the use of virtual assessments and home fittings. Section two was designed for the P&O, who did not use digital technology in their facility (**P&O-nonDT**) Questions included the number of patients seen per day, attitudes towards digital technology, and its importance to the future of the profession. Section three was for P&O who are currently using digital technology in their facilities (**P&O-DT**). Additional questions about the use and limitations of technology were included in this section.

All three sections included demographic questions, and questions on the use of virtual assessments or fittings. A variety of formats were used: multiple choice with single or multiple answers, ranking of answer options, 5-point Likert-scale questions, and open-ended questions. Where options were provided, the option “Other” was included to allow respondents to enter a different answer.

Follow up interviews were conducted on selected patients and P&O respondents. Interviews were unstructured and conducted *via* face to face, phone and email.

Survey responses were analysed with Stata/SE software (StataCorp LLC). All tests were carried out using a 5% level of significance. Answer options were presented as counts (%), mean (standard deviation) or median (interquartile range) as appropriate. Pearson's chi-square test was used to assess difference between frequencies as observed and expected for certain answers.

RESULTS

We received 113 survey responses, of which 83 were eligible for inclusion (n=13 lower limb amputees (LLA), n=70 P&Os). Surveys were excluded if less than 10% of the questionnaire were answered. On average, the survey took 13 minutes for the P&O to answer and 15 minutes for the LLA to complete. Table 1 shows the demographics of the respondents. Singapore was well represented: although only 18.6% of the respondents (n=13) this constitutes 68% of all P&O in SIngapore. LLA were from Singapore (n=12) and India (n=1). Follow-up interviews were conducted with LLA from Singapore (n=3) and with P&O who were using at least one digital technology (P&O-DT) from Singapore (n=3) Thailand (n=2), Malaysia (n=1) and Cambodia (n=1).

Table 1. Demographics of the respondents

	Prosthetists/ Orthotists (n=70) N (%)	**Lower Limb Amputee (n=13)** N (%)
Age range		
18-24	5 (7.14%)	1 (7.69%)
25-34	**33 (47.14%)**	2 (15.38%)
35-44	22 (31.43%)	3 (23.08%)
45-54	8 (11.43%)	**4 (30.77%)**

55-64	2 (2.86%)	3 (23.08%)
Gender		
Male	41 (58.57%)	**13 (100%)**
Female	29 (41.43%)	0
Country		
SE Asia + Asia	N=56 (80%)	N=13 (100%)
Singapore	13 (18.57%)	**12 (92.31%)**
Myanmar	8 (11.43%)	0
Thailand	8 (11.43)8	0
Malaysia	7 (10.0%)	0
Cambodia	6 (8.57%)	0
Indonesia	4 (5.71%)	0
Sri Lanka	4 (5.71%)	0
India	3 (4.29%)	1 (7.69%)
Hong Kong	1 (1.43%)	0
Philippines	1 (1.43%)	0
Japan	1 (1.43%)	0
Middle East	N=2 (2.85%)	
Yemen	1 (1.43%)	0
Saudi Arabia	1 (1.43%)	0
Europe	N=8 (11.43%)	
Bulgaria	2 (2.85%)	0
UK	2 (2.85%)	0
Germany	1 (1.43%)	0
Ireland	1 (1.43%)	0
Scotland	1 (1.43%)	0
France	1 (1.43%)	0
Other		
Australia	4 (5.71%)	0

Tables 2 shows the characteristics of the LLA respondents. LLA were primarily of K3 and K4 activity levels in the US Medicare Functional Classification levles (12/13, 92%) and had their amputation due to trauma (62%). They reported a long duration of daily use (mean 8.69 hours, SD 5.12), and a mean socket comfort score of 6.97 (SD 1.15). 84% of LLA had their prostheses measured using plaster and only 2 patients used only measurements. 0% of LLA used scanning to make their prosthesis. LLA mobility was mostly impacted by pain, followed by the ease of wearing their prosthesis, their ability to access care, and the temperature.

Table 2. Characteristics of Lower Limb Amputees

	Lower Limb Amputee (N=13)
K2 – Community ambulator	1 (8%)
K3 – Unlimited community ambulator	7 (54%)
K4 – Unlimited and recreational sports	5 (38%)
Non-trauma (cancer, diabetes, vascular disease,)	5/13 (38%)
Trauma	8/13 (62%)
Mean hours of using prosthesis each day	
Min – Max	0 – 18
Mean (SD)	8.69 (5.22)
Median (IQR)	8 (6.3)
Level of comfort with a prosthesis (0=least comfortable, 10=most comfortable)	
Min – Max	4 – 9.4
Mean (SD)	6.97 (1.15)
Median (IQR)	7.3 (1.5)
Methods of casting	
Plaster wrap	11 (84.62%)
Scanning	0 (0%)
Measurement alone	2 (15.38%)
Mean ranking of factors most impact on mobility (SD)	
Pain	**2.46 (1.89)**
Easy to wear	2.92 (1.85)
Access to care	4.54 (1.51)
Breathability/temperature	4.54 (1.90)
Durability	4.69 (1.93)
Stability	4.85 (2.91)
Weight	4.92 (1.71)
Appearance	7.08 (1.66)

Table 3 shows the characteristics of the P&O respondents. The P&O had an mean of 9.33 (SD 7.37) working years. The mean number of patients seen per day was 5.81 (SD 4.28). Almost half of the P&O used digital technology (31/70, 44%). Singapore had (11/13, 85%) of P&O use digital technology compared to Myanmar (0/8, 0%)

Table 3. Characteristics of P&O respondents

	Prosthetist &Orthotist (n=70)	
Years of working		

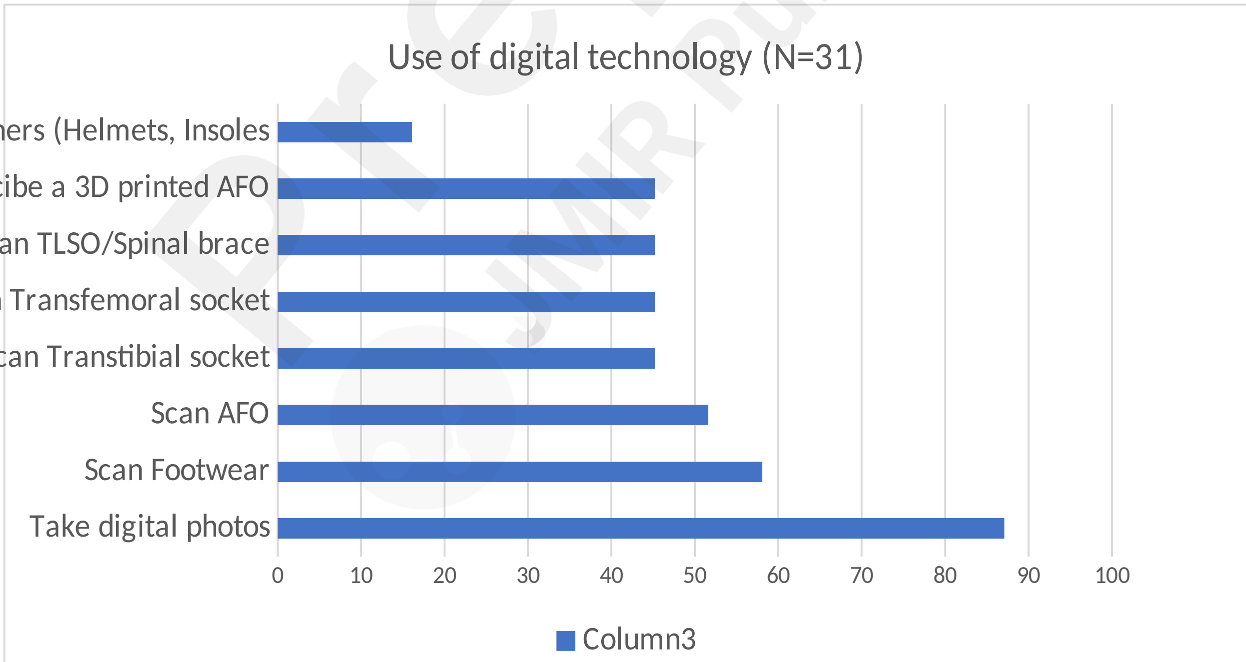
Min-Max Mean (SD) Median (IQR)	1 – 32 9.33 (7.37) 7 (10.0)	
Number of patients seen per day Min-Max Mean (SD) Median (IQR)	 0 – 20 5.81 (4.28) 4 (6.0)	
Using digital technology as part of work	**Yes (P&O-DT) 31 (44.29%)**	**No (P&O-nonDT) 39 (55.71%)**
SE Asia + Asia	N=24	N=34
Singapore	11	2
Myanmar	0	8
Thailand	4	4
Malaysia	1	6
Cambodia	1	5
Indonesia	2	2
Sri Lanka	1	3
India	0	3
Hong Kong	1	0
Philippines	0	1
Japan	1	0
Middle East	N=1	N=1
Yemen	0	1
Saudi Arabia	1	0
Europe	N=5	N=3
Bulgaria	2	0
UK	1	1
Germany	0	1
Ireland	1	0
Scotland	1	0
France	0	1
Other		
(Australia)	3	1
Years using technology	**(N=31)**	
Min-Max Median	0.5-24 2	

Use and Types of Technologies

The number of years, the P&O who use digital technology have been doing so varies greatly, from 0.5 to 24 years, with for a median of 2 years. Many of the P&O had CADCAM facilities where they worked (23/31, 74%). The iPad with a structure scanner was the preferred method for digital capture (12/31, 39%) with a mix of other scanners used, including Artec Eva Lite, Omega, and Rodin 4D. Geometrical modification of the scans were performed using various programs, which can be grouped into P&O specific software (24/31, 77%), and engineering software such as Rhinoceros or Solidworks (6/31, 19%). One P&O respondent was unsure of the program they use (1/31, 4%).

Figure 1 shows the application areas of the technology. Predominantly, the technology seems to show that taking digital photos to monitor care and to inform the design (87%) is the most common use, followed by scanning for custom footwear (58%). Approximately, half of the subjects would scan for an AFO, spinal braces, transtibial or transfemoral sockets.

Figure 1. The applications of digital technology used in clinical practice.



5-point Likert-scale questions showed that the attitudes towards digital technology among P&O using technology, were generally positive (see Table 5). 77% of the respondents agreed or strongly agreed that it improves patient outcomes. 81% agree that they have the necessary skills to incorporate digital technologies. 96% acknowledge a strong need to continue using the technology to maintain efficacy and improve skills and 65% are conscious that patients prefer them to use digital technology for their care. However, only 55% agreed that 3D printed devices were cost-effective, and 71% felt that digitally produced prosthetic and orthotic devices did not fit better than traditionally made ones.

Singaporean P&Os who use technology agree significantly less strongly (p=0.038) than non-Singaporean P&Os that the future of prosthetics and orthotics is digital. Interviewees from Singapore suggested their current experience with technology has been both positive and negative, limiting their expectations for the future. They felt a need to use digital technology “for appropriate cases” or “when they improve efficiencies such as casting for a large transfemoral socket or making a scoliosis brace.” One interviewee stated that using digital software to “modify such large devices was more efficient and required less physical strength.”

The common barriers to greater integration of digital technology (DT) for the P&O-DT respondents as obtained using open-ended questions can be seen in Figure 2. The top barriers were cost (36%) and the lack of skills and training (34%). The third identified barrier was the effectiveness of technology (19%). P&O-DT cited material strength, the need to outsource, and the constant software updates limiting the effectiveness of greater integration. These main barriers were similar to P&O-non-DT, highlighting an on-going need for continual financial reinvestment and training even when digital services have been established.

Fig 2. Barriers to greater integration of technology (n=31, P&O who use technology).

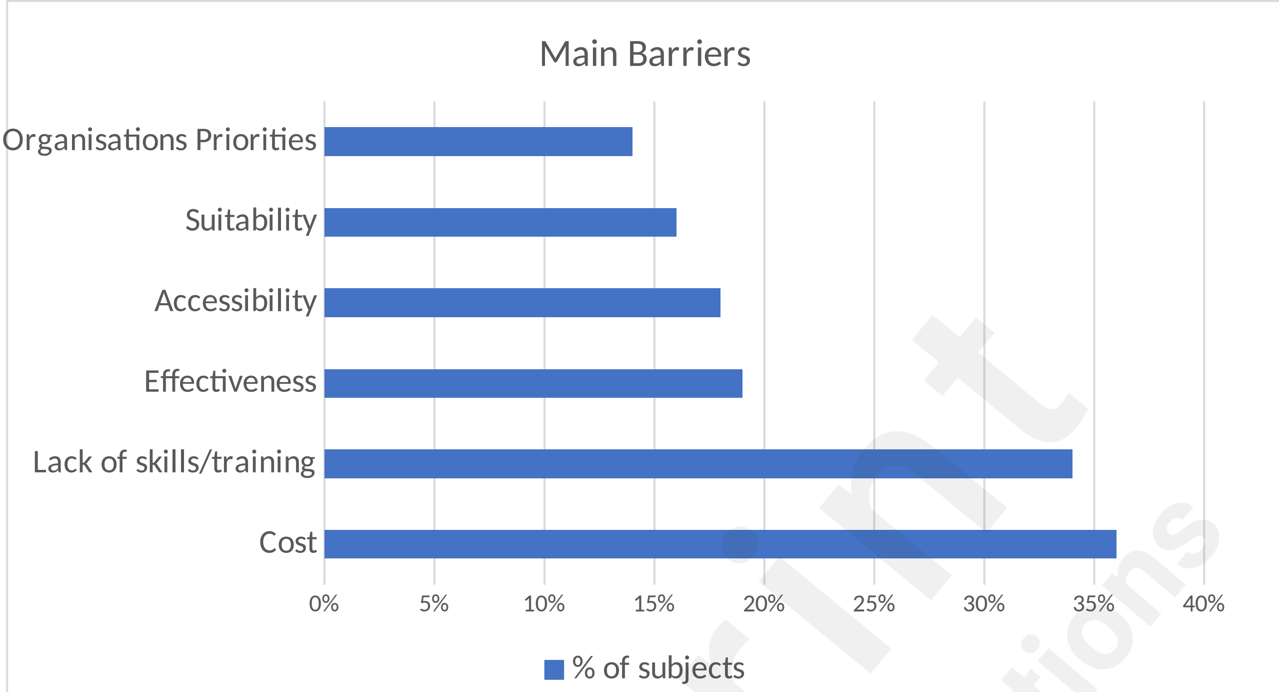


Table 5. Attitudes of P&O who use digital technologies at work

	Total (n=31)	Singapore (N=11)	Non-Singapore (N=20)	p-value
Digital technology improves patient outcomes				
Strongly Agree	9 (29.03%)	2 (18.18%)	7 (35%)	0.125
Agree	15 (48.39%)	8 (72.73%)	7 (35%)	
Disagree	7 (22.58%)	1 (9.09%)	6 (30%)	
Strongly Disagree	0 (0%)	0 (0%)	0 (0%)	
Patients prefer me to use digital technology when making their devices				
Strongly Agree	4 (12.90%)	3 (27.27%)	1 (5%)	0.123
Agree	16 (51.61%)	6 (54.55%)	10 (50%)	
Disagree	11 (35.48%)	2 (18.18%)	9 (45%)	
Strongly Disagree	0 (0%)	0 (0%)	0 (0%)	
It is important to practice with the hardware/software to be more efficient and effective.				
Strongly Agree	21 (67.74%)	8 (72.73%)	13 (65%)	0.276
Agree	9 (29.03%)	2 (18.18%)	7 (35%)	
Disagree	0 (0%)	0 (0%)	0 (0%)	
Strongly Disagree	0 (0%)	0 (0%)	0 (0%)	
Missing	1 (3.23%)	1 (9.09%)	0 (0%)	
I do not have the technical skills to use digital technology with my patients.				
Strongly Agree	0 (0%)	0 (0%)	0 (0%)	0.188
Agree	5 (16.13%)	0 (0%)	5 (25%)	
Disagree	20 (64.52%)	8 (72.73%)	12 (60%)	
Strongly Disagree	5 (16.13%)	2 (18.18%)	3 (15%)	
Missing	1 (3.23%)	1 (9.09%)	0 (0%)	
Digitally produced devices always fit better				

Strongly Agree	2 (6.45%)	0 (0%)	2 (10%)	0.554
Agree	5 (16.13%)	1 (9.09%)	4 (20%)	
Disagree	22 (70.97%)	9 (81.82%)	13 (65%)	
Strongly Disagree	0 (0%)	0 (0%)	0 (0%)	
Missing	2 (6.45%)	1 (9.09%)	1 (5%)	
3D printed devices enable high cost-effectiveness				
Strongly Agree	2 (6.45%)	0 (0%)	2 (10%)	0.394
Agree	15 (48.39%)	4 (36.36%)	11 (55%)	
Disagree	11 (35.48%)	6 (54.55%)	5 (25%)	
Strongly Disagree	1 (3.23%)	0 (0%)	1 (5%)	
Missing	2 (6.45%)	1 (9.09%)	1 (5%)	
The future of prosthesis and orthosis industry and practice is digital				
Strongly Agree	12 (38.71%)	2 (18.18%)	10 (50%)	***0.038***
Agree	16 (51.61%)	9 (81.82%)	7 (35%)	
Disagree	3 (9.68%)	0 (0%)	3 (15%)	
Strongly Disagree	0 (0%)	0 (0%)	0 (0%)	

$p<0.05$

Non-Use of Technologies

Where non-use of technology was common, stable internet was still a problem, particularly in developing countries such as Sri Lanka (2/3, 66%), Cambodia (2/5, 40%) and Myanmar (2/6, 33%), and many of the P&O respondents in these countries did not have computers (35/39, 89%). Other reasons mentioned for not using technology were cost (25/39, 64%) and the lack of awareness and skills (20/39, 51%).

Virtual Care

The use of virtual assessments and virtual fittings were analyzed for agreement. A primary benefit of virtual services is to reach those who face obstacles in coming for their appointments. 41% of all P&O respondents felt their patients had difficulties coming for their appointments. The main reasons mentioned were transportation (19%), cost (13%), and the lack of family members or caregivers to bring them to their appointment (12%). P&O respondents found that virtual assessments would benefit the patient in these situations (84%). Interestingly, 85% of LLA did not find access to care an issue and preferred to come to the clinic for their follow-ups even during the pandemic.

73% of P&O respondents would use virtual assessments if it was made available. 75% agreeing or strongly agreeing that virtual assessments would be suitable for rural areas. The potential benefits mentioned were to save clinical time and reduce the need to travel (45%), this often reduces costs (24%), and – of relevance during this current pandemic – 14% suggested it would be safer for the patient and decrease the risk of infection.

Some confusion arose when P&O were asked about the format of the virtual assessments. 71% of selected interviewees revealed they had merely agreed to the statement without thinking how they might apply this service. Suggestions for the service included a "*triage-like*" service or checking "*simple things like whether all is well or not*" to "*assess the problem*" and "*determine whether a trip to the clinic was necessary*". When asked if they felt patients would be willing to pay for this service, many '*did not think so*" unless "*it adds value*." The LLA responses concur with these statements. Only 6 of the 13 surveyed LLA are prepared to pay for this service, and another 2 would do so only if their needs were met.

The major potential challenges with virtual assessment mentioned by the P&O respondents were difficulties in assessing the limb for strength, ROM, palpation, and pain (37%). Other problems were concerns of the skills the patient had to use items such as computers (17%), the high chance of miscommunication when giving advice (16%), and internet connectivity (12%).

39% of all 70 P&O respondents were open to providing virtual fittings using a third person 'fitter' with a further 15% considering it depending on the fitter's skills and training. 54% of all P&O respondents said it would be beneficial to their patients, citing reasons like it provides greater outreach and maintains the ability to overcome the common barriers like the need to travel to the clinic. When the P&Os were asked about patients doing the task of fitting themselves, safety concerns were mentioned during the interviews, despite LLAs feeling confident in their ability (Table 6). There were mixed results for the level of confidence LLA have to adjust their own prosthesis with or without internet guidance. We found that those LLA who were less confident with internet guidance than by themselves, tended to be over 45 years of age.

Table 6. The confidence of LLA adjusting their own prosthesis (n=13)

Confidence in adjusting the prosthesis	By self	With internet guidance
Extremely confident	4 (30.77%)	4 (30.77%)
Very confident	2 (15.38%)	1 (7.69%)
Somewhat confident	4 (30.77%)	2 (15.38%)
Not so confident	0 (0%)	**5 (38.46%)**
Not at all confident	3 (23.08%)	1 (7.69%)

DISCUSSION

Principal Findings

To date, research has focused on the development of digital technologies or how new technology can be applied to the industry for a particular application. This survey reports the actual current use of digital technologies in the prosthetic and orthotic industry and its suitability during pandemics such as COVID-19. Whilst infection prevention practices like social distancing, the wearing of masks and regular washing of hands have been implemented, the use of digital technology for prosthetic and orthotic services remains challenging with many barriers to overcome. Current adoption levels of technology despite the pandemic suggest the potential benefits of safer care have not outweighed the limitations of the technology to provide sufficient value to both the patient and P&O. Furthermore, changing organizational behaviors in delivering digital healthcare require the right skills among healthcare professionals to leverage technology-driven solutions towards technology adoption.

Use

Approximately half of the P&O respondents use some form of digital technology. The use of scanners, computers, and CADAM are the most common ones. The use of scanners provides a mess-free and reduced physical-contact environment, improving patient safety during the pandemic. The P&O respondents preferred the more cost-effective iPad with a structure scanner (Occipital) over high-end accurate scanners such as Vorum's Spectra scanner or Artec EVA scanner. P&O interviewees stated that the wireless iPad was easier and lighter to maneuver to capture the limb shape but can be limiting when capturing the posterior view due to the screen's position forcing an awkward posture of the person scanning. It is the lead author's opinion, as a principal P&O with over 21 years of experience, that having a small external camera connected via a cable or wirelessly to an external screen to view the captured imaged would be a simple solution to overcome these issues.

The use of low-cost cloud-based engineering modeling and analysis software programs such as Rhinoceros (Robert McNeel & Associates, North America), Fusion360 (Autodesk, United States), and Solidworks (Dassault Systèmes, France) was also common due to their affordability, usability and applicability. Considering the P&O respondents stated that more training and skills are needed to increase adoption of technology, in the authors' opinion specific P&O software could utilize industry-specific auto-features that perform tasks like extending a footplate on an AFO, or building up over a prominent bone, at the click of a button (41). This would remove the need for advanced CAD skills, making the technology more appealing and user-friendly (42).

Interviewees appreciated the improved efficiencies of digital scanning and software for the making of larger casts like transfemoral sockets or spinal braces. Stating that these types of casts can be modified using preloaded templates in the software in a shorter amount of time than physically removing or adding plaster via traditional methods. This process is more convenient for the patient and faster for the P&O.

The use of 3D printing is often touted as the next big transition for the industry (43). Our results suggest its use is relatively low. 3D printing is similar to traditional production methods, where it is necessary to get throughput, part demand, and production planning right in order to minimize part manufacturing cost (44). 3D printing may change the way many products are developed and produced and herald an era of "personal manufacturing" (45). However, unless a facility is consistently 3D printing prostheses, outsourcing is more economical.

Barriers

The main barriers (cost, lack of skills/experience and effectiveness of the technology) for adopting digital technology were found to be the same issues that prevented greater adoption in facilities already using some form of digital technology.

The initial cost outlay in purchasing scanners, computers, or 3D printers can cause apprehension over the ROI. Interviewees reported that prosthetic and orthotic specific software requires special training, software updates and yearly licensing, often based on the number of modules needed, adding to the cost and deterring more users from greater adoption. The use of 3D printing was found to be limited by the same factors identified in a systematic review of 3D printed sockets (43) including the quality of the part, choice of materials available, and the cost-effectiveness. Literature also points to associated costs of printing ignored when comparing to traditional methods, including; the additional material costs for support structures, machine utilization rates, labor and print preparation, machine maintenance, and the error costs (46).

Even though design and manufacture of highly accurate prostheses and orthoses is possible with the help of digital technology, it was concerning to see that a majority of P&O who already use digital technology did not find the devices had a better fit. This result may be attributed to the need for on-going training and practice to enhance the skills: most P&O were only using the technology for less than five years. Another reason could be the printing quality, which has increased over recent years, but still requires the more expensive printers.

The use of scanning for Ankle Foot Orthoses was high but limitations in contactless scanning were voiced during the interviews as the P&O would often need to position the limb on a clear Perspex plastic scanning platform or the ground before scanning. The scanning of residual limbs for prosthetic sockets was easier, although – as discussed earlier – positioning the scanner still remains troublesome to obtain a full 360-degree image.

Our survey suggests a low use of digital technology for transtibial socket design, with the LLA respondents complaining of poor design, fit, and ease of wearing their prostheses as major factors inhibiting their mobility. This is despite digital technology such as Finite Element Analysis, MRI, computer tomography and photogrammetry showing benefits to improve outcomes by predicting accurate interface pressures through better imaging of the muscles and tissues. It also allows further optimization in the design of comfortable high quality devices (47–51),

Virtual Care

Patient

85% of LLA did not find access to care an issue and preferred to come to the clinic for their follow-ups even during the pandemic. It should be noted all but one patient was from Singapore. Almost half of all P&O respondents outside Singapore found their patients had difficulties coming for their appointment.

Our study found support for virtual assessments, particularly during the COVID-19 pandemic, P&O interviewees noting it was safer for patients and protected them from infection. Questions remain about what types of tasks are suitable for virtual care: all P&O interviewees suggested that triaging a patient or providing education to patients may be most suitable. The NHS program "Attend anywhere" that virtual care is only useful if it results in improved efficiencies, significant time savings, no need to take time off work, no travel costs, and no technical issues (52). Our study also showed the lack of IT skills and connection issues of the patients as concerns, highlighting the need for reliable infrastructure. Although virtual care would be an excellent solution for patients in remote areas and developing countries, this is also where infrastructure is likely to be poor.

The issue of trust was highlighted by both LLA and P&O respondents. In an industry that customizes devices, any change in the care model should reflect a strong need for such change. By merely moving consultations online, we may overcome some barriers found in this study, such as the travel burden, the lack of support to bring patients to their appointments and reduced overall costs. However, there appears a need to develop a rapport between P&O and LLA before the use of virtual care and certain P&O tasks may be difficult to fulfil (see next section). A thoughtful application and design of digital technology is needed, considering all stakeholders involved.

Prosthetist/Orthotist

Concerns over how to conduct shape capturing, residual limb assessment, palpation, and gait analysis may limit the effectiveness and adoption of digital technology, unless it can be developed to overcome these challenges. The lack of touch and feel was found to be a major hurdle to adoption. Virtual assessment tools allow implementing triage at the point of need (53), but advice-only consultations may not prove valuable. LLA suggested they may be unwilling to pay for such services. Both LLA and P&O respondents are used to a consultation/physical-contact combination. The information garnered through physical examinations such as tissue consistency, identifying painful areas or range of movement (ROM), may prove challenging to overcome in a virtual setting.

In rural settings, our survey suggests the use of virtual care may be more suitable. This study found that P&Os would use virtual care where patients have to travel long distances for care or are too sick to come to a facility. However, in such rural locations, there may be other challenges, such as internet connectivity and the IT skills of patients, limiting its applicability. The survey suggested the use of a third, local person to assist with data collection and fitting of devices might help to overcome some limitations. Attitudes towards the use of such person were mixed. They would need sufficient competencies to ensure the appropriateness and quality of care. In the case of pandemic related social distancing laws, the viability of such a third-person service would also be affected. Third person or support staff was used as a means to provide care in rural New South Wales, Australia, in combination with video calling for the provision of AFOs (54). In this study the authors trialed the assessment of the ROM over a video call with a third person performing the task. They found when using the primary care giver as the third person, the measurements of the ROM were less accurate than the P&O. However, when a third person has a healthcare background the results were acceptable, suggesting a possible minimal educational background.

Hospital/Facility

The impetus for change and adoption of digital technology varies based on the funds and infrastructure available. Budgets may be too small to invest in digital technology and on training, government support may be low, and the utilization may be too infrequent to justify the investment. The purchase power to outsource may also present challenges, particularly if it is too low. Digital technology would be more widely adopted if it demonstrated enhanced patient care and outcomes, and lowers overheads of the facility, provided the infrastructure of the country can support the technology.

LIMITATIONS

Our online survey was developed to obtain abroad understanding of digitalization in the P&O industry. Its length may have been the reason why 30 of the 113 respondents answered less than 10%. Furthermore, as this was an online survey, only respondents with internet connection would be able to respond. This may have particularly affected the number of LLA responses; 12 of the 13 LLA respondents were from Singapore, contacted through the amputee support chat group, where internet connection is not an issue The P&O respondents may have been less affected as they could have used the internet connections at work. Another reason for the low LLA response might be that they were contacted indirectly, via their P&O. The LLA in Singapore were contacted directly by the first author.

The responses for Singapore are considered an accurate reflection of the P&O use of digitalization with over 65% of all P&O in Singapore participating. Although the respondents came from a large number of countries their numbers were limited. The study is therefore not representative for current practices outside of Singapore, even though the results are informative.

FUTURE DIRECTIONS

Further investigation should focus on the exact nature of how virtual assessments are and can be conducted, particularly the lack of the element of touch in an assessment by the P&O. There is a clear need for the development of a digitalization framework for the industry to facilitate digital technology implementation in the industry. Understanding how, when, and why to utilize digital technology is vital for successful outcomes to both clinic and patient. Particular attention should be paid to delivery care models that overcome the shortfalls with current technology, including sensory feedback through palpation, low IT awareness, and poor connectivity. The use of distributed care models (DCM) is an alternative to switching all business to digital means. DCM consists of a hybrid of care that includes central-based fabrication, satellite clinics, mobile clinics, and digital technology.

Using a third person trained to digitalize the anatomy of a limb, should be considered to enhance the outreach where prevailing laws allow.

CONCLUSION

The utilization of digitalization during a pandemic such as COVID-19 can mitigate the concerns regarding on-going patient care and safety for both patient and P&O. The use of scanning and virtual assessments provides avenues for the continuum of care for the patient. However, essential characteristics of care, such as palpation and sensory feedback, have yet to be overcome. Right citing the patient with the appropriate technology and answering what needs the technology is addressing is essential and may encourage adoption among the industry. Education and training should be provided to centers and individuals to enhance confidence levels and awareness of digital care benefits. Ensuring the staff has a high technology readiness level is critical. The delivery care model should be evaluated to provide sufficient outreach and an optimal level of digital technology.

Technology advancements such as virtual platforms, digitalization methods, and improved connectivity, will change the future of healthcare. Digital technology is transforming healthcare into a new normal. This transformation is expected to continue in the years to come. The prosthetic and orthotic industry should keep an open mind and move towards creating the required infrastructure to support this digital transformation or risk being left behind.

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