ISSN: 2634 - 8853

Journal of Engineering and Applied Sciences Technology

SCIENTIFIC Research and Community

Research Article

Open Access

Implementation of Additive Manufacturing Workflows into the Prosthetic & Orthotic Industry: Case Study

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ABSTRACT

The prosthetic and orthotic industry is evolving to include innovative technologies as solutions to material and labour usage, promoting more sustainable and cleanly practises for both staff and patients. 3D printing, scanning and software have revolutionised the workflows of clinicians, technicians and administrative staff.

To determine the reliability and repeatability of additive manufacturing (AM) workflows in a P&O company, observation and interview analyses were undertaken within an established prosthetic and orthotic company. The collection of data from these opportunities offered valuable insight into workflow sessions, employee feedback and predetermined themes regarding both traditional and AM processes for the production of Transtibial prosthetic sockets.

Findings revealed the reduction in workflow sessions, technician resource and storage requirements when working through AM processes, although there is a lack of opportunity and resource for clinicians and technicians to learn how to use these digitalised processes. Although both traditional and 3D printed sockets receive similar feedback from patients regarding comfort and fit, discrepancies in socket weight were noted. A further understanding on the culture and adoption barriers of AM processes should be investigated for clinicians, technicians and administrative staff across a larger sample size.

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Received: April 05, 2024; **Accepted:** April 08, 2024; **Published:** April 18, 2024

Keywords: Prosthesis, Additive Manufacturing, 3D Scanning, Socket, Clinician, Technician

Introduction

The developments within the prosthetic and orthotic (P&O) industry have seen the end product, manufacturing process and possibilities of performance constantly evolving. For decades the clinical and manufacturing processes and procedures have remained relatively consistent to methodologies and approaches with high cost, waste and physical data volumes [1]. Current materials involved with the end product are reliable, consistent and measurable through approved material standards and product requirements. Materials involved with the process and manufacturing, however, had not developed from plaster moulds, liquid resins, thermoplastics, metals, leather and carbon fibre, up until the possibilities of additive manufacturing (AM) were explored [1]. Waste material from prosthetic and orthotic production is high in volume, cost and time consumption with traditional approaches. All physical data imperative for the production of a prosthesis (such as the plaster moulds of the client) must be retained for a period, resulting in the need for large storage areas and physical records [2]. The traditional process of obtaining data from a client is somewhat invasive, with plaster moulds physically captured by qualified clinicians directly from the patient's limb. In a company setting with multiple patients, the manufacturing process can take from days up to several weeks including steps from fitting the socket, assembling componentry (such as the foot and other components) and refitting to ensure correct alignment and comfort [2]. These adjustments, assemblies and manufacturing processes are all unique and vary per person, yet each must meet certain medical regulations per product.

The introduction of new technology has the ability to impact the design methodology of prostheses and orthoses for the better, however it has yet to be utilised to its full potential [3]. AM, 3D scanning, software modelling and haptic technologies are just a few examples of the future for prostheses and orthoses [2]. The introduction of these technologies will form new design and production workflows, processes and clear the path for the introduction of new products that can be more functionally pleasing and sustainable through human-centred and emotional design practises [4]. The digitalisation of workflows in the prosthetic and orthotic industry marks the beginning of a new era, where there is potential for the end product to include more emotional design principles to be adopted far easier into the culture and society that surrounds it.

Context

A prosthesis acts as a replacement for a lost or missing limb or body part. These products can range from purely cosmetic, such as a prosthetic nose or eye, to radically functional. Functional prosthetics most commonly appear for upper and lower body limbs. Anatomy such as fingers, hands, wrists, elbows, knees and feet allow the body to move in complex motions, however it is possible to live without these. This is why prosthetic limbs range from basic tools with little movement, to complex technological parts which can rotate, stabilize, shift and compress – controlled by electronic pulses in the body, and prostheses with integrated microprocessors.

A qualified prosthetist/orthotist (clinician) in the P&O field is obligated to determine the needs of each patient and record significant landmarks, measurements, pain points and other notes regarding the patient needs prior to determining what device may be suitable [5]. The clinician must also capture a plaster cast of the patient limb in order to fabricate a socket for the patient. Before handing over the plaster mould to a technician for socket fabrication, a clinician will carry out what is known as the rectification process, where they will shape the plaster mould manually to apply sufficient loading and offloading to the socket walls, depending on the patient needs. This is a learned skill that is gained by a clinician through their qualification [6].

The duty of a P&O technician is to fabricate a physical medical device using instructions and notes communicated by a clinician regarding componentry, material and other requests such as aesthetic additions. The technician does not hold the same qualification as a clinician however apprenticeships in the field are common to learn practices through experience [5].

Prosthetic and orthotic manufacturing is on the brink of digitalization across the globe, with the positive effects such as sustainability and time efficiency, that additive manufacturing has had on the industry [7]. Prosthetic and orthotic design is a state of the art example of positive convergence between a variety of industries and technologies, to improve the quality of life for the end user, develop and progress new and innovative technological solutions and evolve our society from a global cultural perspective. As an engineer in the 21st century, the approaches necessary to take for the current engineering trends are those based around sustainability, convergence, and innovation [8].

With traditional methodologies still being at the forefront of education and day-to-day workflows, and in the presence of busy clinical caseloads, it is difficult for clinicians and technicians to value the benefits of 3D printing in their roles [5].

Hypotheses and Objectives

This paper aims to provide evidence of a reliable and repeatable AM workflow for the creation of load bearing below knee (transtibial) prosthetic sockets in Ireland.

With additive manufacturing working at current for the production of prosthetic and orthotic devices, it is important to understand how the production workflows will compare to that of traditional workflows.

Working in collaboration with Atlantic Prosthetic & Orthotic Services Ltd (APOS), this paper will recognise the current standings, user needs and acceptance barriers for the adoption of AM workflows for P&O clinicians and technicians.

The proposed hypotheses (H) are as follows:

- **H1:** Is it possible to implement a reliable and repeatable digitalised workflow, that includes 3D scanning, modelling, and printing for load bearing transtibial prostheses, within an established P&O company?
- **H2:** Will this new workflow be adopted by P&O clinicians and technicians?

Proposed Methodology

To address H1, data has been collected through observation of the AM process and through 1:1 interviews with staff including both clinicians and technicians within an Irish SME (APOS) specialising in the manufacture of prosthetic limbs. While observing clinicians and technicians manufacture load bearing transtibial sockets using AM processes, notes were recorded on the following:

1. Time taken to complete each session as observed:
   - Initial consultation.
   - Patient scanning.
   - Rectification.
   - Fabrication.
   - Printing.
   - Fitting of the device.
2. Responsible departments per session.
3. Issues arising during each session.
4. Comments made by the clinician/technician.
5. Materials used.

The scanning technology used by the company is run through mobile phone cameras in a clinical setting. Where scanning is not possible, a cast can be taken and filled as per traditional method and then scanned in a workshop setting. Rectification and fabrication is completed through licenced software tailored to the needs of P&O users in an office space. In some cases, a cast can be rectified manually and then scanned in a workshop setting. The sockets are printed with selective laser sintering (SLS) technology externally.

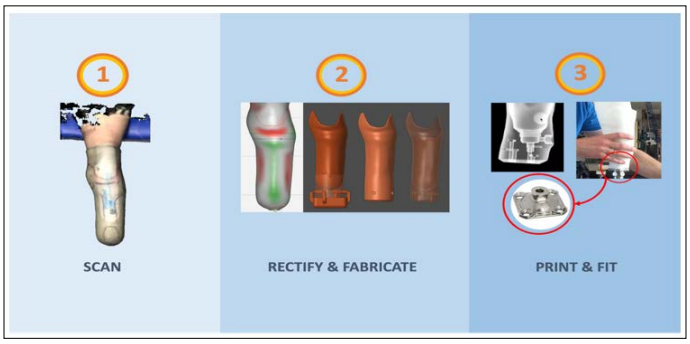

Figure 1: Visual Representation of 3D Scanning (1), Rectification & Fabrication (2), and Print & Fit (3) Steps Involved in the Production of 3D Printed Transtibial Sockets

In order to compare AM workflows to a traditional approach, the same observations were recorded for the traditional production of a load bearing transtibial socket. The following questions must be addressed when comparing traditional to additive manufacturing workflows for prosthetic devices:

- What are the effects of time and labour on the transition of workflows from traditional to AM prosthetic device production?
- How does the AM workflow compare to the traditional for the patient experience?

- How would moving to an AM workflow impact the outputs of a company/service provider?

To address H2, six 1:1 interviews were recorded with APOS employees, with the participation of three clinicians and three technicians. An even amount of male and female participants were involved. All participants were of Irish and Scottish ethnicity. The range of experience for both clinicians and technicians in the P&O field was between 4-24 years. Each interview lasted between 15-20 minutes, where questions were structured as open ended and discussed the following themes:

- Traditional processes.
- Innovative / AM processes.
- User focus.
- Product focus.
- AM adoption barriers.
- AM workflow ideation / solutions.
- Employee personal experience in the industry.

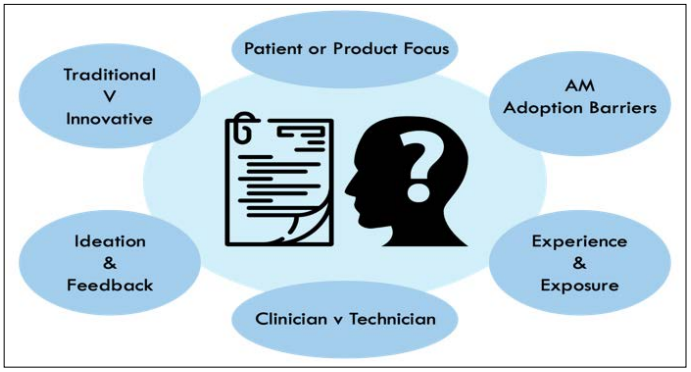

Figure 2: Infographic Outlining Key Themes and Comparatives aimed to be discussed for 1:1 interviews with P&O Clinicians and Technicians

Results

After observing the traditional manufacturing workflow for a load-bearing transtibial socket, 11 sessions were identified from the moment of appointment booking by a patient, to the fitting and release of the final product. It is important to note that these results are based on correct measurements with no product faults identified at either the check socket or final fitting stages. Figure 3 identifies all steps involved with socket production, with each taking one session to complete. A session is not indicative of a specific time period. Depending on demand in the company, there may be multiple sessions completed in one day, or several days

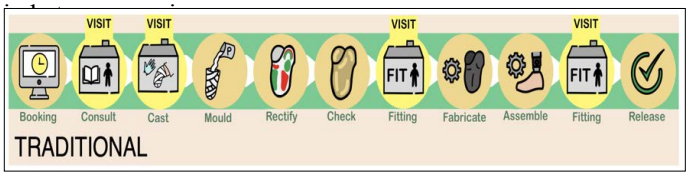

Figure 3: Breakdown of the Steps Involved in the Production of traditionally Manufactured Transtibial Prostheses

To further understand the manufacturing workflow, it was also decided to note where each session was taking place, and what departments or employees were responsible for their completion. Because of this it was noted to include the responsibilities and actions of the administrative staff. Their role was deemed crucial in the delivery of a final product to the patient.

Three key areas were identified as the clinic, workshop and office/storage spaces for the successful manufacturing of a transtibial socket. The resource of clinicians, technicians and administration is distributed for traditional manufacturing as shown in Table 1.

Table 1: Employee and Area Resource for Traditional Manufacturing Processes Involved in the Production of Transtibial Prostheses.

Clinic	Workshop	Office/Storage
Consultation	Plaster mould	Initial booking
Plaster Cast	Rectification	Rectified socket
Check fitting	Check socket	Socket storage
Final fitting	Fabrication	Cast storage
	Assembly	Paper trail
		Report writing

Clinician
Technician
Admin

The digitalised manufacturing workflow involving AM processes was then observed and recorded and a total of 9 sessions were identified from initial booking to product release. Again, this workflow describes successful fitting in both check socket and final fitting sessions. Figure 4 showcases the steps for the AM process in APOS. Table 2 identifies the changes in resources specific to the clinic, workshop and office/storage spaces for clinicians, technicians and admin.

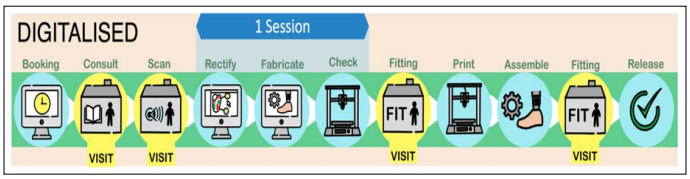

Figure 4: Breakdown of the Steps Involved in the Production of Traditionally Manufactured Transtibial Prostheses

Table 2: Employee and Area Resource for Digitalised Manufacturing Processes Involved in the Production of Transtibial Prostheses

Clinic	Workshop	Office/Storage
Consultation	Assembly	Initial booking
Scan		Rectification
Check fitting		File storage
Final fitting		Fabrication
		Printing
		Report writing
		Paper trail

Clinician
Technician
Admin

The results of all six interviews were recorded and translated to the following chart shown in Figure 5, based on the predetermined themes discussed.

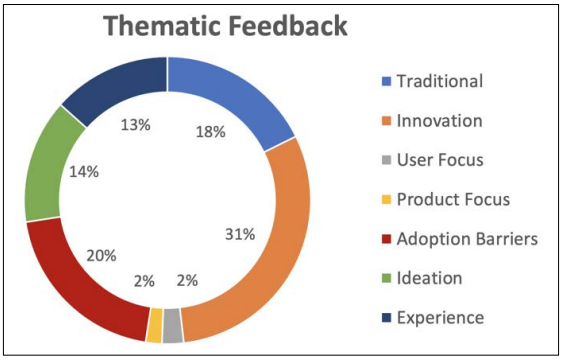

Figure 5: Results of 1:1 Interviews with P&O Clinicians and Technicians According to Predetermined Themes

Discussion

H1: AM Workflow Implementation

Compared to a traditional linear outlined workflow, there is a decrease of overall sessions to completion when converting to additive manufacturing. Where the mould casting, rectification and fabrication of a check socket would traditionally take three individual sessions to complete by both clinician and technician in the workshop space, the AM workflow simplifies this to one online session by the clinician. This change also decreases the labour and responsibility of the technician if printing is outsourced by the company.

There is minimal material waste involved with socket printing in AM processes, compared to traditional waste volumes when fabricating a socket. It is also apparent that when working though AM processes, digital storage reduces office space for check sockets compared to traditional manufacturing requirements, resulting in less physical space being occupied for AM if printing is outsourced.

AM workflows that include scanning not only reduces material consumption in clinical appointments, but also reduces physical contact during form capture for the residual limb, promoting cleanly practices and a more satisfactory experience for the patient.

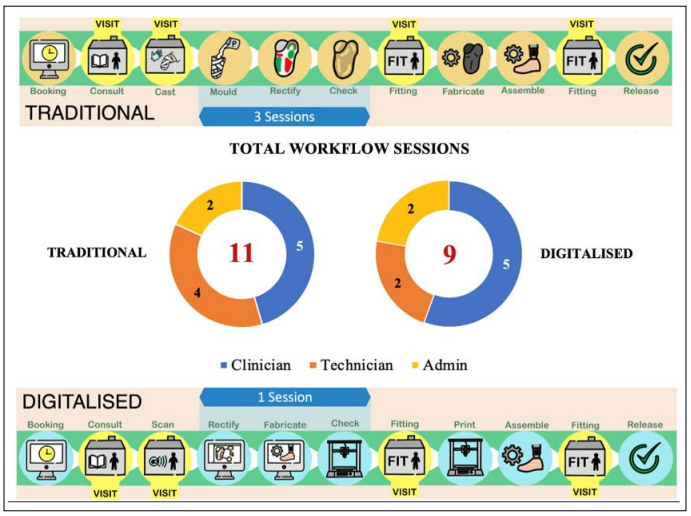

Figure 6: Comparing the Traditional Manufacturing Workflow Against the AM Workflow

H2: Clinician & Technician Adoption

The themes identified for these interviews proved sufficient in gaining an insight into the culture and current standings of both clinicians and technicians in the P&O industry. By further breaking down the data collected, it is clear that there was an even emphasis on all themes when comparing clinician feedback with technician. Administrative staff were not included in the planning of interviews for this study, as it was following the analysis of H1 results that administrative staff were identified as key participants in the production of Transtibial sockets.

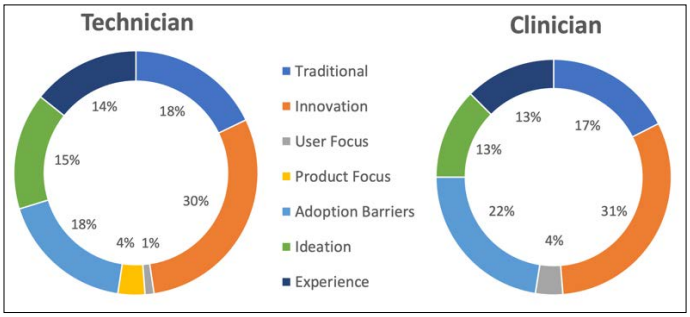

Figure 7: Technician and Clinician Feedback Recorded from 1:1 Interviews

By looking at slight discrepancies, it can be noted that a higher level of adoption barriers were identified by clinicians over technicians, despite there being a higher experience level among technicians. This may be due to higher rates of exposure to AM technologies with clinicians compared to technicians. Due to the miniscule sample size for these interviews, these discrepancies are not indicative of the P&O industry as a whole, but only within a singular company.

Through discussion within clinician and technician interviews, important feedback was recorded for each theme as follows:

Traditional Processes

Although AM can save on resources, traditional manufacturing and approaches cannot be replaced by AM for more complex P&O cases. Not all P&O componentry can be incorporated or adapted to combine with 3D printed sockets. Technical skill will still be required for finishing and assembly of componentry, as well as for socket/prosthetic limb adaptions.

Innovative / AM Processes

AM workflows reduce rectification & fabrication times, freeing some time for clinicians and technicians to work on more complex cases that must be made using traditional methods. Initially, there is increased time required in order to gain fluency with AM processes.

User Focus

Not all forms can be captured efficiently with 3D scanning methodologies available to APOS, resulting in the need to continue using traditional approaches for more complex cases.

Product Focus

Patients have stated that 3D printed sockets have the same fit and comfort of sockets traditionally made, traced back to material feel. However, clinician experience and feedback indicates that socket weight can sometimes be significantly higher when 3D printed (with SLS printing technology in APOS).

AM Adoption Barriers

The AM process is efficient and valuable for those who understand the technology; There is a need for time and resource to educate clinicians and technicians in the use of digitalised workflows.

AM Workflow Ideation / Solutions

There is scope in AM processes to enhance patient adoption through customisable device options that are not as readily available in traditional approaches, such as icon embossments and text additions, including patient reference numbers and dates of manufacture.

Employee Personal Experience in the Industry

As with traditional approaches, a clear communication path is necessary for digitalised processes in terms of file, material and device tracking and storage, department responsibilities, handover stages and quality control, in order to effectively produce consistent, reliable and safe devices. When storing digital files, patient confidentiality and data security must be acknowledged and addressed to ensure correct measurements are taken against data breaches.

Our current world suggests a development in technologies that may suit better to new industry recruits, however may prove to be challenging to those who are not familiar or comfortable with digital working. It is suggested that an understanding of the culture of P&O companies be captured, to evaluate the true potential of additive manufacturing in the prosthetic and orthotic space.

Conclusions & Considerations

A reliable and repeatable workflow for AM processes was identified within an Irish SME company specialising in P&O, where overall manufacturing sessions decreased and technician resource was reduced. Administrative staff have been identified as key employees for the control of communications, file storage, product tracing and workflow efficiency with digitalised processes. AM has the capability to reduce resource, material and storage needs, however data security must be controlled to ensure patient confidentiality.

Digitalisation in comparison to traditional prosthetic production naturally comes with an entirely new skillset to the clinician/ technician. Because traditional manufacturing processes have been practised for decades in P&O industries, this change of workflow to an online and less physical state may or may not be easily adopted into the culture of current P&O companies. Our current world suggests a development in technologies that may suit better to new recruits into the industry however may prove to be challenging to those who are not familiar or comfortable with digital working.

It is suggested that an understanding of the culture of more P&O employees and industry members be captured in order to evaluate the true potential of additive manufacturing in the prosthetic and orthotic space. It should be considered to include administrative staff in future data collection when understanding P&O culture and AM adoption barriers into this field.

Funding & Acknowledgements

This publication has emanated from research conducted with the financial support of Science Foundation Ireland and Atlantic Prosthetic & Orthotic Solutions Ltd., under grant number PF00090. For the purposes of open access, the author has applied a CC BY public copyright license to any Author Accepted Manuscript version arising from this submission.

Thank you to Coogan's & Dagge's for the use of facilities.

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