Systematic Review

Prosthetics and Orthotics International

OPEN

A scoping review of digital fabrication techniques applied to prosthetics and orthotics: Part 1 of 2—Prosthetics

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Abstract

Background: Traditionally, the manufacture of prostheses is time-consuming and labor-intensive. One possible route to improving access and quality of these devices is the digitalizing of the fabrication process, which may reduce the burden of manual labor and bring the potential for automation that could help unblock access to assistive technologies globally.

Objectives: To identify where there are gaps in the literature that are creating barriers to decision-making on either appropriate uptake by clinical teams or on the needed next steps in research that mean these technologies can continue on a pathway to maturity.

Study design: Scoping literature review.

Methods: A comprehensive search was completed in the following databases: Allied and Complementary Medicine Database, MEDLINE, Embase, Global Health Archive, CINAHL Plus, Cochrane Library, Web of Science, Association for Computing Machinery, Institute of Electrical and Electronics Engineers, and Engineering Village, resulting in 3487 articles to be screened.

Results: After screening, 130 lower limb prosthetic articles and 117 upper limb prosthetic articles were included in this review. Multiple limitations in the literature were identified, particularly a lack of long-term, larger-scale studies; research into the training requirements for these technologies and the necessary rectification processes; and a high range of variance of production workflows and materials which makes drawing conclusions difficult.

Conclusions: These limitations create a barrier to adequate evidence-based decision-making for clinicians, technology developers, and wider policymakers. Increased collaboration between academia, industry, and clinical teams across more of the pathway to market for new technologies could be a route to addressing these gaps.

Keywords

prosthetics, digital fabrication, CADCAM, additive manufacture

Date received: 8 February 2023; accepted 1 February 2024.

Introduction

Approximately 0.5% of any population globally requires prostheses, orthoses, and rehabilitation treatment. This estimate corresponds to 35–40 million people, and the need is expected to double by 2050.[1] The World Health Organization estimates that although in high-income countries a median of 64% people who need assistive products have access to them, in medium-income and low-income countries, the rates of access are much lower at 33% and 11%, respectively.[2] One possible route to improving access and quality of these devices is digital technologies, with the number of commercial digital fabrication offerings multiplying every year. In this study, the first of 2 papers, a scoping review of digital technologies is presented as applied to prosthetic fabrication. The aim of this study was to understand whether the research literature has the necessary forms of evidence to enable evidence-based decisions on either appropriate clinical uptake or further development. Where this is not the case, the aim was to identify what these limitations of study design constitute to guide future research planning.

Traditionally, the manufacture of prostheses involves several steps and processes. A patient typically visits the facility so that a prosthetist can perform a clinical assessment, collect body measurements (e.g., residual limb dimensions) that are taken manually, and then make a negative cast using plaster bandages to

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Associate Editor: Adam Arabian

DOI: 10.1097/PXR.0000000000000351

capture the stump or limb shape. From the negative model, a positive model is made, and the prosthetist modifies the shape according to the patient's needs. The prosthetic socket is then manufactured by either the prosthetist or the technician using thermoforming and/or thermosetting plastics, fiberglass, and carbon fiber. Given the complexity, this manufacturing process is labor intensive for prosthetists and technicians, with some devices taking many days to complete. This presents a major barrier to increasing access to devices. This traditional workflow is captured in Figure 1, which also captures digitally enhanced workflows. A key potential benefit to digitalizing the fabrication process may be the reduction in manual labor, and the potential for automation that could help unblock access to assistive technologies globally.

It is important to note that it is not just through digital methods that promising solutions to these barriers are arising. Direct socket manufacturing, where fitting and fabrication of the socket occurs all in one go directly on the residual limb, offers significantly lower fit time. Depending on the particular direct socket manufacturing approach, the reduced equipment needs could also make mobile fitting services for harder to reach users more possible.[3-5]

In the 1980s, digital technologies were introduced for manufacturing prostheses, with the use of computer-aided design (CAD)/computer-aided manufacturing (CAM) technologies.[6,7] With this digital method, traditional hand-casting of the residual limb is replaced by scanning it. Manufacturing and rectification of the positive model is replaced by (1) the use of software to rectify the digital model and (2) computer numerical controlled carving to manufacture the positive model, on which the prosthetic socket is manufactured.

During recent years there has been an increase in the number of research activities from the prosthetic sector to use additive manufacture (AM) to produce prostheses. CADCAM tools already enable professionals to minimize hand fabrication of devices, but AM can extend the reach of digital fabrication up to the definitive prosthetic socket. AM-based fabrication comprises several methods, generally based on (1) digital scanning of the residual limb, (2) CAD-based modeling and rectification, and (3) additive manufacture of the socket directly, followed by various postprocessing. A plethora of different technologies are available for each of these stages, enabling various service delivery models applicable to different contexts. This literature review covers all combinations of the digital fabrication processes of CADCAM and AM, along with traditional processes when these are combined with digital elements in some manner. Recent good reviews cover a subsection or similar aspects of the topic of interest. Notably, Savsani et al[8] reviewed AM for prostheses, examining in detail the types of AM processes and materials used and the challenges and opportunities that these studies suggest, and Ribeiro et al[9] carried out a comprehensive data extraction including the sample sizes and study design of included articles, discussing the limited available data. However, we see a lack throughout the available reviews of a quantitative breakdown of the maturity, scale, and strength of evidence being gathered on these technologies and recognize the need for this to make clear the gaps in the available research literature.

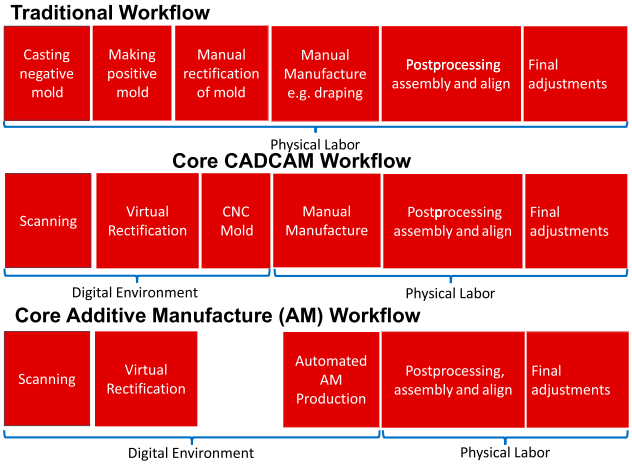


Figure 1. Traditional and core CADCAM and AM workflows for device fabrication.

A consortium was, therefore, assembled incorporating the International Society of Prosthetics ad Orthotics (ISPO), representatives, industry, and academic partners to gather evidence on digital fabrication approaches for prostheses and orthoses as part of a process of consensus building and identify whether the necessary forms of evidence for these technologies are being achieved in the literature. Particularly, the aim is to identify where there are gaps in the literature that are creating barriers to decision-making on either appropriate uptake by clinical teams or on the needed next steps in research that mean these technologies can continue on a pathway to maturity. This scoping review aims to fulfill this and is broken into 2 parts—part 1: prostheses and part 2: orthoses. Therefore, the research questions for this review are the following:

1. In terms of study formulation, what are the forms of evidence that the current research literature provides to the prosthetics community?
2. What are the gaps in the available research that are creating a barrier to the progression of digital fabrication methods of prosthetic devices?

Methods

Studies were included based on the inclusion and exclusion criteria detailed in Figure 2, which were devised to identify appropriate original research done on the digital fabrication of external prosthetic devices.

Eligibility criteria

Figure 2 shows the eligibility criteria for this study.

Information sources

Articles were searched in Allied and Complementary Medicine Database, MEDLINE, Embase, Global Health Archive, CINAHL Plus, Cochrane Library, Web of Science, Association for Computing Machinery, Institute of Electrical and Electronics Engineers Explore, and Engineering Village.

Search strategy

The search strings were designed to identify all articles concerning digital fabrication of external prosthetic and orthotic devices. The strings and protocols were developed iteratively with reference to a known set of expected articles and refined with Boolean operators

Inclusion Criteria	Exclusion Criteria
Cohort studies, controlled trials, case reports, field studies, prototype developments and other original research published in a peer-reviewed journal or conference abstract,	Systematic, scoping or other forms of literature reviews
Concerns an external prosthetic device	Internal prostheses (implants) or joint replacement. Dental, facial, teeth prostheses
Concerns components including all parts of any existing or proposed prosthesis, including sensors and actuators aimed at advanced powered devices	Cosmetic periphery devices such as device covers (where their purpose is purely aesthetic)
Research concerns either fully digital fabrication workflows or any combination of digital and traditional processes or any individual digital aspect of such workflows in isolation (ie. scanning, digital processing or physical fabrication).	Article only eludes to possible use in prosthetics and orthotics, rather than having an actual specific P&O case study
Fully or partial digital manufacture is intended to be the final production method, not stated as only for prototyping	Not published in English, or no English translation available, or not available through authors' institutional access to databases
	Studies on devices designed for non-human users, ie. other animals

Figure 2. Eligibility criteria.

and wild cards to limit the number of excluded articles, particularly those concerning internal and dental prostheses. The search terms was therefore of the format (keywords related to prostheses) AND (keywords related to digital fabrication) NOT (excluded prosthesis types, in particular dental)—an example string is given in Supplemental Digital Content 1, http://links.lww.com/POI/A232. Searches were conducted on all timestamps up to and including July 28, 2021. Manual reference lists and Google Scholar citation searches were completed to identify additional articles.

Selection process

Articles were imported into the Endnote citation software,[10] and duplicate articles were deleted. After deduplication using the Bramer method,[11] the titles and abstracts of the remaining articles were imported into Rayyan.[12] A broad screening review was conducted to include or exclude each article based on the title and abstract using the aforementioned criteria, with at least 2 investigators screening each article. All investigators were blind to other's decisions until after all decisions had been completed.

At least 2 investigators then reviewed each included full text and classified it within a device category to facilitate analysis. During review and appraisal, conflicting decisions were discussed by the 2 deciding investigators, with a third investigator breaking ties if a decision could not be reached. Finally, an additional request for missing articles to be identified was made on the November 1, 2021, at the ISPO World Congress, where the database list was made public, and people were invited to point out articles that should have been included. These articles were then screened following the original procedure outlined above and added to the set.

Data collection process

A subset of articles was used to develop the method and guidelines on data field extraction, before full data set extraction and tabulation in Excel.

Data items

This review examines various study features in the Results section. Below is a brief description of these features and the data items extracted to do this.

Distribution of papers by device type

1. The device-body position or device type the study investigates.

Digital manufacturing process

1. The specific digital manufacturing process employed in the article. Where no manufacturing took place, the

TRL1	**Basic Research** Basic Principles observed and reported.	**Research Concept**
TRL2	**Technology Formulation** Concept and application have been formulated.	
TRL3	**Applied Research** First laboratory tests completed; proof of concept.	**Proof of Concept**
TRL4	**Small-Scale Prototype** Prototype built in a laboratory environment.	
TRL5	**Large-Scale Prototype** Prototype tested in intended environment.	**Minimal Viable Product (MVP)**
TRL6	**Prototype System** Prototype tested in intended environment close to expected performance.	
TRL7	**Demonstration System** System operating in operational environment at pre-commercial scale	
TRL8	**First Commercial System** Manufacturing issues solved.	**Commercial Product**
TRL9	**Fully Commercial Application** Technology available for consumers.	

Figure 3. National Aeronautics and Space Administration Technology Readiness Level (NASA TRL) scale adapted to assistive technology, data taken from WIPO (2021).[13]

premanufacturing digital process such as "scanning only" or "modeling only" was indicated.

Primary process focus + digital workflow

1. Primary process focus refers to whether there is a clear primary focus of the study, on for example modeling, although all parts of the workflow were completed to achieve this.
2. Digital workflow describes the full set of stages that took place to fabricate a device. A key describing our breakdown of digital workflows can be found in Supplemental Digital Content 1, http://links.lww.com/POI/A232.

Technology readiness level

1. One of the tools we have used to analyze the available literature is the National Aeronautics and Space Administration Technology Readiness Level (NASA TRL) scale adapted to assistive technology which can be seen in Figure 3[13] to rate the maturity of technologies being presented.

Sample size

1. The number of participants involved in the study.

Qualitative methods

1. Whether qualitative evaluation was undertaken at all, whether data were collected for more or less than a week, and the nature of the evaluation in the following categories: "off patient," that is, discussion of the produced device/prototype without patient involvement or "on patient"—evaluation/feedback or observational analysis of a fitted patient.

Quantitative methods

1. Whether quantitative evaluation was undertaken at all, whether data were collected for more or less than a week post fitting, and the nature of the evaluation in the following categories: "off patient mechanical"—mechanical testing of the device without patient involvement e.g., International Organisation for Standardisation (ISO) equivalent, structural/material testing; "off patient computational modelling" e.g., finite element analysis; "on patient" e.g., quantitative gait analysis and instrumented data collection of fitted patient.

Materials used

1. The materials used for the digitally fabricated components in the study. To note, if the component is made indirectly, for example, a digitally created mold to cast a component in another material, this refers to the final component's material only.

Chronology of submissions

1. The date of when the article was published.

Results

Study selection

Figure 4 shows a Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) breakdown of the articles selected and included or excluded for final data collection. Supplemental Digital Content 1, http://links.lww.com/POI/A232 provides a table of all articles discussed specifically in this study.

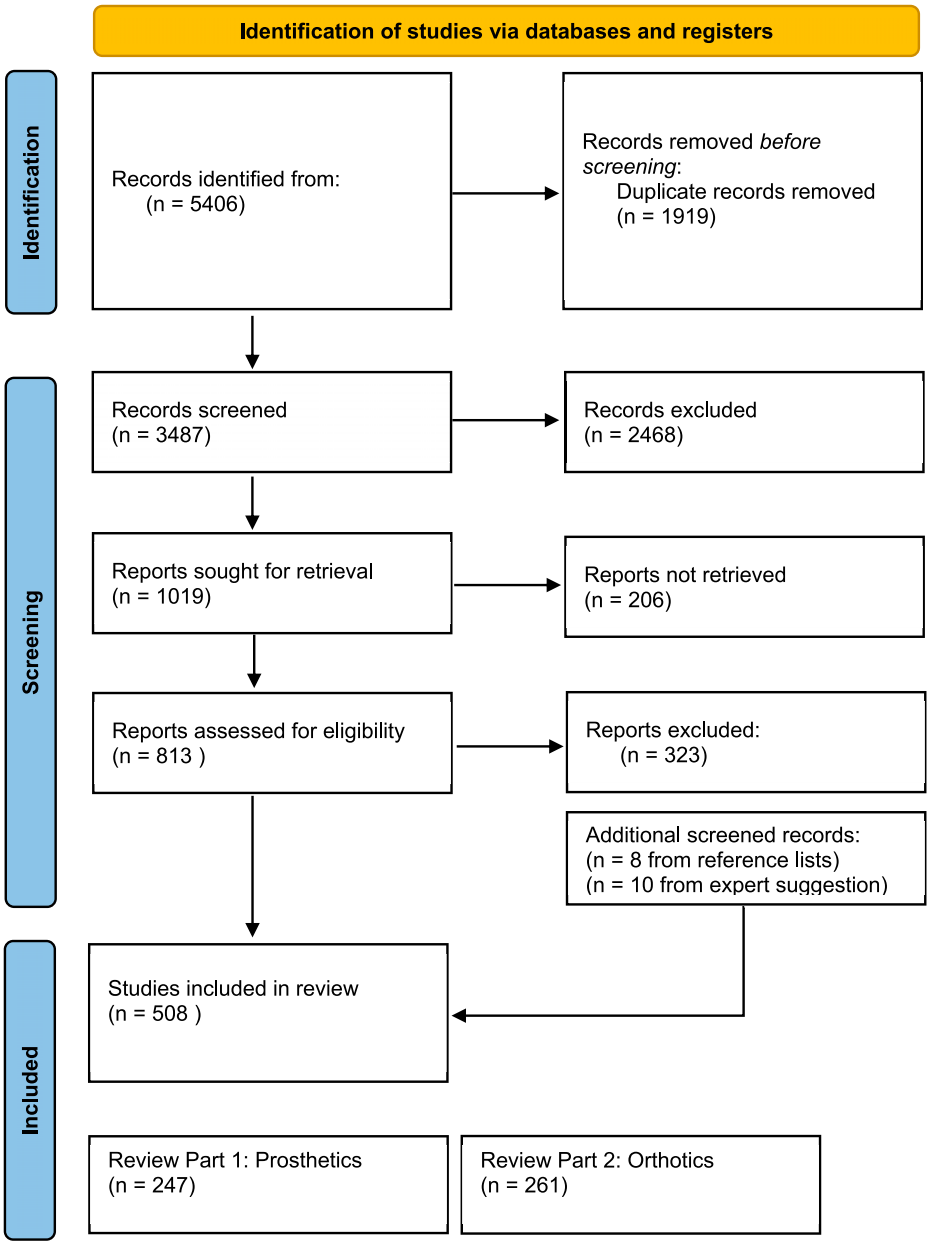


Figure 4. Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) diagram of search protocol.

The articles were split into device categories with 130 lower limb prosthetic (LLP) and 117 upper limb prosthetic (ULP) screened articles included in this part of the review.

Distribution of papers by device type

Figure 5 shows the distribution of LLP articles, unsurprisingly, most articles concerned transtibial (TT) sockets. One of the clear digital fabrication (DF) advantages centers on economical customized one-off devices, and sockets represent the most common instance of this type. The fact that TT amputations are more common than transfemoral[14] most likely leads to the dominance of TT sockets in the literature.

Most of these socket articles focus on design and manufacturing processes, rather than radically new final product outputs. However, digital techniques could lead to exciting new socket designs and functionality in the coming years.[15,16] A notable number of articles looked at novel prosthetic foot designs, particularly utilizing and optimizing designs for single piece construction through digital fabrication.[17-19] AM bespoke socket inserts are notably included in the literature, potentially providing material efficient fit adjustment for end-users.[20]

In Figure 6, we can see that the ULP articles found were heavily dominated by hands and fingers, with few studies on DF upper limb sockets. AM has allowed the design and prototyping of highly complex mechanical products, such as hands, to be achieved with limited manufacturing resources, in many cases a single filament deposition modelling (FDM) printer and minimal extra tooling. For fingers particularly, AM opens up the avenue of direct production of cosmetic replicas at a scale very

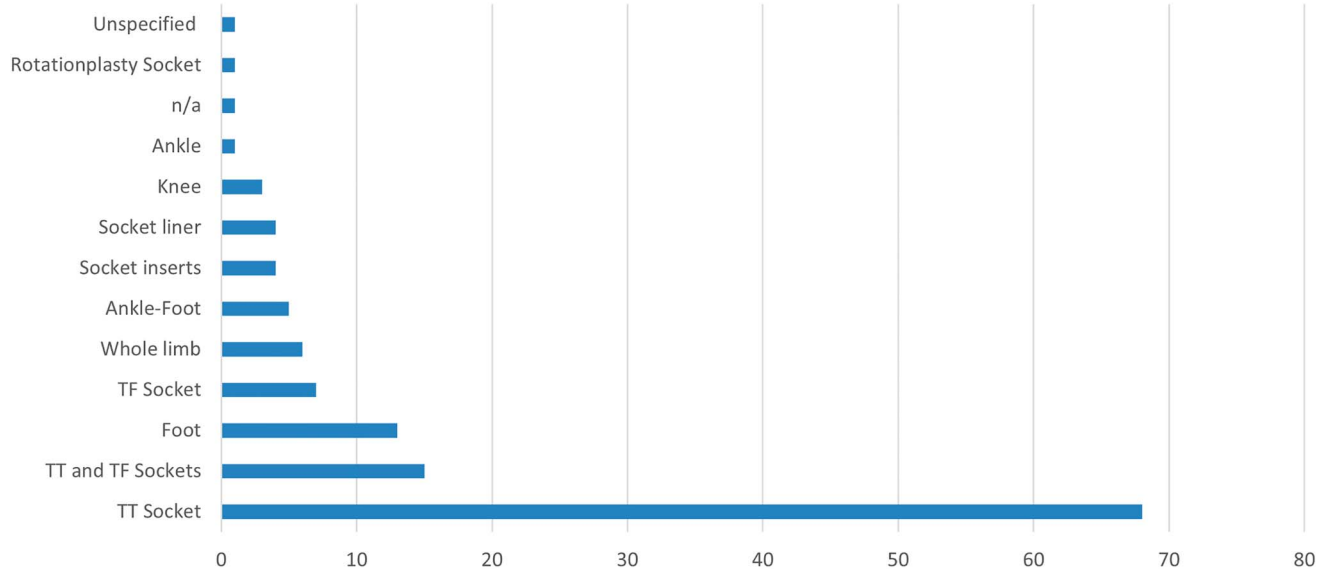


Figure 5. Chart showing the distribution of LLP articles by device/component types.

suited to the build volume and capabilities of current low-mid range 3D printers.

Major digital manufacturing process

Figure 7 shows that the literature is dominated by FDM, particularly in ULP, but also for LLP to a lesser extent, with very few articles using powder or resin based AM techniques. FDM is heavily used for prototyping, for which it is well suited. A common suggestion by authors is to carry FDM manufacturing forward to mature product delivery, particularly for low-cost devices or low-resourced contexts; however, there was very little scaled implementation of this suggestion. This said, some of the very few articles with larger-scale trials were in the FDM components domain for low-resource settings. Although CADCAM has been around for nearly 40 years, only 25 articles were included that use the CADCAM technique.

Primary process focus + digital workflows

The intended primary process focus of the articles, for example modelling, were categorized, while cognizant that generally all elements of a fabrication workflow are at least summarized in most articles because they are necessary to produce a testable device. In Figure 8, a large portion of articles were designated as design testing (i.e., research that is focused on the physical design of a product, e.g., a prosthetic finger) or complex device prototyping (i.e., prototypes comprising construction of many multiple parts, e.g., AM produced hands). For ULP, complex device prototyping of hands contribute most to the literature. For LLP and overall, articles that describe a full workflow were the largest portion of the literature, that is, no single process dominated the narrative; rather, the full workflow approach is the result. The range of these workflows is large, with varying incorporation of manual and traditional methods alongside digital processes.

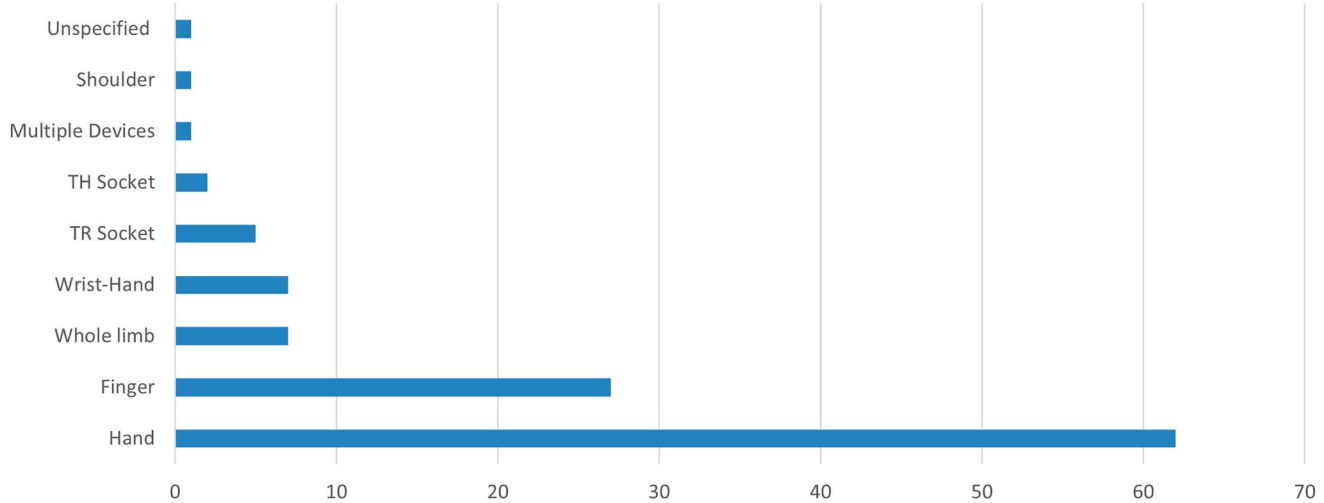


Figure 6. Chart showing the distribution of ULP articles by device/component types.

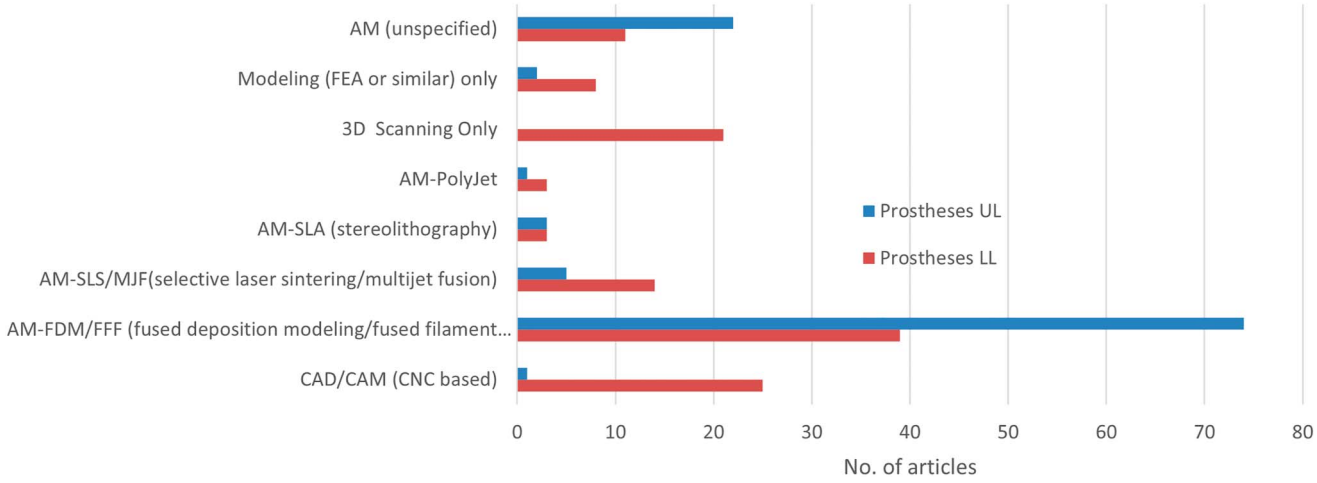


Figure 7. Digital manufacturing processes employed by LLP and ULP articles.

Figure 1 represents the processes that are commonly viewed as the core full workflows of AM and CADCAM. It can be seen that differing levels of digital and physical labor were used.

Both within core flows and more broadly across the literature, a wide range of combinations of different processes are used at each distinct production phase. To understand the prevalence of different approaches, workflows within the literature were mapped, with 26 different process groupings defined for prosthetics (Figure 9).

A large portion of articles were CADAM (designed without anatomic measurements in CAD and simply AM produced), which for proof-of-concept papers with no user testing is often adequate. It is noted that many articles are classified as AnatCADAM (anatomic measurement usually 3D scanning, rectified in CAD, and AM produced), but with no documentation of critical postprocessing or device adjustments that are typically done. Anat/CAD/AM/P articles have some representation in the data, but

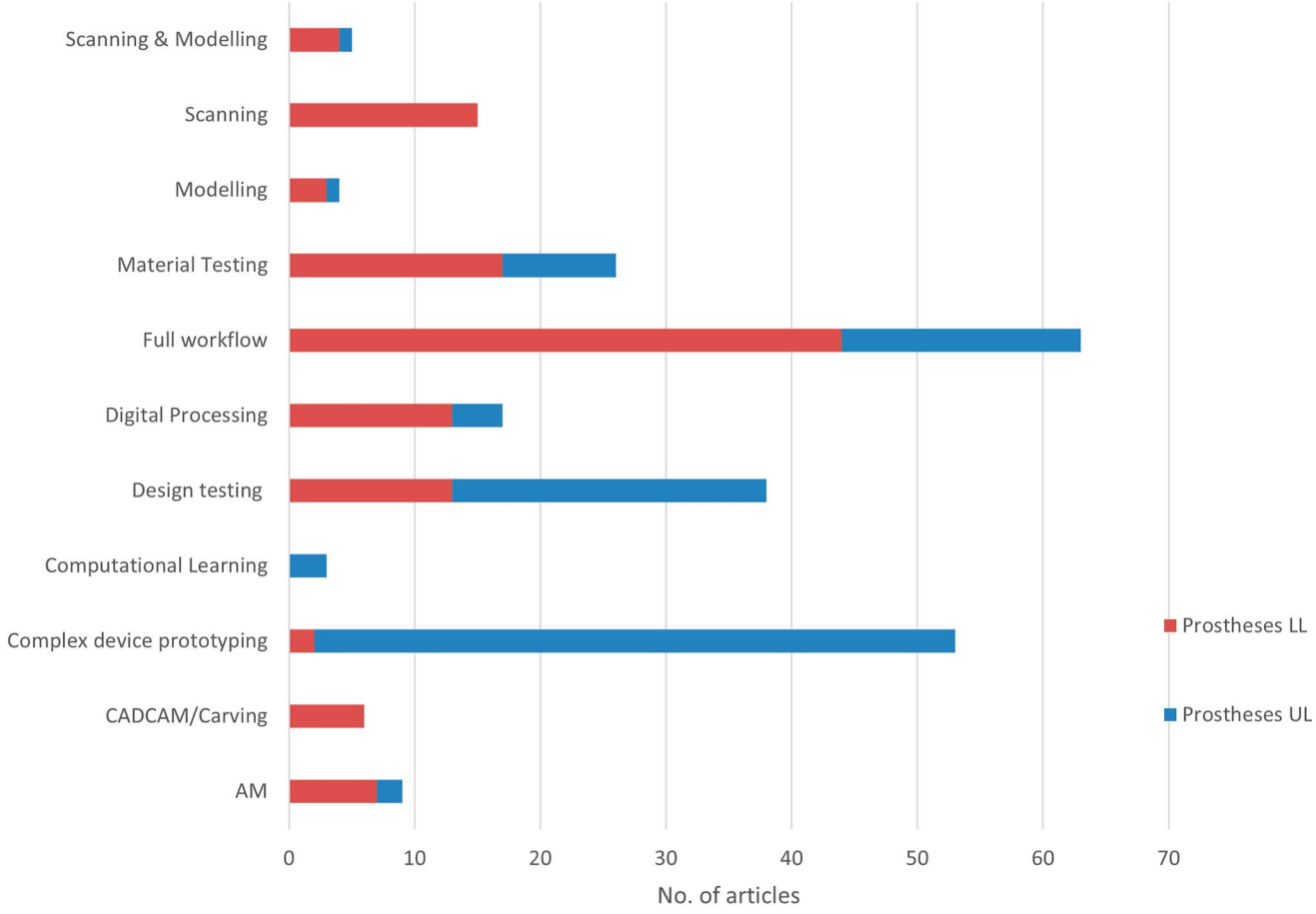


Figure 8. Primary focus of articles for LLP and ULP.

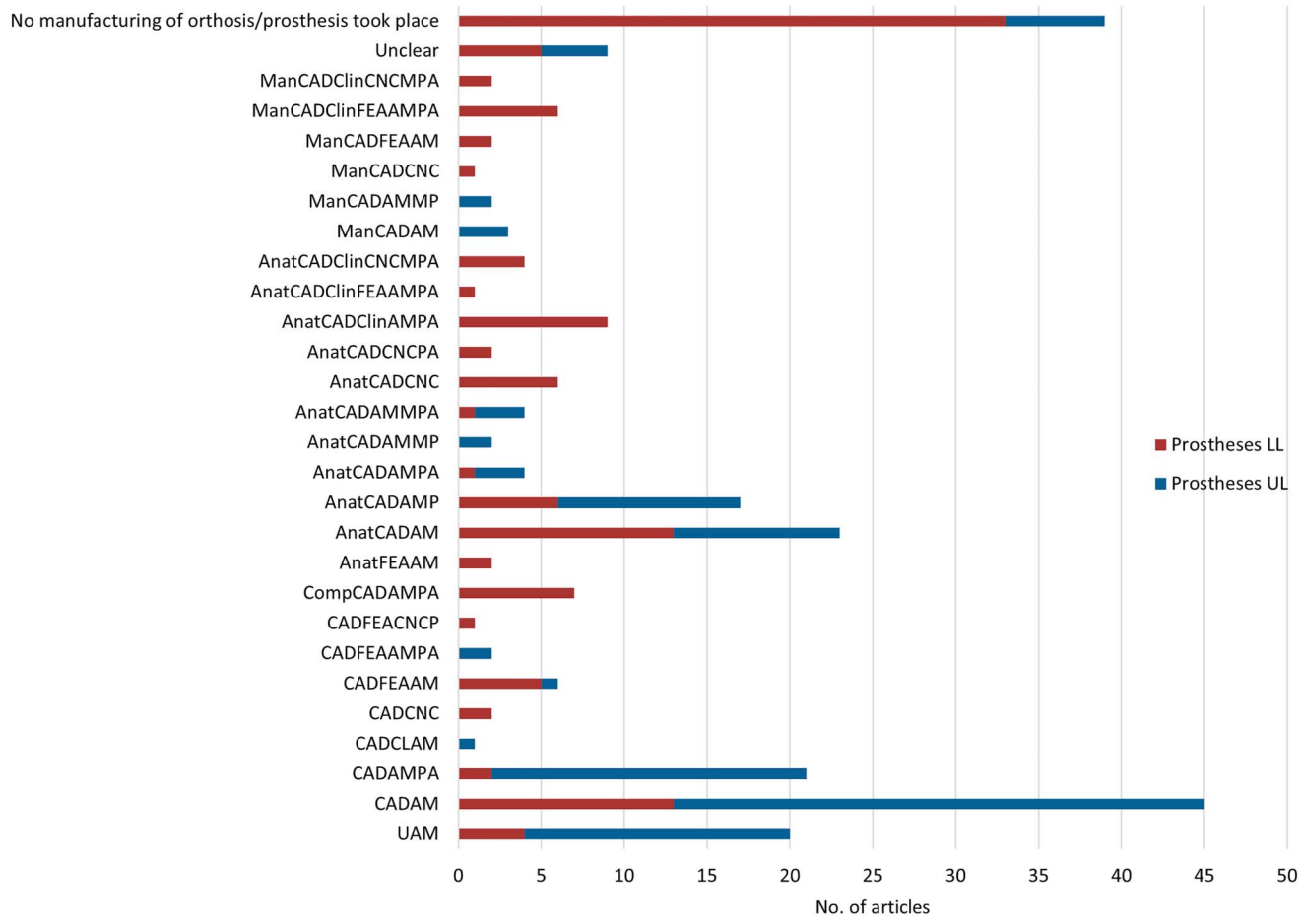


Figure 9. Prevalence of categorized digital workflows used in articles for LLP and ULP.

there are very few articles which document both post processing and adjustments (adjustments Anat/CAD/AM/P/A). Anat/CAD/Clin/AM/P/A descriptions represent what would be needed in true clinical application, with an explanation of the critical clinical decisions present in the article. The reader may assume that all the steps are undertaken, but they are often not described fully in the literature. As every step in the processes affects the outcome, the lack of these full descriptions in the literature is problematic. With often limited journal word counts, the authors may have no choice but to exclude information on these steps.

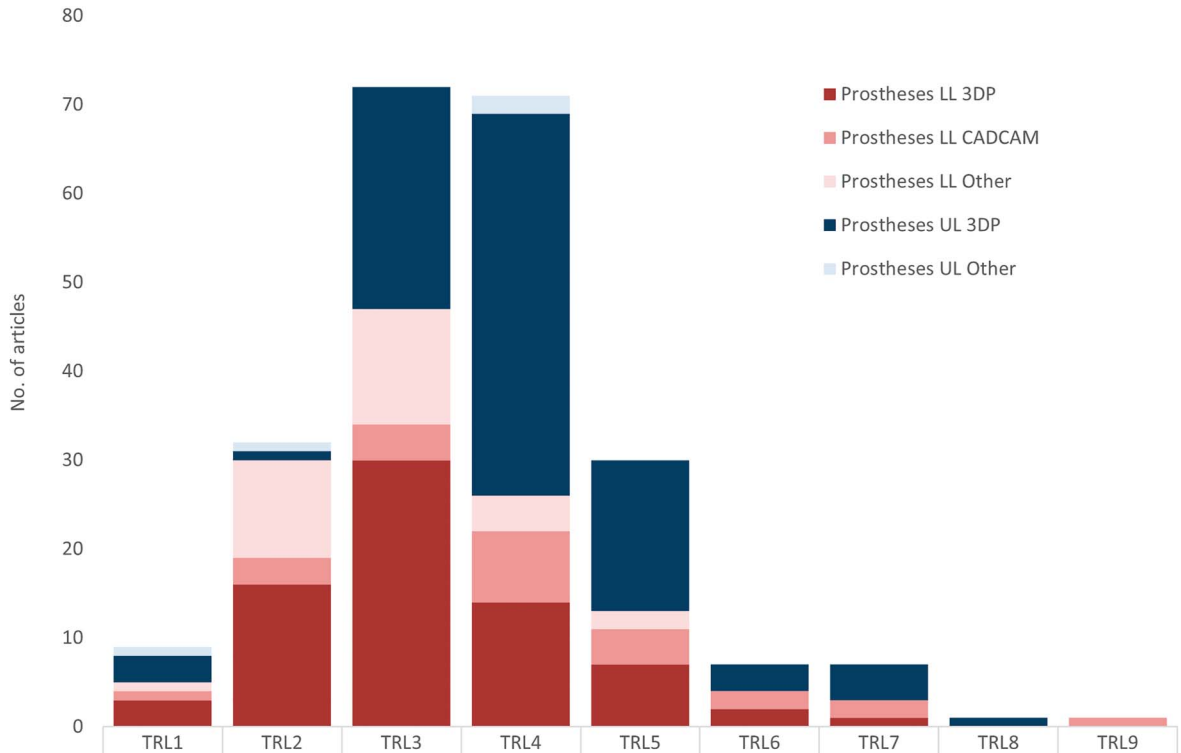
TRL level

Technology readiness levels (TRLs) are a type of measurement system used to assess the maturity level of a particular technology. Each technology project is evaluated against the parameters for each technology level and is then assigned a TRL rating based on the project's progress. There are 9 TRLs. TRL 1 is the lowest, and TRL 9 is the highest. Figure 3 shows that the NASA TRL scale has been adapted to assistive technology.[13]

It is important to state that larger-scale longitudinal data collection is only appropriate if sufficient technology development warrants the effort and enables ethical practice.

From Figure 10, it can be seen that the literature centers around TRL 3 and TRL 4, which are proof of concept levels, conducted in laboratory environments and generally do not have long-term assessments or testing in the intended environment (i.e., TRL 5 and TRL 6). This is to be expected since a major function of academic investigation is to explore immature ideas and what is possible. However, although many commercialized products are available on the market, there is a near total lack of peer reviewed and unbiased investigations that would support evidence-based practice.

Nevertheless, some studies were at TRL 6 and beyond. LLP CADCAM has been an established "mature" technology for over a decade, and there are 5 studies at TRL 6 that contain developed evaluation of technologies, all looking at TT sockets. In particular, Ellepola et al (1993)[21] conducted a trial with the VA Seattle BK Prosthesis on 46 participants, with 22 participants giving 6-month postfitting feedback. More recently, Karakoc et al[25] conducted a trial on 72 participants using the commercialized Tracer-CAD system across a 3-week period. Both found very favorable results and represent some of the most useful evidence for clinical practitioners in this literature set. Ellepola et al (1993)[21] completed a TRL 6 trial study with the technology developers conducting the trial. Studies by Ruder et al,[22] Oberg et al,[23] and Kohler et al[24] are the other notable articles with 30, 22, and 8 participants, respectively, all with trial use outside the laboratory and data collection beyond a week of fitting. These 3 studies included comparisons with traditional manufacturing as part of the study design, which is enlightening for this discourse.[22,23,25]



	TRL1	TRL2	TRL3	TRL4	TRL5	TRL6	TRL7	TRL8	TRL9
Prostheses UL Other	1	1	0	2	0	0	0	0	0
Prostheses UL 3DP	3	1	25	43	17	3	4	1	0
Prostheses LL Other	1	11	13	4	2	0	0	0	0
Prostheses LL CADCAM	1	3	4	8	4	2	2	0	1
Prostheses LL 3DP	3	16	30	14	7	2	1	0	0

Figure 10. Number of LLP and ULP articles per technology readiness level (TRL) for technologies.

For LLP 3DP, 2 studies were deemed to be TRL 6 and a single study at TRL 7, again all concerning TT sockets. At TRL 6, Rogers et al[26] trialed an selective laser sintering (SLS)-produced TT socket with advanced comfort features on 5 participants, with some evaluated beyond a week. This was the only study with multiple participants looking at powder-based AM sockets, which is an unfortunate gap in the literature.

For FDM TT sockets, the largest cohorts in this category were from the studies by Ratto et al (Uganda and Tanzania, 61 participants)[27] and van der Stelt et al (Cambodia and Sierra Leone, 8 participants).[28]

For ULP 3DP, there is a broader range of technology maturity in the literature; however, higher categories still had lower number of studies, with 3 at TRL 6, 4 at TRL 7, and 1 at TRL 8 (Duong et al[29]; however, it was conducted on people without any limb difference—this was possible as it was focused on testing myoelectric response efficacy only). The 4 TRL 7 articles are all led by Zuniga (2016, 2018, 2019, 2019) and are pediatric trials investigating hands and wrist-hand combinations. Patient quantitative data were gathered beyond a week, but all lacked qualitative data beyond a week.

Sample size

It can be seen in Figure 11 that few studies had N > 5, with most research being done with N = 0 or 1. While this small scale is typical for immature technology, it is only with larger population samples that the effect of individual bias and personal circumstances of the participants can be averaged out sufficiently. The ethics of moving to larger-scale trials is important to consider, and technologies should not be arbitrarily fast tracked to larger-scales if this brings too much uncertainty and risk of injury.

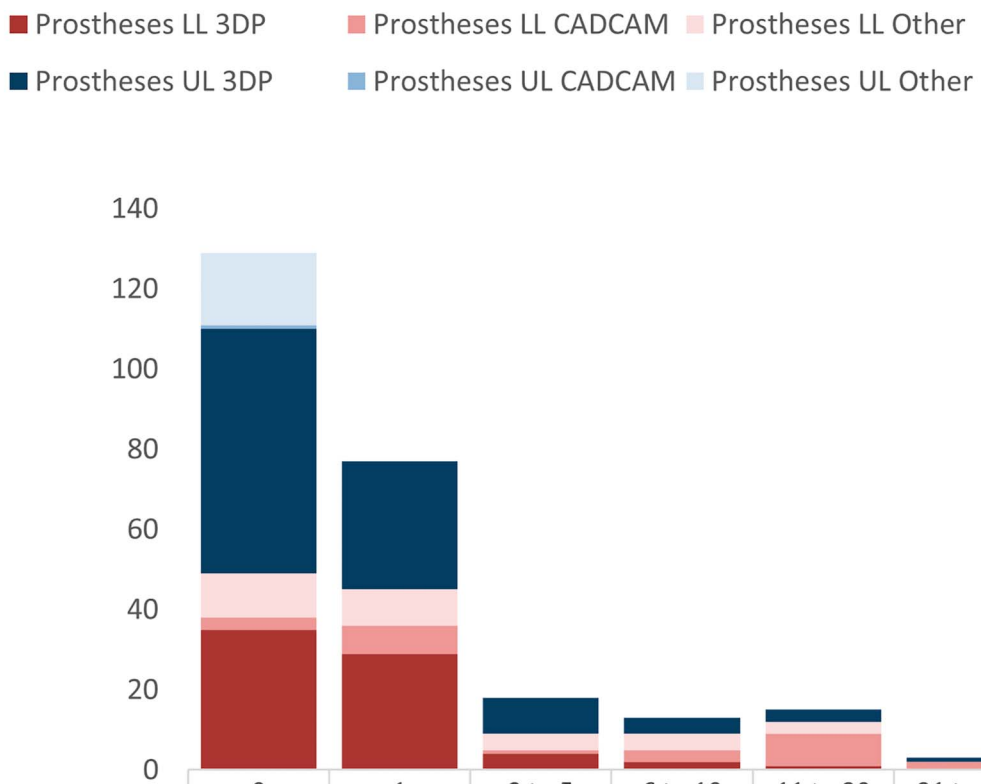
As a more mature technology, lower limb (LL) CADCAM does have some articles with larger numbers, with 8 studies having N = 11–30, 2 with N = 31–60, and 1 with N = 72. The N = 72 paper is from Karakoc et al[25] and relative to the lifespan of CADCAM technology was conducted recently. The next largest was from Ellepola et al.[21]

For LL 3DP, sample sizes are small, with only 4 trials larger than N = 5, specifically N = 8 (van der Stelt et al[28]), N = 10 (Goldstein et al[30]), N = 12 (Fey et al[31]), and N = 61 (Ratto et al[27]). Goldstein et al looked at amphibious LL prostheses, and Fey et al[31] looked at SLS-produced prosthetic feet.

For upper limb (UL) 3DP, only 3 articles had more than 10 participants, specifically N = 11 and 12 (Zuniga et al[32,33]), N = 24 (Duong et al,[29] which compares myoelectric hands—the printed limitless arm with the I-limb ultra), N = 40 (Dally et al[34] which examines the E-NABLE Raptor reloaded using a Southampton Hand Assessment Procedure like test; however, the participants did not actually have a limb difference).

Qualitative methods

The number of studies using qualitative methods is shown in Figure 12. Most articles do not include any qualitative evaluation



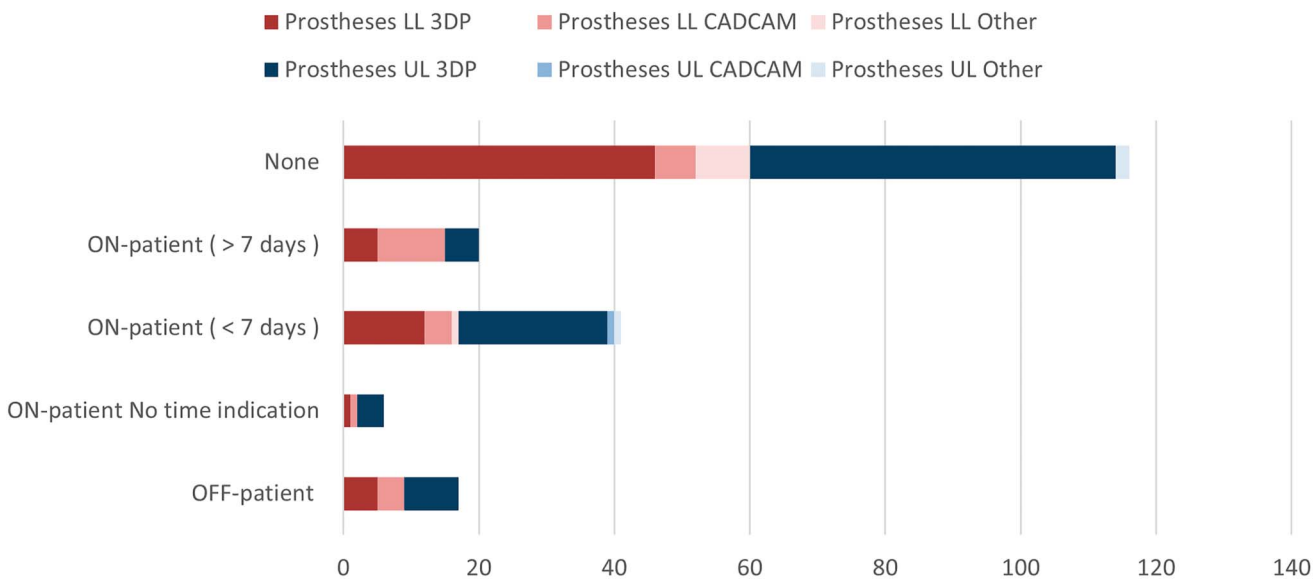
	0	1	2 to 5	6 to 10	11 to 30	31 to 60	60 to 100
Prostheses UL Other	18	0	0	0	0	0	0
Prostheses UL CADCAM	1	0	0	0	0	0	0
Prostheses UL 3DP	61	32	9	4	3	1	0
Prostheses LL Other	11	9	4	4	3	0	0
Prostheses LL CADCAM	3	7	1	3	8	2	1
Prostheses LL 3DP	35	29	4	2	1	0	1

Figure 11. Number of LLP and ULP studies with a range of sample sizes.

of the outcomes. For LLP CADCAM, there were 10 articles using qualitative methods beyond a week, the most of any device category as expected as this technology has been around and in use for much longer and is in regular clinical use. Karakoc et al, the largest of these trials, reports a N = 72 study comparing CADCAM sockets with those which are traditionally produced. They assessed quality of life using the 36-item Short Form Health Survey questionnaire and the Trinity Amputation and Prosthesis Experience Scales, finding that, with the exception of emotional role limitation, all 36-item Short Form Healthy Survey questionnaire parameters were significantly better in the group provided with a CADCAM device. Within the Trinity Amputation and Prosthesis Experience Scales, activity limitation scores of the CADCAM group were lower, and satisfaction with the prosthesis scores were higher. The second largest, but rather old, study from Ellepola followed the progress of 46 participants over 6 months with questionnaires covering a range of topics across satisfaction, fit, comfort, appearance, and activities of daily living, finding high acceptability across participants.

For LLP 3DP, only 4 articles included qualitative outcomes documented beyond a week: The only N > 10 study was by Ratto et al[27] in which a 2 × 4-week trial set up was carried out at sites in Uganda, Tanzania, and Cambodia, with a total of N = 61. Participants used the TT sockets made using FDM printing in Nylon for 4 weeks then completed a 28-question Likert Scale Questionnaire based on the Prosthesis Evaluation Questionnaire. This was repeated over another 4 weeks, but participants wore a socket made using the traditional International Committee of the Red Cross (ICRC) method for comparison. The Tanzania site (N = 10) users rated the ICRC device significantly higher in a variety of categories measuring stability, fit, and comfort, whereas no significant difference between the ICRC and printed sockets was found at the other 3 sites.

van der Stelt[28] carried out a 6-week N = 8 trial on 3DP TT sockets also using FDM printed Tough polylactic acid (PLA), with questionnaires covering personal goals set by participants and a variety of functional attainment measures, as well as end-of-study questions on general feedback. Goals focused on mobility without crutches, with the majority of users accomplishing these. A



	OFF-patient	ON-patient No time indication	ON-patient (< 7 days)	ON-patient (> 7 days)	None
Prostheses LL 3DP	5	1	12	5	46
Prostheses LL CADCAM	4	1	4	10	6
Prostheses LL Other	0	0	1	0	8
Prostheses UL 3DP	8	4	22	5	54
Prostheses UL CADCAM	0	0	1	0	0
Prostheses UL Other	0	0	1	0	2

Figure 12. Number of LLP and ULP studies using qualitative evaluation methodologies. ON-patient refers to measures performed when the tested device is in situ and in use on a person. OFF-patient refers to when the tested device is not on a person.

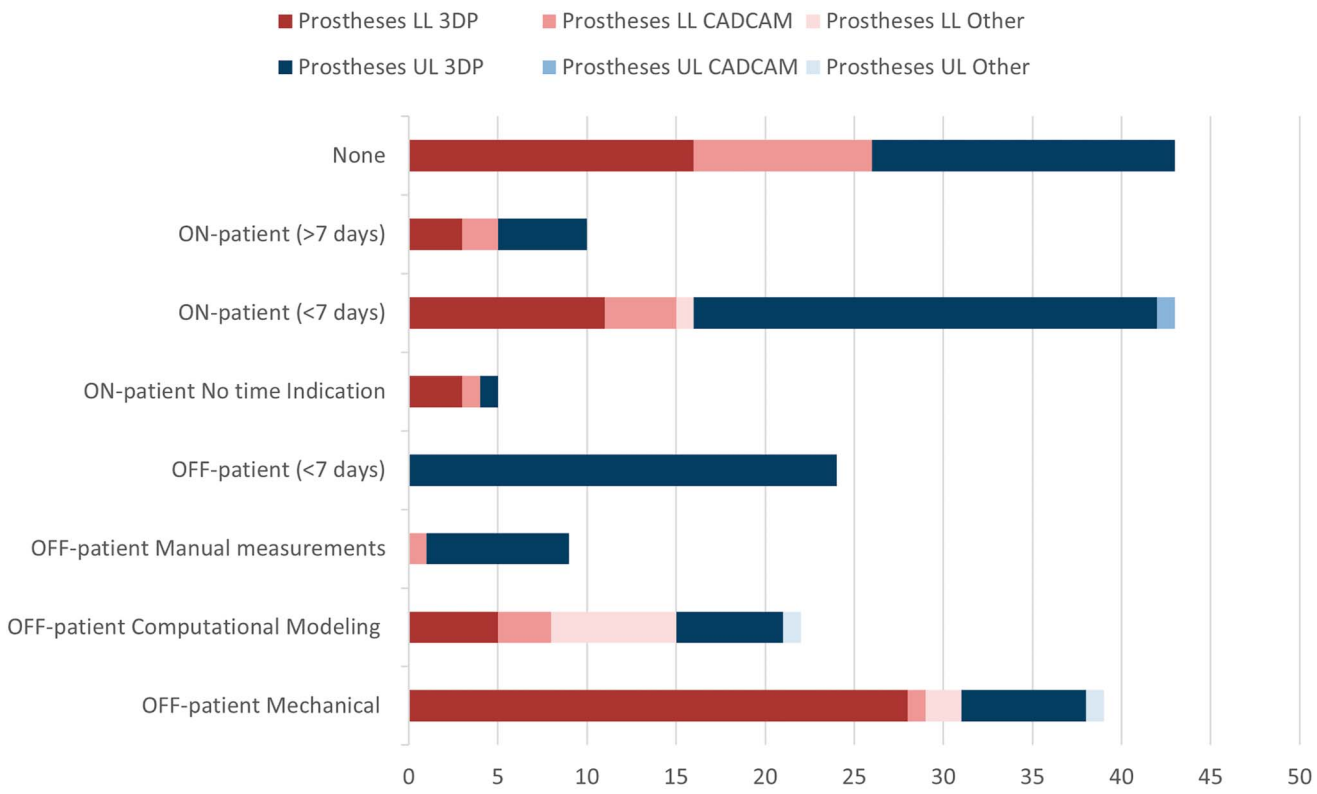
physiotherapy program was followed by participants to aid rehabilitation, which is not normally accessible. The other trials were by Rogers et al[35] and Tay et al,[36] and each had only single participant.

For UL 3DP, 5 studies followed up beyond a week; however, only 2 of these articles reported studies involving multiple participants—Giaconi et al[37] with 5 adolescent participants who were individually interviewed and their caregivers concerning the Cyborg Beast prosthetic hands—the interview analysis sought subjective evaluation, looking at what meaning and characteristics the participants found in the devices and aesthetic and design evaluations. Participants mainly reported difficulties in using the prostheses and negative opinions regarding use and aesthetics. Zuniga et al[38] with 8 participants, also using a modified Cyborg Beast, evaluated remote fitting procedures and implemented the Orthotics Prosthetics User Survey and QUEST 2.0 survey. 12 items (dimensions, weight, adjustments, safety, durability, easy to use, comfort, effectiveness, and 4 items concerning service) were evaluated, finding particularly high scores in weight, safety, and ease of use, after 5 weeks of use.

While the high numbers of articles focusing only on OFF-patient evaluation is appropriate, the paucity of ON-patient data beyond a week of use (in reality less than a week generally refers to zero evaluation outside the lab or clinic) severely limits the community's ability to understand the state of these technologies as a whole. In reality there is a near total lack of studies of that go far enough. It is thought that studies over 4 months are needed to adequately assess outcomes—these are entirely missing from the literature for nearly all device categories. Without this formal evidence, it is extremely difficult to make informed, justified decisions on the use of these technologies or the future direction that they should take.

Quantitative methods

Quantitative outcome measure data are important for enabling easy communication of technology efficacy to both the prosthetics community and wider audiences such as funders and policymakers (Figure 13). Four articles provide quantitative analysis beyond a week for LL CADCAM: Ruder et al[22] with a N = 30 comparative trial on TT sockets versus a conventional control group, measuring rehabilitation duration—finding significant increased rehabilitation duration requirement for the CADCAM sockets; however, this was deemed because of 67% of patients requiring at least one additional attempt. Narayanan et al[39] looked at prosthetic feet manufacture using CADCAM of ethylene vinyl acetate foam. Using the existing Jaipur Foot, they applied modifications it in terms of ankle support, design and method of fabrication, foot molds profile, and the inner core material to improve the performance and durability. They found on testing rigidity with load deflection analysis that the new feet performed better over 10 successive compressive cycles and on patient feedback. Karakoc et al[25] performed a N = 77 TT socket trial analyzing prosthesis



	OFF-patient Mechanical	OFF-patient Computational Modeling	OFF-patient Manual measurements	OFF-patient (<7 days)	ON-patient No time Indication	ON-patient (<7 days)	ON-patient (>7 days)	None
Prostheses LL 3DP	28	5	0	0	3	11	3	16
Prostheses LL CADCAM	1	3	1	0	1	4	2	10
Prostheses LL Other	2	7	0	0	0	1	0	0
Prostheses UL 3DP	7	6	8	24	1	26	5	17
Prostheses UL CADCAM	0	0	0	0	0	1	0	0
Prostheses UL Other	1	1	0	0	0	0	0	0

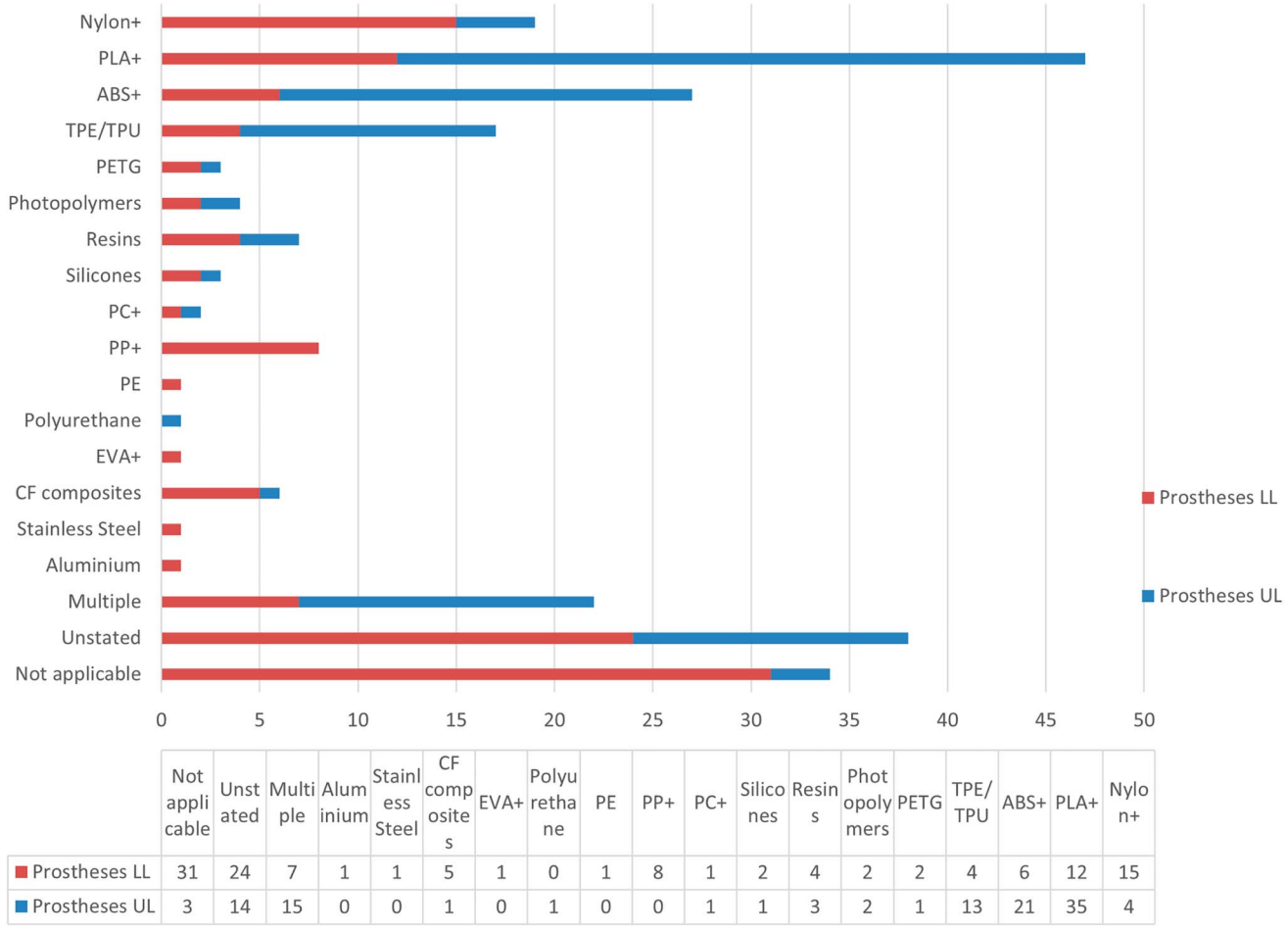
Figure 13. Number of LLP and ULP articles with quantitative methodologies. ON-patient refers to measures performed when the tested device is in situ and in use on a person. OFF-patient refers to when the tested device is not on a person.

lifetime, walking time and distance with prosthesis, pain-free walking time with prosthesis, production time of the prosthesis, and adaptation time to the prosthesis, all with better performances from the CADCAM sockets against a control group. They also performed a 36-item Short Form Health Survey, demonstrating across a range of outcomes that the CADCAM sockets yielded better outcomes in quality of life for patients.

For LL 3DP, Sanders et al[20] studied printed socket inserts with N = 5 analyzing insert geometries after 4 weeks compared with original digital designs, finding very little change, and improvement after the wear period. Rogers et al[26,35] studied SLS-produced TT sockets on N = 5 trials with instrumental gait analysis and a complete biomechanical assessment after 2 weeks, finding no significant differences between patients given the SLS sockets and conventional sockets. Long-term durability tests are stated as ongoing; however, updates in the literature could not be found.

A more consistent offering of longer-term data in UL 3DP of hands was provided by Zuniga and a varying team (2016, 2019, 2019, 2018),[32,33,38,40] with an extensive range of tests on the Cyborg Beast prosthetic hand, finding highly positive results to indicate the beneficial provision of these devices. For example, in the study by Zuniga et al,[32] the Cyborg Beast was tested on 11 children before and after 24 weeks assessing gross manual dexterity using the box and block test, with significant increases in dexterity found. In the study by Zuniga et al,[40] they tested 9 children with congenital limb reduction. They aimed to investigate the effect of device provision on co-contraction—the simultaneous activation of agonist and antagonist muscles that produce forces around a joint. This coactivation is an essential and common motor control strategy; however, excessive coactivation can impair. After 6 months of prosthesis use, they found an average 70% reduction in the coactivation index, which is expressed as a percent activation of antagonist over agonist muscles indicating possible improvement in motor control strategies that could be implemented.

Finally, also notable was Xu et al[41] who conducted tests up to 3 months on a prosthetic hand based on the "Raptor reloaded"



	Not applicable	Unstated	Multiple	Aluminium	Stainless Steel	CF composites	EVA+	Polyurethane	PE	PP+	PC+	Silicones	Resins	Photopolymers	PETG	TPE/TPU	ABS+	PLA+	Nylon+
Prostheses LL	31	24	7	1	1	5	1	0	1	8	1	2	4	2	2	4	6	12	15
Prostheses UL	3	14	15	0	0	1	0	1	0	0	1	1	3	2	1	13	21	35	4

Figure 14. Materials used for the final product investigated in articles for LLP and ULP.

open-source design produced for an 8-year-old boy who suffered a traumatic wrist amputation. The function of the prosthesis was evaluated at 1-month and 3-month follow-up using the Children Amputee Prosthetics Projects score and the University of New Brunswick Test of Prosthetic Function for Unilateral Amputees (University of New Brunswick test). These showed significantly improved function over the study period.[40] These studies give a good combined outlook on the functional efficacy of 3DP prosthetic hands.

An entire category that could be of great utility, but does not appear at all in the literature, is ON-patient, long-term mechanical testing. This could entail the re-evaluation of a device's structural integrity and various material properties after a prolonged period of use and shed light on the key question of device durability.

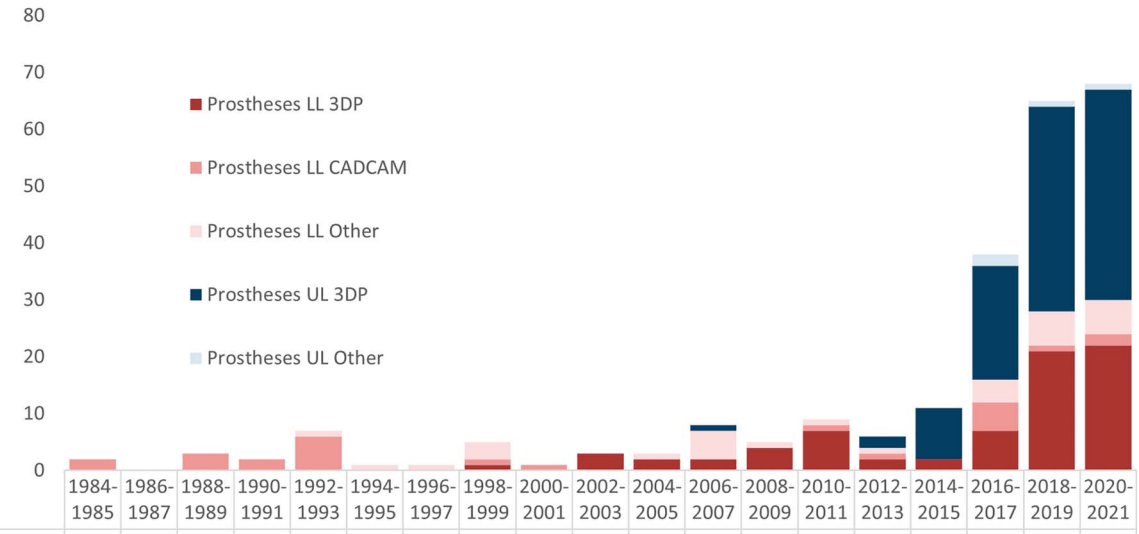
Materials used

Across articles, more than 60 distinct materials were found that are used for the primary construction (Figure 14). These materials were grouped to analyze the data with a "+" denoting the inclusion of various composites of the given material. Photopolymers and resins contained a wide range of proprietary materials. A few noteworthy trends arise from this. First, there are a disconcerting number of articles that do not state the material being used.

Second, the literature is dominated by Nylon, acrylonitrile butadiene styrene, and PLA derivatives, rather than the materials typically used, such as polypropylene, fiberglass, and carbon fiber. The main reason for this is driven by their suitability for AM processes rather than their material properties in application. It is also important to note that the manufacturing process dictates much of the resultant material properties; for example, FDM extruded polypropylene is not equivalent to vacuum formed sheet polypropylene. The material properties of AM-produced devices are one of the most talked about concerns around the technology, with strength and durability being most in question. The required material properties differ depending on component type; however, tensile strength in a range of static and dynamic cyclic loading conditions is often of particular importance. For LLP sockets as a key example, although no definitive test exists, the ISO Standard 10328 is generally considered the best reference available as it applies to the components that are attached to the socket.[42] Multiple very informative articles specifically investigate these various properties, particularly, the studies by Gershutz et al,[43,44] Pousett et al,[45] Campbell et al,[46] van der Stelt et al,[47] Fadzil et al,[48] Stewart,[49] Pentek et al,[50] Owen et al,[51] and Nickel et al.[52]

Chronology

When we look at the chronology of digital fabrication articles for prosthetics in Figure 15, the literature concerning CADCAM did



	1984-1985	1986-1987	1988-1989	1990-1991	1992-1993	1994-1995	1996-1997	1998-1999	2000-2001	2002-2003	2004-2005	2006-2007	2008-2009	2010-2011	2012-2013	2014-2015	2016-2017	2018-2019	2020-2021
Prostheses UL Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1	1
Prostheses UL 3DP	0	0	0	0	0	0	0	0	0	0	0	1	0	0	2	9	20	36	37
Prostheses LL Other	0	0	0	0	1	1	1	3	0	0	1	5	1	1	1	0	4	6	6
Prostheses LL CADCAM	2	0	3	2	6	0	0	1	1	0	0	0	0	1	1	0	5	1	2
Prostheses LL 3DP	0	0	0	0	0	0	0	1	0	3	2	2	4	7	2	2	7	21	22

Figure 15. Number of LLP and ULP articles by year.

not accelerate until after 2015, with important mature studies being conducted in recent years. 3DP of ULP and LLP publications rapidly increased in number in the past 5 years, and it should be understood that data for 2020–2021 would be larger, considering data collection was only in the first half of 2021. However, the forms of evidence that are suggested as needed for clinical decision-making and resource planning are not appearing appropriately—yet, industry shows are filled with commercial DF technology offerings.

Discussion

The high range of variance in production workflows and materials creates great difficulty in drawing conclusions across the literature reviewed. This is not necessarily a problem that can or should be solved—it represents the huge breadth of application and the exciting range of influence that these technologies could have. Although there are many commercial systems that suggest maturity and market readiness, there are very few studies that give adequate longitudinal evaluation at a scale above small user group tests.

Without these, it is extremely difficult for clinicians to adopt these methods in an evidence-based manner, without incurring a significant amount of unknowns and therefore, risk. It is noted that both of the larger-scale trials on AM sockets with evaluation on use outside the clinic were in low-resource settings. This is where the greatest need for service improvements is found and therefore where the potential for AM to critically improve service models might be the greatest—but where safeguarding participants in trials is much more difficult. Some very useful guidelines on research ethics in this area have recently been published through ISPO and the Exceed Research Network.[53]

The need for large DF studies does not mean that these products are not ready it simply means that the evidence is not available, and until it is, the community cannot make clear recommendations for practice, either at the individual clinic level or for national level health service rollouts. Why are there no formal studies in well-resourced high-income clinics using the commercial systems being advertised? Are there, but they are unavailable for wider audiences? It is assumed that a great deal of R&D must occur in-house at prosthetics companies—it would be strongly beneficial if these were translated into peer-reviewed clinical trials to build the evidence base.

These evidence gaps are not just a barrier to adopting commercial systems; the gaps present themselves at all levels of innovation progression. Many promising technologies at lower TRL levels do not seem to progress to appropriate mid-level investigation while some technologies jump to larger-scale trials, which can present ethical issues in terms of risk to participants as already stated.

Another finding is that there is a paucity of research available on the training of personnel on using the equipment. Training and maintenance of digital production equipment must be factored into the decision to switch to digital workflows or elements of workflow. If these factors are not recognized, we may end up with the unfortunate scenario of decision makers seeking to reduce the workloads of overstretched workshops by implementing a different, but equally time-consuming and resource-consuming workflow. This is of particular concern in clinics that are already critically under-resourced, especially in low-income countries. There is also very little research focused on modification/rectification practices, whether from a training or simply process perspective. It seems, therefore, from this that it is the "human" aspects around DF processes and learning to apply them, which is mostly unavailable in the evidence. Although possible in the future, we are far from AI-led or high levels of automation in this area;

therefore, improving the documented understanding of these human aspects is critical if evidence-based decision-making is to be made possible.

There is a good range of literature which investigated material and mechanical properties in application of these techniques. In addition to these mainly laboratory-based tests, however, knowledge of long-term strength and durability could be obtained by material testing after prolonged use "in the wild," giving truer material response data.

Finally, although this work is focused on the importance of evidence to inform practice, a question arises on the actual level of necessity for that evidence to be presented in an academic format. If commercial systems are being put into practice, will the market answer these questions for us? To contribute evidence to the community, it would be useful to have more visibility on what is occurring in clinics already using these technologies, the outcomes for their clients, and the geographic spread of these activities.

Summary

1. Lack of appropriate long-term, large-scale studies.
2. There are very few formal studies found for mature technologies; however, we know that commercial systems are in use.
3. There is very little formal discussion on the training of personnel on the use of equipment, even for established digital fabrication technologies.
4. Although most papers mention an approach to rectification, there is very little research that focuses on modification/rectification practices.
5. Very broad range of testing methodologies, with some devices lacking any standardized test at all.
6. High range of variance of production workflows and materials is exciting, but makes drawing conclusions difficult.
7. The number of new articles concerning digital fabrication of P&O is rapidly accelerating, yet are overall conclusions becoming clearer?
8. The numbers, outcomes, or geographic spread of the actual use of digital technologies is unclear.

Limitations

Although we have attempted to be as comprehensive in our searches, along with invitation to the community at ISPO World Congress 2021 to check the body of literature for missing articles, there will inevitably be articles that have been missed from this.

For some of the topics of enquiry, there is a degree of subjectivity in the designations. We hope that overall, however, there would not be major deviations to be found in the data.

Conclusion

This scoping review has identified multiple limitations in the forms of evidence being produced for the prosthetics community, particularly a lack of long-term, larger-scale studies, research into the training requirements for these technologies and the necessary rectification processes, and a high range of variance of production workflows and materials which makes drawing conclusions difficult. This creates a barrier to adequate evidence-based decision-making for clinicians, technology developers, and wider policymakers. Increased collaboration between academia, industry, and clinical teams across more of the pathway to market for new technologies could be a route to addressing these gaps. It may, however, require new mechanisms and ways of working to encourage this and requires further in-depth discussion.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This research was funded by Foreign, Commonwealth and Development Office (FCDO, formerly Department for International Development [DFID]), grant number GB-GOV-1-300815 Award date: January 28, 2019.

Declaration of conflicting interest

The author(s) disclosed no potential conflicts of interest with respect to the research, authorship, and/ or publication of this article.

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Supplemental material

Supplemental material for this article is available in this article. Direct URL citation appears in the text and is provided in the HTML and PDF versions of this article on the journal's Web site (www.POIjournal.org).

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