JÖNKÖPING UNIVERSITY
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Accuracy and Reliability of 3D Scanning Spatial Data when Capturing Limb Morphology for Use within Prosthetics and Orthotics: A Scoping Review

Nøjagtighed og pålidelighed af 3D scanning for spatial data ved afbildning af lemme morfologi til brug indenfor bandagistfaget: et scoping review

PAPER WITHIN *Prosthetics and Orthotics*
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Abstract:

Background:

Scanners are becoming widespread in Prosthetics and Orthotics, replacing plaster casting in the manufacture of some types of devices. P&O shape capture must be accurate and reliable, so the device is comfortable and reproducible between clinicians/sessions.

Objectives:

To map knowledge on measuring accuracy and reliability of spatial data produced from 3D scanners

Methods:

The study design was a scoping review using the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR). Studies published in or after 2010 in English with a full-text available that analyse either the accuracy/validity or reliability of human 3D scanning data within a P&O context. Sources were obtained from Pubmed, CINAHL, Scopus, Cochrane Library, Web of Science, and AMed databases on 25th March.

Results:

The search identified 115 studies of which 9 were included (7 experimental [4 prosthetic, 3 orthotic], 1 systematic review, 1 literature review). 7 analysed both reliability and accuracy/validity and 2 analysed reliability. High heterogeneity amongst studies' methods, techniques, and equipment.

Conclusion:

Methods, techniques, and equipment used to measure accuracy/validity and reliability varied greatly though more so in the measurement of accuracy/validity. Within the studies, researchers called for more research on standardisation of measurement methods and techniques.

Keywords:

Scanner, 3D, Accuracy, Reliability, Validity, Prosthetics, Orthotics, Shape capture, Measurement, Human, Shape, Morphology, Assessment

Problemformulering

Baggrund

Scannere bliver mere og mere udbredt i bandagistfaget, de erstatter gipsafstøbninger i produktionen af flere typer hjælpemidler. De rumlige data skal være nøjagtigt og gentageligt så hjælpemidlet er komfortabelt og reproducerbart imellem klinikere og sessioner.

Mål

At kortlægge den tilgængelige viden om at måle nøjagtighed og gentagelighed af spatial data lavet med 3D scannere.

Metoder

Dette studie type er et scoping review som benytter Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR). Artikler udgivet i eller efter 2010 på engelsk med en tilgængelig full-text der analyserer enten nøjagtighed eller gentagelighed af menneskelig 3D scannings data i en bandagist sammenhæng. Kilder blev indsamlet fra Pubmed, CINAHL, Scopus, Cochrane Library, Web of Science, and AMed databaserne på 25 marts.

Resultater

Søgningen identificerede 115 studier, af hvilke 9 blev inkluderet (7 eksperimentelle [4 proteser, 3 ortoser], 1 systematisk review, 1 litteratur review). 7 analyserede både gentagelighed og nøjagtighed, og 2 analyserede blot gentagelighed. Høj heterogenitet mellem undersøgelsers metoder, teknikker og udstyr.

Konklusion

Metoder, teknikker og udstyr benyttet til at måle nøjagtighed og gentagelighed varierede meget, mest i målingen af nøjagtighed. I studierne, efterlyste forskerne mere forskning i standardisering af målemetoder og -teknikker.

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Glossary:

The glossary comprises of definitions from both the Merriam-Webster dictionary (Merriam-Webster, n.d.) and self-authored explanations of terms with context to this review.

Term	Definition
3D Scanning	Digitisation of a real-life object, surface, or environment's shape through the use of scanning technology
Accuracy	Within the context of this review, the degree to which a measurement, calculation, value, etc… conforms to a standard or normal (Merriam-Webster, n.d.)
Artefacts	A defect in an image (such as a digital photograph) that appears as a result of the technology and methods used to create and process the image (Merriam-Webster, n.d.)
Computer Aided Design (CAD)	Creating or altering a model or design through the use of computers
Computer Aided Manufacture (CAM)	The use of software to control machines used for manufacture
Inter-rater Reliability	Reliability of measurements between operators with the same scanner
Inter-scanner Reliability	Reliability of measurements with the same operator between scanners
Intra-rater Reliability	Reliability of measurements with the same operator and the same scanner with emphasis on the rater's reliability
Intra-scanner Reliability	Reliability of measurements with the same scanner with the same operator with emphasis on the scanner's reliability
Method	Within the context of this review, a procedure for accomplishing something to achieve a certain goal or state (Merriam-Webster, n.d.)
Model	Within a 3D scanning context, a 3D representation on an object, surface, or environment
Morphology	A study of structure or form (Merriam-Webster, n.d.)
Noisy Data/Noise	Irrelevant or meaningless data or output occurring along with desired information (Merriam-Webster, n.d.)
Point cloud	Within a 3D scanning context, a set of data points in space, representing an object or shape
Post processing	Within a 3D scanning context, digital rectification such as removing artefacts or cropping models
Protocol	A detailed plan of a scientific or medical experiment, treatment, or procedure (Merriam-Webster, n.d.)

Rectification	To correct by removing errors (Merriam-Webster, n.d.)
Reliability	The extent to which an experiment, test, or measuring procedure yields the same results on repeated trials (Merriam-Webster, n.d.)
Spatial Data	A broad term encompassing the location of features of an object and how it is represented in 3D space i.e., volumetric data, positional data, geometric data, etc…
Technique	Within the context of this review, the way a certain objective has been fulfilled
Test-retest Reliability/Inter-session Reliability	Reliability of measurements taken at different points in time/between sessions with identical testing group and conditions
Validity	Within the context of this review, the degree to which a measurement, calculation, value, etc… is correct or true (Merriam-Webster, n.d.)

1 - Background:

1.1 – Importance of Shape Capture Within P&O

One of the most important facets of Prosthetics and Orthotics (P&O) is ensuring a good fit of the assistive device. Whether you're manufacturing an orthotic brace or a transtibial prosthetic socket, the fit and comfort of the device ranks among one of the highest concerns and determiners for patient satisfaction (Bettoni et al., 2014) with the assessment of comfort/fit also appearing in most orthotic/prosthetic-based satisfaction surveys (Peaco et al, 2011). The concept of 'a good fit' changes from device to device due to different aims and indications i.e., certain braces aim to apply specific force systems, certain sockets intend to encapsulate and stabilise movement, and so on. From the initial shape capture of the relevant area where the device will be worn, rectification through removal/addition of material from specific areas, volume, and other techniques are used to achieve these different functions within the device. These rectifications however rely on the initial shape capture being both accurate and reliable so the rectifications are applied to the intended spots and the manufacture of the device can be repeated without considerable error.

1.2 - History of Shape Capture Within P&O

The most common technique of capturing limb morphology in recent history for use within orthopaedics has been plaster casting with Plaster of Paris (POP) (Hemant & Dhanasekara, 2013). This is due to its relatively cheap cost and reputation among the field as the go-to shape capture format established since its popularisation in the 1800s. In other orthopaedic disciplines (such as orthopaedic surgeons) where it once was widely used for purposes of immobilisation (for bone fracture patients and others), clinicians have been moving to other alternatives such as fibreglass (Kowalski et al., 2002). In prosthetics and orthotics POP, fibreglass, and other similar materials are used to capture the shape of the limb where the cast is then filled, rectified, and used in the manufacturing of the orthosis/prosthesis. Despite the benefits of plaster casting however, advancements in technology have opened up avenues to other shape capture techniques/equipment including, 3D scanning.

In recent decades, both Computer Aided Design (CAD) and Computer Aided Manufacture (CAM) principles have steadily been making their way into the medical field. Coming into use in the 60s, CAD/CAM techniques and equipment were primarily adopted by the automotive industry. Since the 80's however, prosthetist/orthotists have been making use of the technology within their field with the capabilities of scanners/printers today dwarfing those of the past (Kemp, 2006). In the 2000's, interest in CAD/CAM grew among P&O clinics (Afiqah et al., 2021; Smith & Burgess, 2001) and by the end of the 2000's, 3D scanning technology had become one of the mainstays of the field. By the 2010's, many different CAD/CAM focused companies began partnering with P&O companies (such as Artec's partnership with Ottobock (Artec Group, 2014)). Increased availability and a decreasing cost of equipment and software made CAD/CAM especially attractive to clinicians in a time where a streamlined clinical workflow was especially important (Golovin et al., 2018). Prosthetics and Orthotics was no exception to this increase in CAD/CAM popularity with the key instance of its use being 3D scanning.

1.3 - Use of 3D Scanning Within P&O

3D scanning is used to capture the morphology of the area where the orthosis/prosthesis will be applied. Generally used in tandem with CAM (i.e., milling, additive manufacturing), the scanned morphology is then adjusted and rectified within CAD software such as Canfit or Vxelements. This rectified model will then usually either be printed/milled out (in clinic or in a centralised manufacturing unit) and used to manufacture the device on (i.e., a foam model for a knee orthosis to be manufactured onto), or the device will be directly milled out (i.e., an insole foot orthosis milled from a block of Ethyl-Vinyl-Acetate (EVA) material), or the device will be modelled onto the scan within the program and this device will be printed instead (i.e., a cosmetic prosthetic cover that is 3D printed).

1.4 - Types of 3D Scanning Equipment

There are several main types of scanning equipment that are used commonly today: Laser, Projected/Structured light/'White light', Photogrammetry, and Contact Scanning. The most popular category is laser-based 3D scanning, more specifically laser triangulation scanners that use multiple laser emitters and sensors and can determine a certain point's position by the angle at which the emitted laser reflects back and enters the sensor in (Tóth & Živčák, 2014). Whilst there are other non-triangulation-based laser scanners that specialise in long distance or other areas, common laser triangulation scanners are by far the cheapest, very portable, are able to scan shiny/dark surfaces, and are not as sensitive to changes in light in the surrounding area compared to other scanners. 'White light' scanners, also known as projected or structured light scanners, are another type of 3D scanning equipment that uses a similar type of triangulation but instead of lasers, it uses white (or blue) LEDs. As a result of this use of white light, these types of scanners are safer to use (lasers can damage eyes of humans and animals (Sliney, 1995)) and can scan very quickly however due to the use of white light, they can be quite sensitive to the light of the surrounding environment and price points usually are inversely proportional to the sensitivity (Javaid et al., 2021). The other two equipment types, photogrammetry (scanning through the systematic patching up of photos of an object from different angles) and contact scanning (scanning through physical contact and probing), are not as commonly used within prosthetics and orthotics either due to the expensive cost associated with the technology needed or the inconvenience and time cost of having to physically probe all over a patient. Contact scanning is also usually better at defining more geometric forms as opposed to organic shapes (Farahani et al., 2017) which would be averse to the aims of scanning within P&O.

The term itself '3D scanning' when applied to P&O refers to a selection of different technologies that are currently used. Scanners today are generally separated into two main groups, mobile and stationary (Tóth & Živčák, 2014), both of which are being used in clinics. Mobile scanners used in clinics today generally range from independent scanning units such as Ottobock's Creaform HCP 3D scanner to smaller units attachable to tablets or phones such as Intel's RealSense scanner. It's important to note that whilst smaller tablet/phone attachable 3D scanning units are becoming more widespread, only a few are used for Orthotic and Prosthetic purposes as the scan resolution (the number of polygons/points the scanner is able to create to make up the scanned surface) required for medical scanning is not often available (Mai & Lee, 2020). Stationary scanning units used in clinics include the ParoScan 3Dm, usually floor scanners such as these are used for specific purposes such as insoles and they tend to be white light or hybrid (mix of two or more of the equipment types) scanners due to the potential danger to users.

1.5 - Lack of Research into Spatial Data Accuracy/Validity and Reliability Within P&O

Due to factors like the fact that there are so many types of scanners available and the fact that different people are performing the scans, there exists the potential for error in both the accuracy and reliability of scans produced. A question then arises as to whether the wealth of recent research related to 3D scanning brought about by the increased popularity of the technology addresses these potential errors. Whilst the interest in 3D scanning within the field of P&O is growing and with it the amount of research, quantifying the accuracy and reliability of each scanner brings problems as there are many ways to do so. Whilst popular guidelines, frameworks, and tools to measure the effect or quality of other topics in research exist, for instance in user satisfaction with a prosthetic/orthotic device via the Orthotics and Prosthetics Users' Survey (OPUS) (Heinemann et al., 2003), no such popularly used tool exists for grading the quality of a 3D scanner, especially within a P&O context. Rather, varied and erratically used commercially developed guidelines such as the VDI/VDE 2634 (VDI/VDE, 2012) from the Verein Deutscher Ingenieure (Society of German Engineers) or various statistical techniques to measure reliability such as inter-rater reliability.

This investigation aimed to address these concerns and used a scoping review to assess the amount and content of literature available in the field that analyses the accuracy and reliability of 3D scanners within a P&O context in addition to assessing the prevalence of chosen methods used to define accuracy and reliability among said literature. Definitions of accuracy, validity, and reliability can vary amongst scientific literature so for that reason a glossary of terms was compiled that are used throughout this review to ensure clarity and understanding of concepts discussed further on. For the purposes of the review, the terms '**accuracy**' and '**validity**' serve similar purposes in quantifying how close a measurement is to a 'given', a 'correct', or 'normal' and were grouped together as such separately from '**reliability**' throughout the review including within the literature search.

1.6 - Definitions of Commonly Used Terms Within the Review

According to the Merriam-Webster Dictionary, **Accuracy** refers to the degree that a piece of data conforms to a standard or true value (Merriam-Webster, n.d.) and **Validity** refers to the quality of being well grounded, sound, or correct (Merriam-Webster, n.d.). Within the context of 3D scanning both of these terms were applied to the concept of the spatial data and subsequent 3D model being as close to the morphology of the real-life object as possible and that is the general definition of these two terms that is used for the duration of the review. Merriam-Webster's definition of **Reliability** is the extent at which an experiment, test, or measurement procedure yields the same results on repeated trials (Merriam-Webster, n.d.). Within the context of 3D scanning and this review, this term was applied to the concept of a 3D scanner yielding the same results on repeated trials/scanning sessions.

Spatial data refers to the data that represents the location of features of an object and how it is represented in 3D space. As explained earlier, light and laser-based 3D scanners bounce light off of a point on a surface or object and are able to calculate the distance and position of that point through the speed/angle at which the light returns and referencing it with other established points. A collection of points with spatial data (i.e., their position) established by the scanner is known as a **point-cloud**, simply a larger 'network' representation of the spatial data of an object or surface. This larger 'network' of spatial data can then be given to CAD software, usually provided, or sold by the 3D scanner manufacturers or larger CAD software companies like Autodesk, that then fills in the gaps of the point cloud to create a 3D model which is a digital representation of the object or surface.

For the purposes of the review, **method** is defined as the scientific method used for the study (i.e., if the study was a randomised controlled trial, how many participants, etc…), **technique** is defined as the technique used to scan and quantify/represent accuracy/validity and reliability (i.e., if they took the first scan or scanned until they got one they deemed good enough for study, if they used inter-rater reliability or intra-rater reliability), and **equipment** meaning the devices, software, and general objects used to carry out the study (i.e., if they used a handheld laser triangulation scanner or a stationary white light scanner, etc…).

1.7 - Scoping Review Objectives

The objective of this scoping review was to identify the available knowledge on the methods, techniques, and equipment used for assessing the accuracy/validity and reliability of the spatial data produced from 3D scanners when used on human subjects within the context of prosthetics and orthotics.

1.8 - Scoping Review Questions

The key questions that aim to be answered by our review are:

- How much literature is there that addresses the accuracy/validity or reliability of spatial data produced by 3D scanners in a P&O context?
- What methods, techniques, and equipment are used amongst the research community to analyse the accuracy/validity and reliability of spatial data produced by 3D scanners in a P&O context?

2 - Methods

2.1 - Study design

The chosen study design was a scoping review of published literature acquired from databases. No participants or special equipment were required to complete the study. This is discussed further in section 4.6.

2.2 - Protocol and Registration

The Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guideline is the protocol used for this study (Tricco et al., 2018). Librarians and prosthetist/orthotists experienced in 3D scanning were not consulted during the review process due to the straight-forward nature of the PRISMA-ScR guidelines and a desire to keep the scope of the search wide for the purposes of the scoping review.

Registration for this study was deemed unnecessary since it is a scoping review and not intended for publishing.

2.3 - Eligibility Criteria

In order to increase the relevance of the studies initially received in our search, these eligibility criteria were used as parameters to follow for the initial uptake of studies:

- The study must have been published in or after 2010 in order to exclude outdated information
- One of the officially translated languages of the study must be English so there is a guarantee of either an original English language study or an official English language translation confirmed by the authors instead of using a potentially inaccurate unofficial translation
- The study must be peer reviewed and have a full-text available so the full detail of the study can be reviewed, this way if relevant information is mentioned, it won’t be overlooked if it isn’t present in the abstract.

Further search strategies were needed in order to ensure that the literature collected was relevant and of sufficient quality. These are explained in the following sections however eligibility criteria related to relevance of the literature includes these topics:

- Analyses **both/either** the accuracy or reliability of spatial data from 3D scanners
- The 3D scanners are used on **human morphology**
- The study is performed within a P&O related context

This relevance related criteria will be explained further on in more detail, this brief outline chiefly serving as clear guidelines for certain steps of the evidence source selection.

Other forms of literature such as manuals or conference papers were not specifically excluded from the study, and some were included in the initial uptake but after screening they were excluded.

2.4 - Information sources

The databases used are displayed in Table 1:

Table 1 - Information Sources with Database Names and Descriptions

Database Name	Database Description
Pubmed	Database search engine that mainly displays references and abstracts from the MEDLINE database with life sciences and biomedical focus, the database is maintained by the United States National Library of Medicine and is free to access
Cumulative Index to Nursing and Allied Health Literature (CINAHL)	Index of studies that mainly focus on allied health, biomedicine, nursing, and healthcare, the database is owned by EBSCO Publishing, and is ran as a for profit
Scopus	Index of Abstracts and citations on top level subjects including health sciences, physical sciences, engineering, social sciences, life sciences, the index is owned by Elsevier and is ran as a for profit
Cochrane Library	A collection of databases in medicine and healthcare primarily focusing on systematic reviews and meta-analysis, the database is owned by Cochrane and published by Wiley and ran as a for profit
Web of Science	Multidisciplinary database with citation indexes covering sciences, social sciences, medicine and technology, the database is owned by Clarivate and is ran as a for profit
AMed	Database mainly focused on medicine and allied health subjects, the database is produced by the Health Care Information Service of the British Library and published by EBSCO publishing and is ran as a for profit

2.5 - Search

The search was conducted on March 25th, 2022.

2.5.1 - Population-Concept-Context Framework

The Population-Concept-Context (PCC) framework was used to identify the main concepts and review questions. This framework is specifically designed to be used for scoping reviews and differs from PICO (Patient/population, Intervention, Comparison and Outcomes) as there is no need for explicit outcomes for the scoping review format (Huang et al., 2006; Peters et al., 2017) and it overall being much less restrictive. The PCC framework was chosen as it functions as a good support system in the same way that PICO would help support a systematic review by identifying key areas and words. PCC helped to inform our search strategy, research question, and find any search criteria that may have been missed.

The application of the PCC framework to the research question has been summarised in Table 2. The key elements of PCC are population, concept, and context. Literature suggests that the 'population' element of the PCC framework isn't relevant for all scoping reviews as some may lack a specified cohort. Chapter 11 of the JBI Reviewer's Manual indicates that this field should include important characteristics of participants for instance age/sex/other qualifying criteria (Peters et al., 2020). The manual also states that the population can be undefined but implied by the concept to keep the question open (Peters et al., 2017). The aim of this review was to map the available literature that assesses the accuracy and reliability of 3D scanning for prosthetics and orthotics, leaving a very vague population for the PCC framework. The population category of the framework hasn't been used so the scope of the search can instead be bounded by the concept and context of the research question, as selecting a specific population risks unnecessarily excluding relevant literature.

The collated PCC framework definitions and subsequent search terms are presented in Table 2:

Table 2 - PCC Framework Table with Search Terms

PCC element	Definitions	Search terms/parameters (standard Boolean operators)
Population	n/a	n/a
Concept	• The accuracy and reliability of 3D scanners	accuracy OR reliability OR validity OR measurement OR assessment OR evaluation AND 3D Scan OR 3D scanner OR scanning OR Surface Scanner 3D Digitizers NOT printing

(Table 2 continued on the next page)

Table 2 - Continued

PCC element	Definitions	Search terms/parameters (standard boolean operators)
Context	• Orthopaedic prosthetics and orthotics (non-dental, non-surgical, non-implant) • Human physiology/morphology (non-animal) • English language studies that are peer reviewed Studies from 2010 or newer	prosthetic OR prosthetist OR orthotic OR orthotist AND prosthesis OR orthosis AND human OR physiology OR morphology OR limb NOT dental OR oral OR implant OR cardiac

The process for determining a good and encompassing search term string for the literature search was iterative. Variations of the final search string were tried and developed until studies of title and abstract relevance according to the eligibility criteria and PCC framework (see Table 2 above) were produced in the search. The following are the progressive iterations of the search shown in Table 3. The search string iterations were tested in Pubmed with no filtering.

Table 3 - Table Showing Iterative Development of Search Terms

No.	Search term string	Number of results
1	((3D Scan OR 3D Scanning OR 3D Scanner) AND (Prosthetist OR Orthotist OR Prosthetic OR Orthotic) AND (Prosthesis OR Orthosis) AND (Human OR physiology OR morphology OR limb) AND (Accuracy OR reliability OR validity OR measurement OR assessment OR evaluation)) NOT Dental	122
2	((3D Scan OR 3D Scanning OR 3D Scanner) AND (Prosthetist OR Orthotist OR Prosthetic OR Orthotic) AND (Prosthesis OR Orthosis) AND (Human OR physiology OR morphology OR limb) AND (Accuracy OR reliability OR validity OR measurement OR assessment OR evaluation)) NOT (Dental OR Oral OR Printing OR Implant OR Cardiac)	53

(Table 3 continued on the next page)

Table 3 - Continued

No.	Search term string	Number of results
3	((3D Scan OR 3D Scanning OR 3D Scanner OR Surface Scanner) AND (Prosthetist OR Orthotist OR Prosthetic OR Orthotic) AND (Prosthesis OR Orthosis) AND (Human OR physiology OR morphology OR limb) AND (Accuracy OR reliability OR validity OR measurement OR assessment OR evaluation)) NOT (Dental OR Oral OR Printing OR Implant OR Cardiac)	60
4	((3D OR Scanner OR Scan) AND (Prosthetist OR Orthotist OR Prosthetic OR Orthotic OR Prosthesis OR Orthosis) AND (Human OR physiology OR morphology OR limb) AND (Accuracy OR reliability OR validity OR measurement OR assessment OR evaluation) AND (CAD OR CAM OR Computer Aided Design OR Computer Aided Manufacture OR shape capture)) NOT (Dental OR Oral OR Printing)	270
5	((3D Scan OR 3D Scanning) AND (Prosthetist OR Orthotist OR Prosthetic OR Orthotic OR Prosthesis OR Orthosis) AND (Human OR physiology OR morphology OR limb) AND (Accuracy OR reliability OR validity OR measurement OR assessment OR evaluation) AND (CAD OR CAM OR Computer Aided Design OR Computer Aided Manufacture OR shape capture)) NOT (Dental OR Oral OR Printing OR Implant OR Cardiac)	26
6	((3D Scan OR 3D Scanning OR 3D Scanner OR Surface Scanner OR 3D Digitisers) AND (Prosthetist OR Ortho* OR Prosthe*) AND (Prosthesis OR Orthosis) AND (Human OR physiology OR morphology OR limb) AND (Accuracy OR reliability OR validity OR measurement OR assessment OR evaluation)) NOT (Dental OR Oral OR Printing OR Implant OR Cardiac)	351
7	((3D Scan* OR Scan* OR Surface Scanner* OR 3D Digitiser*) AND (Prosthe* OR Orthotist OR Orthotic OR Orthosis) AND (Human OR physiology OR morphology OR limb) AND (Accuracy OR reliability OR validity OR measurement OR assessment OR evaluation)) NOT (Dental OR Oral OR Printing OR Implant OR Cardiac)	2805
8 (Final)	**((3D Scan OR 3D Scanning OR 3D Scanner OR Surface Scanner OR 3D Digitisers) AND (Prosthetist OR Orthotist OR Prosthetic OR Orthotic) AND (Prosthesis OR Orthosis) AND (Human OR physiology OR morphology OR limb) AND (Accuracy OR reliability OR validity OR measurement OR assessment OR evaluation)) NOT (Dental OR Oral OR Printing OR Implant OR Cardiac)**	**61**

Note for Table 3 - Standard Boolean operator syntax (Bramer et al., 2018) was used to display our search term strings within Table 3. In all but one of the databases and registers used throughout the review, the same standard Boolean syntax was used. In the database **Scopus**, the Boolean operator 'NOT' was substituted with the operator 'AND NOT', otherwise standard syntax was used.

As shown in Table 3, tests were done using asterisks such as 'Ortho*' to search all forms of the words it was applied to, this produced a lot more results in testing (n=351) the majority of those being focused on general surgical orthopaedics rather than corrective orthotic bracing, so the search string was altered to not utilise asterisks.

Through the use of the initial exclusion criteria and streamlined search terms, a population of studies could be obtained that could then be screened further to then get a population of relevant studies that could be used for the scoping review. PRISMA offers different types of flow diagram templates on their website that are specifically tailored for evidence selection within meta-analysis. Pictured in Figure 1 is a flow diagram template taken from the PRISMA updated guidelines by Page et al. (2021). This flow diagram has been used and adapted for use in studies (Pham et al., 2014) and books on scoping review study design (Peters et al., 2017). This flow diagram was used within our review to further screen literature after the initial uptake.

Both authors independently searched for studies on these databases and as specified in the previous flow diagram, duplicate studies were removed both between the pools of studies collected by the authors and repeat studies between the different databases/search engines. Further data collection was then carried out on each of the studies after the screening was complete where data relevant to our scoping review was logged for further analysis. This data included the methods used by the authors of each study to quantify accuracy and reliability, then whether studies specify just accuracy or reliability or include analysis of both, interpretations of data and other relevant points. These processes are explained in the following sections of the review.

2.6 - Selection of Sources of Evidence

The process for selecting sources of evidence for the review contained several steps to ensure the relevance of the sources used. The flow diagram design suggested by PRISMA for meta-analysis (Page et al., 2021) was used to plan out the selection (Figure 2). This flow diagram lays out the selection process into two main sections, identification/ screening, and a final 'included' section as pictured in Figure 1. The method of the search is laid out here:

1. The search string that was developed was used to return an initial pool of literature noted in **box 1**. Duplicates and records removed for other reasons were not included going further and noted in **box 2**. The remaining records after this first stage were noted in **box 3** ([**box 1**]-[**box 2**]).
2. The studies in **box 3** were screened by reading the titles and abstracts of each study and determining if they were relevant. The number of studies found not relevant were noted in **box 4** and removed from the pool. The number of studies that were found relevant were noted in **box 5**.
3. The **box 5** studies were then checked to see whether they have a full-text version available. The studies that didn't were removed from the pool and noted in **box 6** and those that did were noted in **box 7**.
4. **Box 7** studies then were full-text screened. Each study was read completely and checked alongside the eligibility and relevance criteria mentioned before. The studies that do not pass this check were logged into **box 8** alongside the reason why each of which were excluded (studies that were excluded for multiple reasons were not logged twice). The studies that passed this check were logged in **box 9** and functioned as our sources for evidence within this study

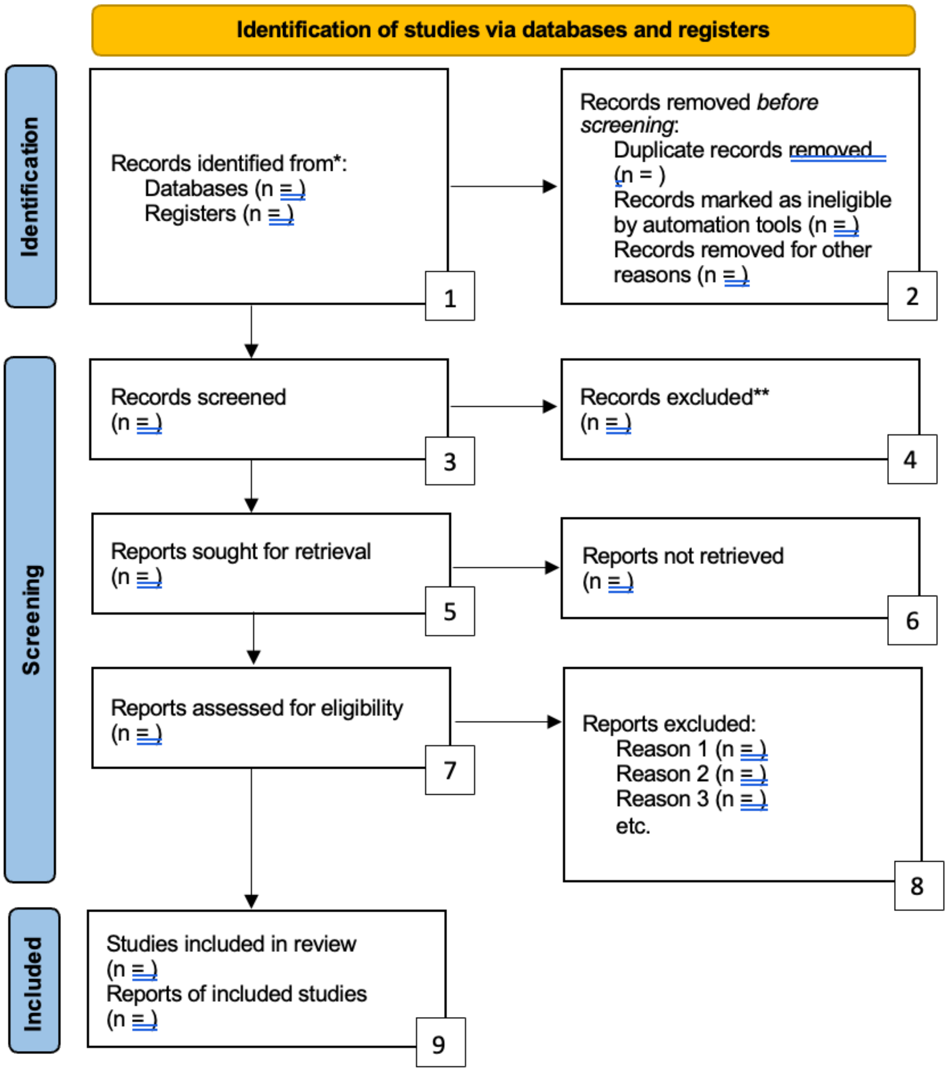

Figure 1 - PRISMA Flow Diagram used for the review (Page et al., 2021) with numbered boxes

The selection was performed by both researchers separately to ensure that the chance of one researcher deeming a relevant study irrelevant could be reduced (Mikolajewicz & Komarova, 2019). Then finally the results of each researcher's data collection were compared, and conflicting studies were discussed and either included or excluded depending on a joint decision between each researcher. The reference lists of each article in our final source literature pool will also be checked for relevant articles.

2.7 - Data Charting Process

Data was retrieved from each of the evidence sources and collated into tables (Table 4, Table 5, Table 6, and Table 7) for ease of analysis. The retrieval of data was performed by both researchers and confirmed by cross-referencing retrieved data between each researcher. The tables in which data was logged each include a shortened version of the reference to the study (including shortened author names i.e., [name] et al.), the database in which it was retrieved from, and short descriptions/indications on the extent of data pertaining to the variables chosen to search for and as to whether they were included in the study. Variables of which data were sought is discussed in the following section.

2.8 - Data Items

For the purposes of clarity, the data items were organised and recorded from the evidence sources into different groups. These were: inclusion data variables, methodological data variables, limitation-related data variables, standards and regulations, and additional themes.

2.8.1 - Inclusion data variables

One group of data variables recorded within this review was centred around inclusion of the topics relevant to our review. This means recording the number of studies that analyse either the accuracy or the reliability of the scanners as well as the number of studies that do both. That provides a numerical context to the amount of literature that exists for each specific topic: accuracy/validity or reliability.

2.8.2 - Methodological data variables

The methods, techniques, and equipment (see glossary for each term) applied in the studies to test the accuracy/validity of the 3D scanner were recorded i.e., comparing between 'control' measurements and 3D-scanned 'test' measurements or other methods. The methods, techniques, and equipment used for testing the reliability of the 3D scanner were also recorded i.e., if it's a comparison between scanners, or a comparison between different users, or under different conditions. In order to distinguish between different techniques, several different terms have been used:

- **Inter-rater** reliability
    - Reliability of measurements between operators with the same scanner
- **Intra-rater** reliability
    - Reliability of measurements with the same operator and the same scanner with emphasis on the rater's reliability
- **Inter-scanner** reliability
    - Reliability of measurements with the same operator between scanners
- **Intra-scanner** reliability
    - Reliability of measurements with the same scanner with the same operator with emphasis on the scanner's reliability
- **Test-retest** Reliability/**Inter-session** Reliability
    - Reliability of measurements taken at different points in time/between sessions where the sample and conditions are the same

For each study, the method, technique, and equipment applied all were recorded separately in addition to how results were quantified/displayed.

2.8.3 - Limitation-related data variables

Any problems, challenges, or limitations with the methods, technique, or equipment mentioned by the researchers in the reviewed studies were recorded in three specific 'limitations' variables, as different scanning technologies, statistical techniques, research methods, etc… can all have their inherent limitations that could have affected the study. Along with knowledge gaps, any overarching conclusions on study limitations in this area made by different researchers in different studies were recorded for further analysis.

2.8.4 - Standards and Regulation

There are some standards and regulations within the field of 3D scanning, however they are either not general or don't cover every aspect of 3D scanners, instead covering smaller areas or principles. An example of this is the ISO 20685-1:2018 which is a standard for assessing the accuracy of measurements of body dimensions from 3D scans for use in design, the standard is however only for one dimensional measurement such as ones that could be obtained with a tape measure or callipers, and not the overall shape of the limb (International Organization for Standardization, 2018).

The EU regulates the laws pertaining to lasers and thereby also laser-based scanners. The regulation for lasers is based on an international standard of classifications (Weiner, 2003) that categorises the lasers based on power output and how focused the laser beam is, the categories are meant to classify the lasers by what safety precautions are needed to use them. Most laser scanners are category 2M which is safe unless it's viewed through an optical instrument. This classification may be relevant in some studies where 3D scanning equipment is used either for safety reasons or with regards to the testing they are being used for. Logging the inclusion/mention of standards and regulation of such technologies within our target studies allows us to discuss the awareness of researchers on these matters.

2.8.5 - Additional themes

Common themes and topics amongst the source literature were also logged in order to identify themes in discussion amongst the authors of each study that may not directly align with our study aims but may still be of interest to this review. These additional themes and topics are discussed in the discussion section.

It was also useful to log where the study was geographically performed as that provides more context to any conclusions made or standards/regulations they may possibly be bound by.

2.8.6 - Data Variables

The data was logged into four tables (Tables 4, 5, 6, and 7), a source literature overview table (Table 4), an accuracy/validity related table (Table 5), a reliability related table (Table 6), and a table that includes the limitations/knowledge gap variables and the standards/regulatory variables (Table 7). The variables included in each table are summed up as follows:

- **Table 4: Source Literature Overview**
  - Title
  - Journal
  - Study type
  - Location of study
- **Table 5: Accuracy/Validity Analysis Within Source Literature**
  - Was the accuracy/validity of the scanner(s) analysed? [yes/no]
  - What method did the researchers use in the study to test accuracy/validity? [description]
  - What technique(s) did the researchers use to test accuracy/validity? [description]
  - What equipment did the researchers use to test accuracy/validity (including the scanner(s))? [description]
- **Table 6: Reliability Analysis Within Source Literature**
  - Was the reliability of the scanner(s) analysed? [yes/no]

    - What method did the researchers use in the study to test reliability? [description]
    - What technique(s) did the researchers use to test reliability? [description]
    - What equipment did the researchers use to test reliability (including the scanner(s))? [description]
- **Table 7: Author Specified Limitations, Standards and Regulations, and Study Context**
    - Limitations of the method
    - Limitations of the technique(s)
    - Limitations of the equipment
    - Standards and regulation discussed
    - What context within P&O?

2.9 - Critical Appraisal

Some reflection and analysis is required to ensure research quality. In this review, the inclusion of a critical appraisal of evidence that would've analysed the quality of sources and evidence included in the study was considered. This inclusion is determined to be optional for scoping reviews in the PRISMA-ScR guidelines for scoping reviews (Tricco et al., 2018) and the logic of performing a critical appraisal of evidence was weighed up when the literature search was complete. Funding sources were initially checked within each study in addition to inclusion bias which pertains to which scanners were used/included by the authors/professionals using the scanners, how prevalent was the use of the scanners, and if comparisons/observations/analysis were relevant or biased. Upon initial checks, the studies were found not to have financial sponsorship or funding from manufacturers, distributors, etc... for the scanners or software used and overall, no conflicting interests were found. For this reason, a critical appraisal was deemed to be unnecessary. This choice is expanded upon within the discussion.

2.10 - Results Synthesis Methods

The data from each source were collated into tables within the results section that were organised into the variables that were mentioned in the section 2.8 data variables. The inclusion related data was collated into a bar chart presenting the number of studies that included an analysis of accuracy/validity, the number of studies that included an analysis of reliability, and the number of studies that included both analyses. Additional graphs were also made presenting the number of subjects and raters in each study between accuracy/validity analyses and reliability analyses as it sometimes differed within the same study. The data presented was mostly descriptive, this is in line with the purpose of the scoping review.

3 - Results

3.1 - Selection of sources of evidence

As stated before, the screening of the sources of evidence for our review was undertaken using the PRISMA flow diagram (Page et al., 2021). Pictured in Figure 2 is the results of our evidence screening.

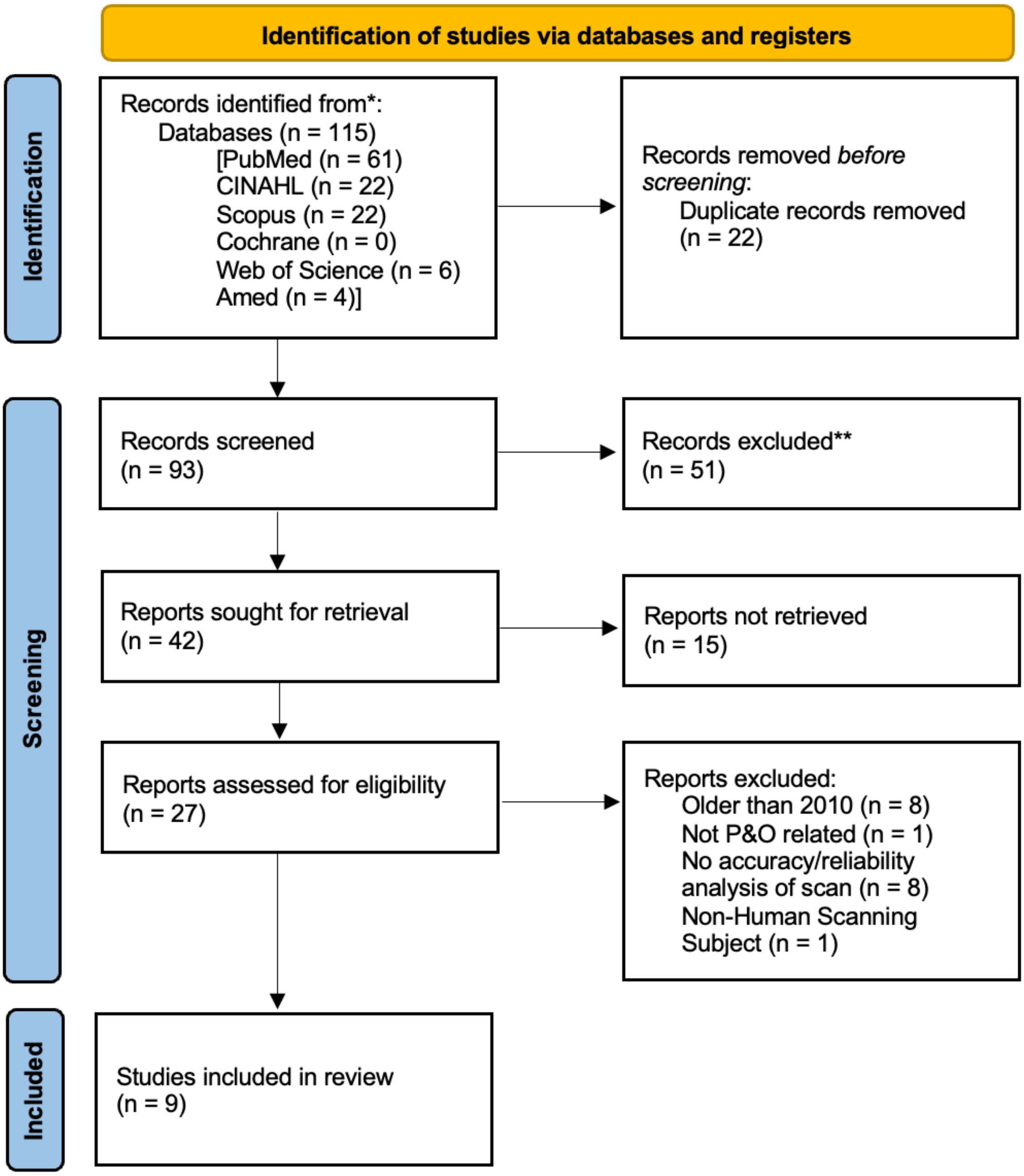

Figure 2 - Completed PRISMA Flow Diagram (Page et al., 2021) for the literature search

The screening was undertaken by both researchers and at compared the end of the screening. Both finished with 10 studies in their final evidence pool, however 2 studies in each of the authors' pools were not found in the other authors' pool (i.e., 2 studies in author 1’s pool were not included by author 2 and vice versa meaning there were in total 4 discrepant studies). Each of the discrepant studies were re-read by each author and 3 studies were excluded for reasons of not having sufficient analysis of accuracy/reliability and the remaining discrepant study was included in the final evidence pool of 9 studies, as it was found to have sufficiently passed our eligibility criteria. The reference lists of the 9 relevant articles were reviewed and no articles deemed of relevance to our review were found.

3.2 - Data Characteristics

Most of the studies were published between 2018 and 2022 (8 out of 9) though one study was published in 2010. All of the studies analysed reliability/repeatability though all but two studies analysed accuracy/validity. Two studies included were meta-analysis based with one being a systematic review of literature that analyses the reliability and validity of different shape capture methods and the other being a more general literature review on the same topic. The rest of the studies were either experimental or comparative, generally comparing the spatial data received from 3D scanning with manual measurements or other non-scanning methods such as water displacement. General information associated with each study is presented in Table 4:

Table 4 - Source Literature Overview table with Information on each study

Study	Title	Journal	Study Type	Location of the study
Armitage et al., 2019a	Reliability and Validity of Measurement Tools for Residual Limb Volume in People With Limb Amputations: A Systematic Review	CINAHL	Systematic review	Unspecified
Armitage et al., 2019b	Reliability and validity of the iSense optical scanner for measuring volume of transtibial residual limb models	CINAHL	Experimental study	Sydney, Australia
Dickinson et al., 2022	Selecting Appropriate 3D Scanning Technologies for Prosthetic Socket Design and Transtibial Residual Limb Shape Characterization	CINAHL	Experimental study	Cambodia
Kofman et al., 2018	Measurement properties and usability of non-contact scanners for measuring transtibial residual limb volume	CINAHL	Experimental study	Netherlands
Powers et al., 2022	Reliability and validity of 3D limb scanning for ankle-foot orthosis fitting	Pubmed	Experimental study	Iowa, United States
Rogati et al., 2019	Validation of a novel Kinect-based device for 3D scanning of the foot plantar surface in weight-bearing	Pubmed	Experimental study	Italy
Rogati et al., 2021	Semi-automatic measurements of foot morphological parameters from 3D plantar foot scans	Pubmed	Experimental study	Italy
Seminati et al., 2022	Reliability of three different methods for assessing amputee residuum shape and volume: 3D scanners vs. circumferential measurements	Pubmed	Experimental study	United Kingdom
Telfer & Woodburn, 2010	The use of 3D surface scanning for the measurement and assessment of the human foot	Scopus	Meta analysis	Glasgow, UK

3.3 - Results of Individual Sources Evidence

Summarised in Table 5, Table 6, and Table 7 is the information that was gathered from each study. Table 5 presents information from each study pertaining to accuracy/validity analysis, identifying if this analysis was done, and if so which methods, techniques, and equipment were used. Table 6 presents the same format of information as Table 5 though for reliability analysis within the source literature. Table 7 presents information from each study pertaining to limitations of the method, technique, and equipment identified by the authors of each study in addition to showing the extent at which standards and regulations were discussed within each study and the context within P&O the study was performed.

Table 5 - Accuracy/Validity Analysis Within Source Literature Table

Study	Was the accuracy/validity of the scanner(s) analysed? (yes/no)	What method was used to test accuracy/validity?	What technique(s) was used to test accuracy/validity?	What equipment was used to test accuracy/validity?
Armitage et al., 2019a	yes	Systematic review that analyses accuracy and reliability of P&O 3D scanning related studies, varied number of raters, varied number of subjects	Intraclass Correlation Coefficient, Pearson Correlation Coefficient, Coefficient of Variation	Multiple mentioned scanners [**Omega tracer, VA Cyberware, Custom-built scanners, VITUS 3D Body scanner**], computed tomography software and equipment
Armitage et al., 2019b	yes	Comparison of scan data to a metal rod, 1 rater, 1 subject	T-test (Mean differences in volume standard deviation)	1 Scanner [**iSense scanner**], known volume Ipad, Netfabb Basic, SPSS 24
Dickinson et al., 2022	no	n/a	n/a	n/a
Kofman et al., 2018	yes	Comparison of scan data to positive foam model, 4 raters, 9 subjects,	Paired sample t-test	3 Scanners [**Omega scanner, Biosculptor Bioscanner, Rodin4D O&P Scanner**], SPSS 22, TT Design System software, BioSculptor Shape software, Omega Tracer Software, Rodin4D Software
Powers et al., 2022	yes	Comparison of scan data to real-life object, 2 raters, 30 subjects	Pearson Correlation Coefficient, Intra Correlation Coefficient Bland–Altman plots	1 Scanner [**Original Structure Sensor scanner**], OriginCal IP54 digital caliper, iPad,Scanner app by Standard Cyborg Inc, Design Studio software, Microsoft Excel 2016 SPSS 25

(Table 5 continued on the next page)

Table 5 - Continued

Study	Was the accuracy/validity of the scanner(s) analysed? (yes/no)	What method was used to test accuracy/validity?	What technique(s) was used to test accuracy/validity?	What equipment was used to test accuracy/validity?
Rogati et al., 2019	yes	Comparison of scan data to real-life object, unspecified number of raters, 14 subjects	Root Mean Square Error (RMSE)	2 Scanners [**Microsoft Xbox Kinect Sensor 2012, i-Qube**], Skanect for Windows, Geomagic Control™, PodoBox, powerful laptop computer, Matlab
Rogati et al., 2021	yes	Comparison of scan data to real-life object, 1 rater, 44 subjects	Non-parametric paired Wilcoxon signed-rank test, average percentage error, Bland-Altman plots	1 Scanner [**Microsoft Xbox Kinect Sensor 2012**], PodoBox, Skanect for Windows, Geomagic Control™, Matlab
Seminati et al., 2022	no	n/a	n/a	n/a
Telfer & Woodburn, 2010	yes	Meta analysis comparing studies that analyse the accuracy and reliability of surface scanning of feet, varied number of raters, varied number of subjects	Studies that include: Intraclass correlation coefficients	1 Mentioned Scanner [**Infoot 3D foot digitiser**]

Table 6 - Reliability Analysis Within Source Literature Table

Study	Was the reliability of the scanner(s) analysed? (yes/no)	What method was used to test reliability?	What technique(s) was used to test reliability (and what was it measured in)?	What equipment was used to test reliability?
Armitage et al., 2019a	yes	Systematic review that analyses accuracy and reliability of P&O 3D scanning related studies, varied number of raters, varied number of subjects	Studies that included: Intra-rater reliability (Intraclass Correlation Coefficient, ICC), Inter-rater reliability (ICC), Between-session reliability (Coefficient of Variation, CV), Within-session reliability (CV)	Multiple mentioned scanners [**Omega tracer, VA Cyberware, Custom-built scanners, VITUS 3D Body scanner**], Water Displacement Equipment, electromagnetic digitization equipment, computed tomography software and equipment
Armitage et al., 2019b	yes	Comparison of scan data to positive plaster cast, 3 raters, 1 subject	Intra-scanner reliability (ICC), Inter-rater reliability (ICC)	1 Scanner [**iSense Optical Scanner**], Netfabb Basic, SPSS 24

(Table 6 continued on the next page)

Table 6 - Continued

Study	**Was the reliability of the scanner(s) analysed? (yes/no)**	**What method was used to test reliability?**	**What technique(s) was used to test reliability (and what was it measured in)?**	**What equipment was used to test reliability?**
Dickinson et al., 2022	yes	Comparison of scan data to positive plaster cast, 2 raters, 11 subjects	Inter-rater reliability (ICC), Intra-scanner reliability (ICC)	3 Scanners [**Creaform Go!SCAN, RealSense SR300, iSense/Structure Sensor**], AmpScan, MATLAB
Kofman et al., 2018	yes	Comparison of scan data to positive foam model, 4 raters, 6 subjects	Intra-rater test-retest reliability (ICC) [2 sessions on separate dates each with 2 scans taken of each subject]	3 Scanners [**BioSculptor Bioscanner, Omega Scanner, Rodin4D O&P Scanner**], BioSculptor Shape software, TT Design System software, Omega Tracer software, SPSS 22
Powers et al., 2022	yes	Comparison of scan data to manual calliper measurements, 2 raters, 30 subjects	Intra-rater test-retest reliability (ICC) [Two sessions within a day with 3 scans taken of each subject in each session]	1 Scanner [**Original Structure Sensor scanner**], iPad, Design Studio, Microsoft Excel 2016, OriginCal IP54 digital calliper, SPSS 25
Rogati et al., 2019	yes	Comparison of scan data to scan data from higher-resolution scanner, unspecified number of raters, 14 subjects,	Inter-rater test-retest repeatability (CV) [3 sessions each a day apart]	1 Scanner [**Microsoft Xbox Kinect Sensor 2012**], PodoBox, Skanect for Windows 1.8, i-Qube scanner, Geomagic Control, MATLAB
Rogati et al., 2021	yes	Comparison of scan data to manual measurements, 1 rater, 10 subjects	Intra-rater test-retest reliability (ICC) [3 sessions within a day with two scans for each subject (one for each foot)]	1 Scanners [**Microsoft Xbox Kinect Sensor 2012**], PodoBox, Geomagic Control, MATLAB
Seminati et al., 2022	yes	Comparison of variance in data between scanners and manual measurements, 3 raters,10 subjects	Inter-rater reliability (ICC), Intra-rater reliability (ICC)	2 Scanners [**Omega scanner 3D, Artec Eva scanner**], Circumferential Manual Measurements, Artec Studio 10, Minitab 18, VXelements
Telfer & Woodburn, 2010	yes	Meta analysis comparing studies that analyse the accuracy and reliability of surface scanning of feet, varied number of raters, varied number of subjects	Studies that included: Intra-rater reliability (ICC)	Mentioned Scanner [**Infoot 3D foot digitiser**]

Table 7 - Author Specified Limitation, Standard and Regulations, and Study Context

Study	Limitations of the method?	Limitations of the technique(s)?	Limitations of the equipment?	Were standards and regulations surrounding scanning discussed?	What context within P&O?
Armitage et al., 2019a	Inclusion criteria could be too tight (i.e., only applicable for transtibial amputees)	Untested reliability/validity of critical appraisal/study quality rating scale for evidence within review	Different types of scanners used potentially more suited to different objects/environments potentially creating a bias in the results when inclusion criteria specified use on human subjects	Recommended standardisation of scanning duration and positioning though no relevant standard/regulations mentioned	Systematic review on reliability and validity measurement tools, residual limb volume
Armitage et al., 2019b	No prosthetist rater, scan time wasn't standardised, inverted limb models don't represent clinical practice	Intra-rater reliability of assessors was not investigated	Scanner not optimised for geometry of residual limb cast (right angles)	Not Mentioned	Comparison of 3D scanner to positive plaster cast, transtibial residual limb
Dickinson et al., 2022	Small sample only representing trauma related amputations, only male subjects, volume of limb could change over casting and scanning session	Inter-rater reliability for the plaster casting was not assessed	Artefacts within the scans could lower validity of the processing of the models in the AmpScan 3D modelling software	The need for "gold-standards" for shape capture tools is discussed though no official standards are used.	Comparison of 3D scanner to positive plaster cast, transtibial residual limb
Kofman et al., 2018	Risk of human error (complex method, multiple independent raters)	Inconsistency of manual measurements (model shrank in size over time) causes inconsistencies in both inter- and intrarater reliability data	Scanner shows limited accuracy with certain geometry, calibration issues, sunlight exposure, scanner not optimised for models' surface	Not Mentioned	Comparison of 3D scanner to positive foam model, transtibial residual limb

(Table 7 continued on the next page)

Table 7 - Continued

Study	Limitations of the method?	Limitations of the technique(s)?	Limitations of the equipment?	Were standards and regulations surrounding scanning discussed?	What context within P&O?
Powers et al., 2022	Access to the plantar surface was difficult due to the small size of the scanning cube, possibility of human error (markers placed manually)	Inter-rater reliability of collecting the scan was not evaluated	Higher scanning apparatus for subjects lower leg needed for better scanner access to plantar surface of foot	A lack of standards pertaining to AFOs is discussed	Comparison of 3D scanners and manual measurements from human subjects, bilateral feet up to ankle, AFO focus specified
Rogati et al., 2019	Small sample of scan subjects, requirements of population are strict (adults only)	Inter-rater reliability not investigated	Noisy data could be present in scanning scenarios which influences statistical analysis if not checked	Not Mentioned	Comparison of target 3D scanner data to high precision 3D scanner data, bilateral plantar surface of foot
Rogati et al., 2021	Possibility of human error in editing of scans	Test-Retest results potentially unreliable with different types of loading within the 'Podobox'	'Podobox' compresses soft tissue on both plantar and sides of foot causing measurements to naturally differ	Not Mentioned	Comparison of target 3D scanner data to manual measurements, bilateral feet plantar surface
Seminati et al., 2022	Actual human residuum volume cannot be known and therefor comparing to it is impossible, sample size is small	Manual alignment of scan data can introduce more variables,	Scans relying on markers introduce more room for error via miscalibration/maladjustment to environment	Not Mentioned	Comparison of 3D scanners to manual measurements, transfemoral and transtibial amputees

(Table 7 continued on the next page)

Table 7 - Continued

Study	Limitations of the method?	Limitations of the technique(s)?	Limitations of the equipment?	Were standards and regulations surrounding scanning discussed?	What context within P&O?
Telfer & Woodburn, 2010	Only two databases used for initial evidence search limiting results, other sources used to find studies kept vague affecting repeatability of study	No study protocol followed for meta-analysis	Lack of focus on scanners that are applicable in clinical context	International standards: ISO 20685, ISO 7250, current standards are limited to linear measurements and relevant girth should be added, missing standard of foot preparations pre-scanning	Meta analysis of areas pertaining to feet

3.4 - Synthesis of Results

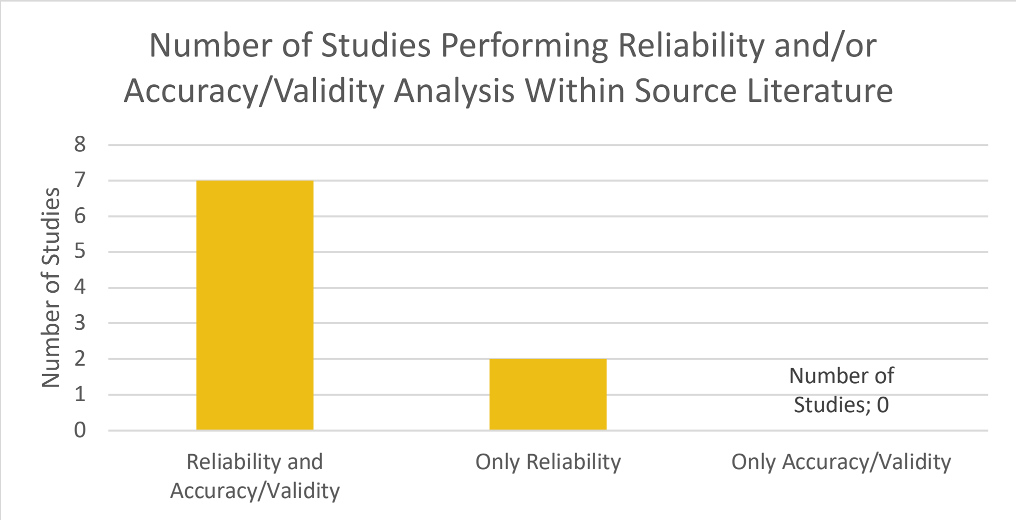

Figure 3 – A bar chart presenting the Number of Studies Performing Reliability and/or Accuracy/Validity Analysis Within the Source Literature

Figure 3 presents the number of studies performing reliability and/or accuracy/validity analysis within the source literature for this study. Of the 9 total studies, 7 analysed both reliability and accuracy/validity, 2 studies only analysed reliability, and no studies only analysed accuracy/validity.

3.4.1 - Accuracy/Validity:

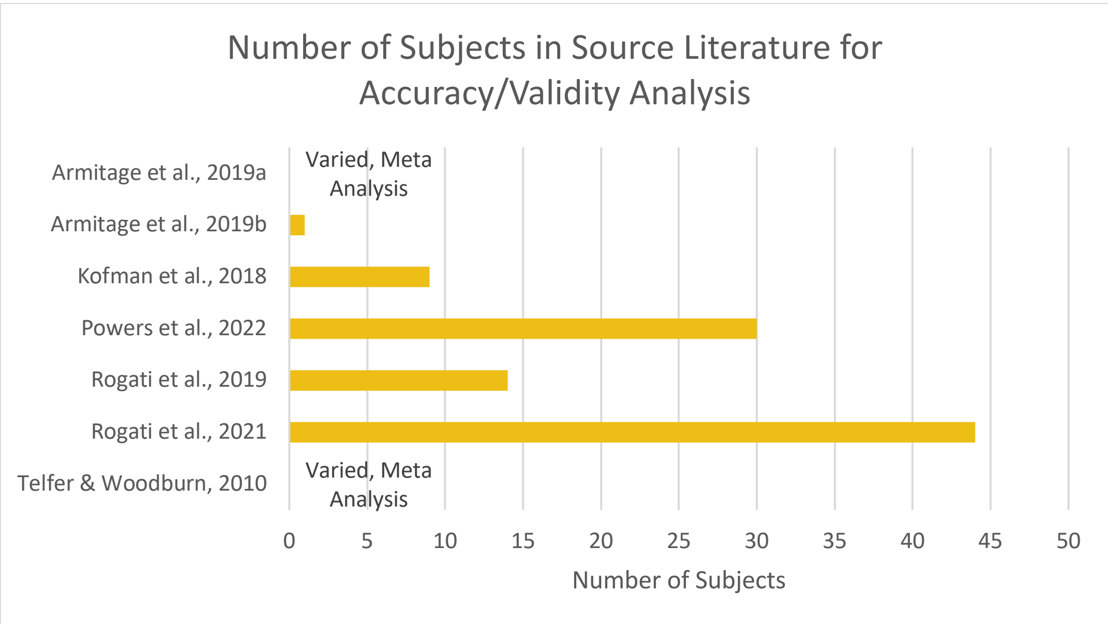

Figure 4 – A bar chart presenting the Number of Subjects in Source Literature for Accuracy/Validity Analysis

Figure 4 presents the number of subjects in the source literature that performed accuracy and validity analysis. 2 of the studies were meta-analyses (Armitage et al., 2019a; Telfer & Woodburn, 2010) and therefore had varied numbers of subjects, the mode was 44 (Rogati et al., 2021) and the study with the lowest number of subjects was Armitage et al. (2019b) with 1 subject. Not including the two meta-analyses, the mean number of subjects in accuracy/validity analysis amongst the studies was 21 (20.6).

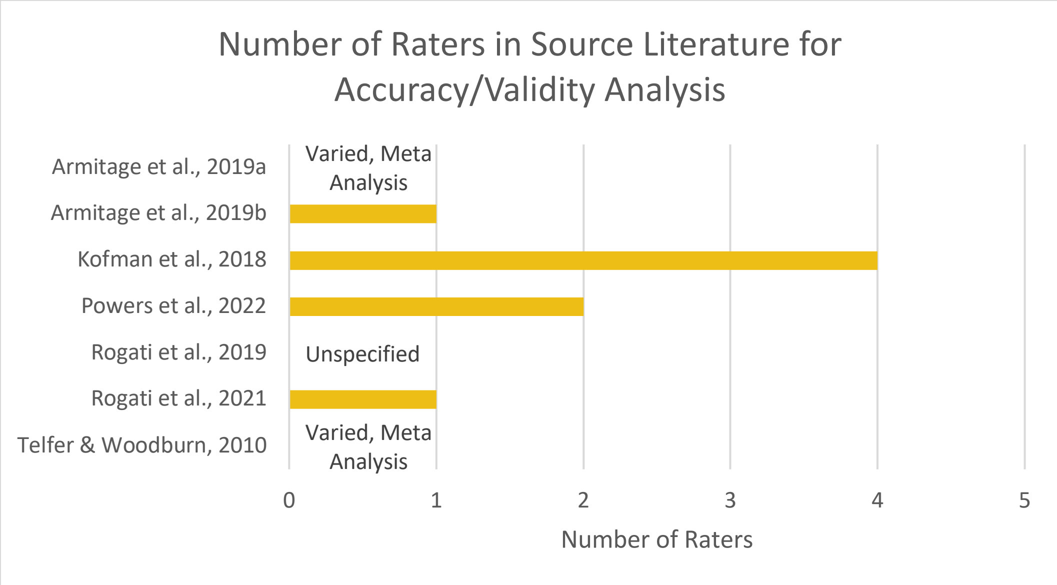

Figure 5 – A bar chart presenting the Number of Raters in Source Literature for Accuracy/Validity Analysis

Figure 5 consists of a graph presenting the number of raters in the source literature that performed accuracy and validity analysis. 2 of the studies were meta-analyses (Armitage et al., 2019a; Telfer & Woodburn, 2010) and therefore had varied numbers of raters. Rogati et al. (2019) did not specify the number of raters. The mode was 4 (Kofman et al., 2018) and the studies with the lowest number of raters were Armitage et al. (2019b) and Rogati et al. (2021) each with 1 rater. Not including the two meta-analyses, the mean number of raters in accuracy/validity analysis amongst the studies was 2.

3.4.2 - Reliability:

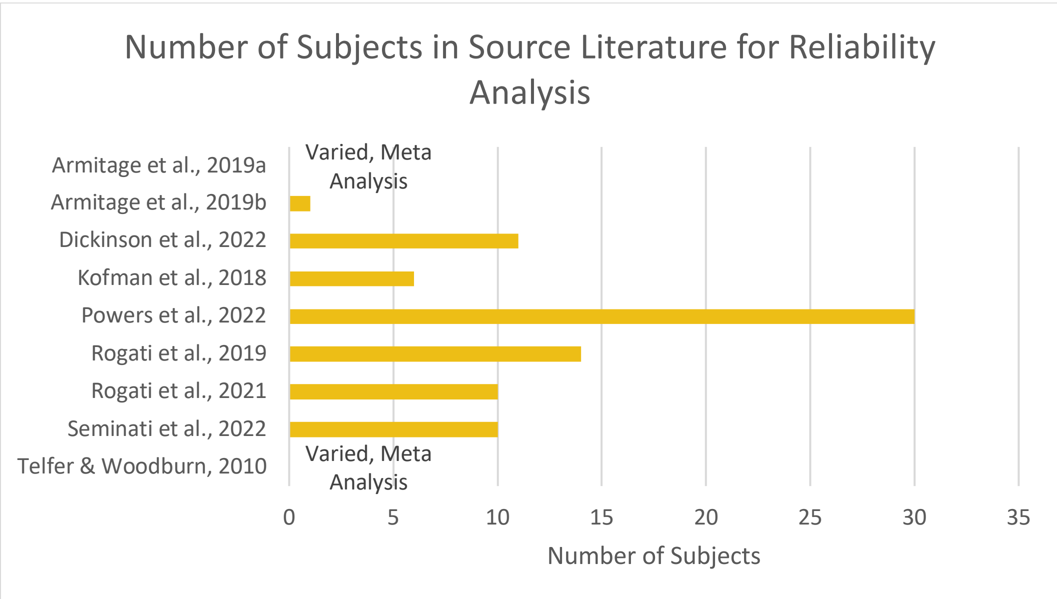

Figure 6 – A bar chart presenting the Number of Subjects in Source Literature for Reliability Analysis

Figure 6 consists of a graph presenting the number of subjects in the source literature that performed reliability analysis. 2 of the studies were meta-analyses (Armitage et al., 2019a; Telfer & Woodburn, 2010) and therefore had varied numbers of subjects. The mode was 30 (Powers et al., 2022) and the study with the lowest number of subjects was Armitage et al. (2019b) with 1 subject. Not including the two meta-analyses, the mean number of subjects in reliability analysis amongst the studies was 12 (rounded from 11.7).

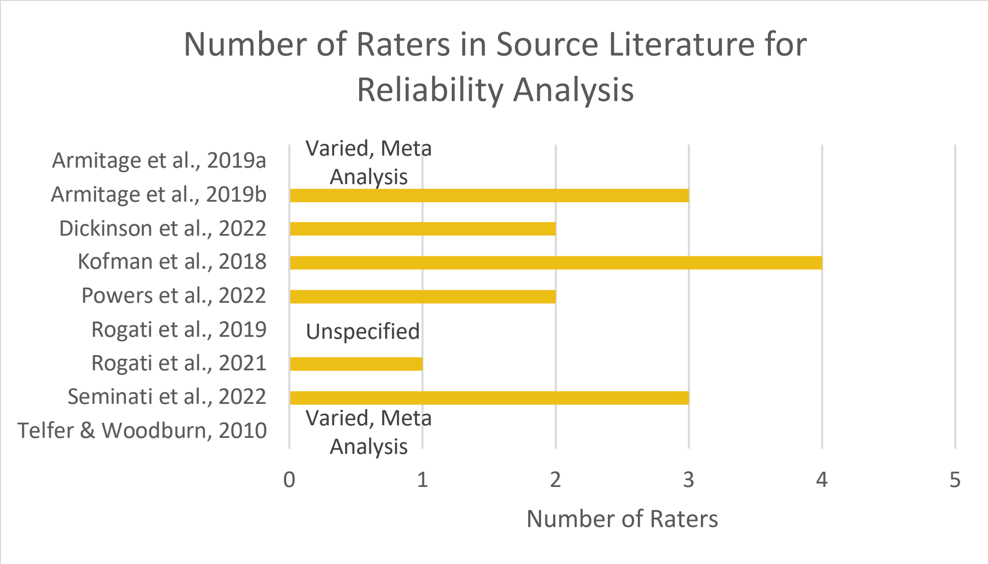

Figure 7 – A bar chart presenting the Number of Raters in Source Literature for Reliability Analysis

Figure 7 consists of a graph presenting the number of raters in the source literature that performed reliability analysis. Two of the studies were meta-analyses (Armitage et al., 2019a; Telfer & Woodburn, 2010) and therefore had varied numbers of raters. Rogati et al. (2019) did not specify the number of raters. The mode was 4 (Kofman et al., 2018) and the study with the lowest number of raters was Rogati et al. (2021) with 1 rater. Not including the two meta-analyses, the mean number of raters in reliability analysis amongst the studies was 3 (rounded from 2.5).

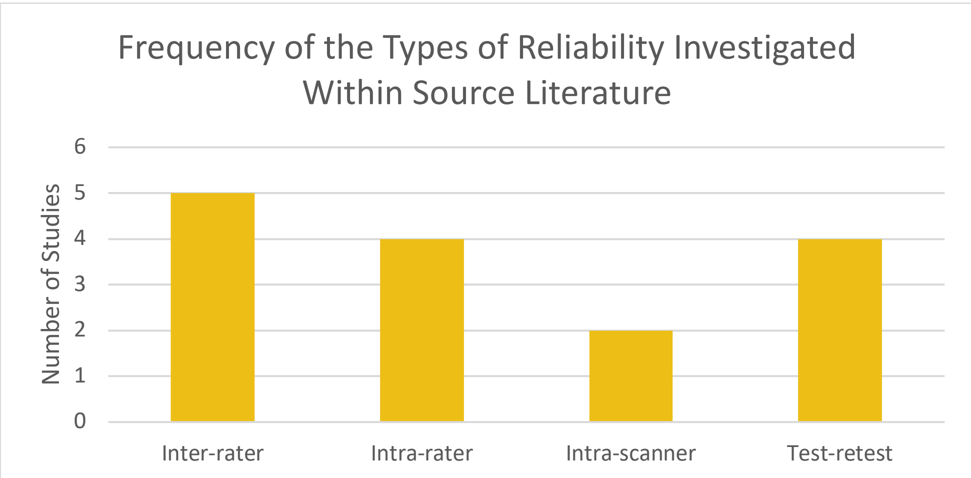

Figure 8 – A bar chart presenting the Frequency of the Types of Reliability Investigated Within Source Literature

Figure 8 consists of a graph presenting the number of studies within the source literature that performed the stated different types of reliability analysis. Of the 9 total studies, most (5) analysed inter-rater reliability. The least investigated technique was inter-scanner reliability (2).

4 - Discussion

4.1 – Addressal of Review Objective and Questions

The main objective or aim of this review is laid out in section 1.7. This objective was split into two questions explained in the following paragraphs that address the amount of literature and the types of methods, techniques, and equipment. In addition to these questions however, additional data variables were included within the review of the source literature in order to understand the thoughts of the researchers who performed the studies in question and compare the discussions between studies. As laid out in section 2.8, information such as limitations specified by the authors of the source literature, inclusion of discussion on standards and regulation within source literature, and further variables mentioned in the section were included in the data collection. This was done so a more encompassing view of the studies and the researchers therein could be attained and through that, a better idea of the handling of accuracy/reliability analysis of 3D scanning spatial data in P&O within a research context. Through this, the main objective of this review, to identify the available knowledge, was deemed to be fulfilled.

Within section 1.8 of the review, the question of how much literature there is that addresses the accuracy or reliability of spatial data from 3D scanners in a P&O context was intended to be answered by our review. Through the evidence search described in section 2, a selection of relevant literature was identified and acted as sources for our review. Amongst our source literature, reliability was investigated at a higher frequency than accuracy/validity with two of the nine studies either failing to mention accuracy or only discussing it at a surface level with no statistical analysis. Amongst the studies that didn't analyse accuracy, more established scanners such as the Omega 3D were used, and study questions were more focused on the ability of an operator to receive similar measurements using the same scanner. Accuracy/validity inclusive studies more commonly analysed custom scanners or those not usually used within prosthetics and orthotics i.e., the Microsoft Xbox Kinect Scanner were used to test their accuracy and identify how well they could function if used in a clinical setting.

The question of which methods, techniques, and equipment are used amongst the research community to analyse the accuracy and reliability of spatial data from 3D scanners in a P&O context too was intended to be answered by this review. Through the review and data collection of our source literature, common methods, techniques, and equipment used to assess the topic of interest were identified. Due to differences in method, technique, and equipment between accuracy/validity analysis and reliability analysis even within individual studies, the types of analysis have been addressed separately within sections 4.2 and 4.3 respectively.

4.2 - Accuracy and Validity Analysis Within Source Literature

Of the selected studies, seven addressed accuracy and validity, both concepts defined earlier in the background section. The methods either use data from a known high accuracy scanner or manual measurement to compare against another scanner, from there the similarities end. The studies employ vastly different methods of analysing the data, both in terms of software used but also of the technique used to quantify accuracy. The studies even differ in the specifics of what the spatial data from 3D scanning is being compared to, some examples being manual measurements of volume or length, or even 3D models created out of data from higher precision scanners. In both studies by Rogati et al. (2019; 2021) they test the Microsoft Xbox Kinect for use as a 3D scanner. The device itself was never intended for this use, instead starting off as a motion capture-based game controller, despite this they achieved a useable level of accuracy from the scans produced with the Kinect. When compared to their reference scanner, the Kinect produced a Root Mean Square Error of less than 3mm for scanning the entire plantar foot surface. The study by Powers et al. (2022) found the Original Structure Sensor scanner to be accurate for scanning the foot and ankle area, including for circumferential measurements. The study by Kofman et al. (2018) and Armitage et al. (2019b) used physical models as subjects to test accuracy and both had problems as a result of that. Armitage et al. (2019b) found the right angles of their known volume caused difficulty for the scanner and led to a loss of accuracy in that area, suggesting a limitation of the scanner tested. Kofman et al. (2018) used models made from either plaster or foam and found that one of their foam models had visibly decreased in volume during the study and had to be excluded from the data pool. The use of physical models to test accuracy for work within P&O does raise some important points for those continuing research in this manner, for instance taking precautions against models changing shape or volume during the study period.

The studies focus on two general areas of the body: residual limbs and the foot and ankle. The accuracy/validity of scanners has not been quantified in other areas of the body, so there is a gap in the research that needs to be investigated.

The studies that report accuracy/validity vary greatly in the number of raters from 1 to 4 and similarly vary in the number of subjects from 1 to 44, there was no consistency found across the studies. Armitage et al. (2019a) highlights the need for standards of how the body of the scanning subject is oriented and supported, as the volume of the subject changes depending on the load, and standardising this would make future studies more accurate and repeatable. The lack of consistency across the studies highlights the need for more standards within this field, in both method and technique, using standardised methods would aid the applicability of the studies and ease further meta-analysis.

4.3 - Reliability Analysis Within Source Literature

Five main techniques of quantifying reliability were identified within this review: inter-rater reliability, intra-rater reliability, inter-scanner reliability, intra-scanner reliability, and test-retest/between-session reliability. Inter-rater reliability appeared the most amongst all of the studies. Such studies either utilised a single scanner between two or more operators and calculated the inter-rater reliability, or they utilised multiple scanners and operators where multiple inter-rater reliabilities were calculated, one for each scanner. In the latter case, comparisons are usually made of the reliability between each scanner used in the study (if there is more than one) though these are often only surface level leading to both inter-scanner reliability and intra-scanner reliability being under-emphasised/analysed throughout the source literature.

Intra-rater reliability, reliability of a single operator with a single scanner (focused on the reliability of the operator), along with test-retest reliability were the second most frequent techniques amongst the source literature. In every instance of test-retest reliability, it was paired with other techniques specifically thrice with intra-rater and once with inter-rater. Test-retest reliability requires a period of time to pass between test sessions so a possible change (or lack thereof) in the reliability of the scanners can be tested. Of the four studies that utilised test-retest reliability, half performed the test-retest throughout a single day and the remaining studies were performed on different dates. Though the time between tests varied, discussions in test-retest studies were similar and expressed the merits of performing test-retest studies as opposed to more common intra-rater reliability tests that take place within a single session. Whilst conditions have a stronger chance of remaining the same in a 'within-session' intra-rater reliability test, test-retest reliability allows time both for the rater and the environment to sit until the next scanning session as it may in a real-life clinical context. This is deemed beneficial for the clinical value of the study; however, it also presents a real difficulty in reducing potential error as marker placement can vary between sessions and raters (Kofman et al., 2018) and scanner training for raters may be less effective after the period of waiting.

Regarding different sources of errors within reliability testing, common observations made by the researchers in each study were that it was difficult to keep conditions the same between tests, especially so with scanners that required markers. When 3D scanning, the conditions of the environment (lighting, surrounding objects, etc…) can greatly affect the quality of the result due to the nature of typical 3D scanning sensor systems being highly sensitive to light and reflective surfaces. The backgrounds/previous experience of the operators were also often considered by researchers and some measures were taken to reduce possible error from a lack of experience such as scanner training sessions employed in the study by Kofman et al. (2018). Only four of the nine studies employed measures such as these and the use of prosthetist/orthotists to conduct the scans varied where some studies like Armitage et al. (2019b) used a physiotherapist, an engineer, and an engineering student. The use of non-P&O raters calls into question the clinical value of the study as there is a distinct difference in knowledge, experience, and priorities between prosthetist/orthotists and for instance engineering students. In the cases where prosthetist/orthotists were used for scanning (in all cases where plaster casts were taken, prosthetist/orthotists were used), they weren't always trained in the use of modelling software, and this provides a potential for error that is discussed by Kofman et al. (2018) where measures were taken to assess user satisfaction amongst the software users through the Post Study System Usability Questionnaire (PSSUQ) (Lewis, 1992). All studies considered this instilling of knowledge (or maintenance of knowledge in the case of test-retest) as a pitfall of 3D scanner related research and a source of error.

4.4 - Author Specified Limitations Within Source Literature

Two meta-analysis studies were included in the source literature with one being a systematic review (Armitage et al., 2019a) and one a more general literature review (Telfer & Woodburn, 2010). Researchers in both studies mentioned similar limitations, one being that deciding the size of the scope for the literature search was often difficult as relevant 3D scanning literature can often vary widely in methods, techniques, and equipment. The systematic review by Armitage et al. (2019a) synthesised literature on both accuracy/validity and reliability though for accuracy/validity the scope of studies was restricted to studies that used water displacement as a comparative measure to 3D scanning data which they self admittedly believe could have excluded relevant literature that used other methods and equipment.

For the experimental studies included, common limitations were a small sample size either due to lack of resources and availability or a belief after the fact that they should have included more participants. Studies that had feet as the scanning subjects of the study, whether it be the plantar surface (Rogati et al., 2019; Rogati et al., 2021) or the whole foot up to the ankle (Powers et al., 2022), scanned bilaterally so they could effectively double their study population whilst studies based on residual limb scanning didn't have that ability.

Another limitation discussed is how 3D scanning often also requires post-processing of the 3D data created whether it be removal of large/obstructive artefacts or processing into a form where statistical analysis can be performed by for instance bounding the volume that will be analysed (Armitage et al., 2019b). For comparison, non-scanning based comparative measures used in studies, i.e., plaster casts made by prosthetist/orthotists, only really require a slight sanding with a wire mesh to remove extra volume left by the plaster as seen in the study by Dickinson et al. (2022). These extra 3D-scan post-processing steps create more room for error as the multiple different software used by the raters could cause confusion.

Different raters may also each have varying levels of experience which can create a disparity between results. The potential error from this could then go on to affect how scientifically valid the results are of the experiment whether the focus is on accuracy/validity or reliability of spatial data as the focus is shifted from how well the scanner can capture morphology to the how well raters can use post-processing software. Whether or not this is intended depends on the study though it could be detrimental to the aims of studies that plan to focus more on the actual scanner itself.

4.5 - Standards and Regulations Consideration Within Source Literature

Standards and regulations are mentioned sporadically throughout the source literature with only surface level discussions happening at most points. After discussion of the issue with different levels of training between raters, Armitage et al. (2019b) suggested future studies on the creation of standards of training for 3D scanning both within research and clinical use. Dickinson et al. (2022) commented on how the fact that plaster casting is seen as the industry standard for shape capture has made it the number one choice of comparative measure to 3D scanning. This perhaps could limit the amount of analysis that can be done on 3D scanners as comparisons are only being made to the effectivity of plaster caster rather than the actual limb itself. Kofman et al. (2018) commented on the absence of an official standard for measuring accuracy/validity, a sentiment that is common amongst our source literature, meaning there is a void to be filled by research where a common standard could be synthesised from existing research. The systematic review by Armitage et al. (2019a) began to synthesise clinical recommendations for measuring residual limb volume though it is clear more research is needed to encompass the new 3D scanning technology and availability that is available.

4.6 - Additional Themes Within Source Literature

As intended, Prosthetics and Orthotics runs as a main theme in almost all of the studies and the focuses of the discussion sections are usually drawn between several main topics: clinical usability of the results, cost, and the possible sources of error in their reliability testing that was discussed before.

Researchers often referenced other areas of P&O to connect their results to clinical use. Dickinson et al. (2022) checked deviations in scanner data against average residual limb volume changes with the adjustments of donning stockings, a common method of filling the extra space left in a prosthetic socket after a reduction in oedema, to see if the scanner data would be able to be used to create a well enough fitting socket in the long term. Other methods of grading clinical value included comparing scanner data to feedback from Prosthetist/Orthotists where 3D scanner data was found to match up well with experienced clinical observations of the real-life foot in the case of the study by Rogati et al. (2019)

Rogati et al. (2019) also emphasised analysis of the clinical compatibility of their (cheaper and widely available) Microsoft Xbox Kinect based scanning system through comparing the cost of their setup to more expensive common commercially available foot scanners used within P&O clinically today. The topic of pricing and cost came up in seven of the nine studies proving to be an area of importance for researchers in this area today. More expensive higher resolution scanners often tend to be more well known by researchers in the field of engineering and by extension medical device technology and as a result have more literature proving their clinical value. Researchers in all of these seven studies argued the need for low-cost 3D scanners as clinics both big and small can often not justify the cost of buying expensive 3D scanners as capital would have to be invested into both buying the equipment and training the clinicians, who are already used to lower cost and effective plaster casting, how to use the new technology (Armitage et al., 2019b). Powers et al. (2022) argued that lower cost alternatives could pave the way to higher cost savings than plaster casting due to eliminating recurring supply costs and decreasing the duration of patient casting sessions.

The issues Armitage et al. (2019b) faced with inaccuracy due to right angles within the target of the scan were also in contrast to what was expected to be found. A simple right angle being a problem does suggest that 3D scanning may still have some technological issues left to resolve when considering it as a solution to medical shape capture. This issue is however not a commonly known issue amongst 3D scanning technology today, the more common issues being listed in the study by Holst & Kuhlmann (2016). This problem with right-angles could rather be associated with the specific scanner or scanning environment, though within human morphology perfect right angles are not as common so this may not be as relevant in a P&O context.

4.7 - Choice of Study Design and Search Framework

Despite an increase in evidence for the accuracy/validity and reliability of 3D scanning, there is a distinct lack of meta-analysis in this field and this topic. When it comes to meta-analysis the most common methods are systematic reviews, scoping reviews, and more general literature reviews. For the purposes of comparing methods, a systematic review generally summarises literature and performs some level of evidence synthesis in order to answer a specific idea or question. Through being much more 'targeted' than other types of meta-analysis, results of such reviews are commonly used to support current or future clinical practice methods, policy decisions, and provide a basis for trustworthy clinical guidelines (Pollock et al., 2021). A scoping review is used more to 'map' or 'chart' available literature in a certain area (Sargeant & O'Connor, 2020). Though the results of such reviews are also often used to inform clinical practice, a major aim is also often to provide a basis and solid ground for more in-depth research by virtue of its mapping nature.

Performing a systematic review of the accuracy/validity and reliability would come with extra complexity due to the increased heterogeneity in the methods and techniques within the studies, this being considered a valid enough reason to not use a systematic review format for meta-analysis by some researchers (Naaktgeboren et al., 2016). This is not to mention different levels of human error, instrument error, etc… within these studies that could further affect research quality as touched upon in the book *Experimental measurements: Precision, error and truth* (Barford, 1995). A scoping review mapping the wealth of knowledge in the field on the topic of accuracy and reliability of 3D scanners would not only be more feasible at this point, but also the results of which would pave the way to potential systematic reviews in the future that would then have more of an idea (or map if you will) of the makeup and scope of evidence available to them for their reviews.

The use of the PCC framework for the scoping review was useful because the nature of a scoping review is to map the available literature. Using a more restrictive framework such as PICO to structure the search would've increased the risk of unnecessarily tightening the scope of the review which could have reduced the quality of analysis as a result of pointlessly excluding certain research that would otherwise be relevant.

4.8 - Critical Appraisal Decision

Quality of evidence on 3D scanning technology generally appears to be quite high however due to the nature of 3D scanners being high value technology (Redaelli et al., 2018) with wide applications in many industries including medically (Joshi & Rowe, 2017), there is danger of bias via the funding sources of the studies. This danger of bias is due to the fact that the scanners are on the market and often studies are commissioned in order to demonstrate certain outcomes or points to a target reader base that would be beneficial to a sponsoring company (Fabbri et al., 2018; Resnik & Elliott, 2013).

Despite these concerns, after reading through the source literature, comparisons between scanners and conclusions drawn thereof appeared to be fair and accompanied by relevant and clear statistical analysis. The choice of scanners was also deemed to be fair with regards to the original intentions of the scanner's manufacturers. Relevant choices were made for comparisons and when scanners of considerably different ability/intention were compared it was done fairly without bias i.e., basic office-oriented scanners weren't unduly advertised as being suited to high level medical-grade shape capture and weren't paraded to be well established in the industry or research community for such purposes.

With initial checks undertaken and the purpose of the scoping review being to map available knowledge, the decision was made that it wouldn't be necessary to utilise a critical appraisal framework such as the Transparency, Accuracy, Purposivity, Utility, Prosperity, Accessibility, Specificity (TAPUPAS) guideline (Long, 2005) which otherwise may have been relevant.

4.9 - Study Limitations

Through choosing to do a scoping review there is a limitation to the goal of mapping the literature available as opposed to deeper evidence synthesis found in other types of meta-analysis. Whilst the results of the scoping review are beneficial in the sense that groundwork is being established for future necessary studies meta-analysis or otherwise, there is an inability to undertake deeper analysis on methods of assessing accuracy/validity and reliability that may be demonstrated in other studies (Armitage et al., 2019a). The eligibility criteria within our evidence search potentially limited the intake of relevant literature with the 2010 cut-off date. 3D scanning has been used within the P&O field before 2010 and some literature that was found to be relevant within the title and abstract screening was removed from the pool due to being older than 2010. Whilst older literature may have outdated understandings of concepts and technology within the field, a new perspective on the challenges faced today with trying to quantify accuracy/validity and reliability of 3D scanning data could have been attained by reading the studies and discussions of authors who did not have as much literature and resources available to them as today.

Another potential limitation is limiting our review to purely human based scanning as an arguably larger wealth of literature exists on 3D scanning for inanimate subjects e.g., for replicating machine parts, etc.… Clinical value could be brought into question with an inclusion of literature of this type though valuable discussion on the methods and application of 3D scanning would become available. The areas of the body scanned within the source literature are also limited to feet and residual limbs which suggests a need for more research on P&O 3D scanning for other areas of the body e.g., hands, facial, thoracic, etc.…

Two meta-analysis studies (Armitage et al., 2019a; Telfer & Woodburn, 2010) were included within the review which provided a contrast to the experimental studies. The experimental studies provided a primary source and allowed for more direct interpretation of the authors thoughts and discussions whereas the meta-analysis provided a secondary source where the authors accounted their interpretations of the literature they reviewed. As a result of this, the information gathered from the meta-analyses depends heavily on the methods and biases of the authors of such studies which raises concerns as to what is being left out or specifically included by such authors. In order to reduce concern, the funding sources, bias assessment (more relevant to the systematic review by Armitage et al. (2019a)), and critical appraisal in the studies were checked against which scanners, data, discussion were included within the study to assess if there were any conflicts of interest in the authors. None were found and the data from each of these meta-analyses were included in the review.

4.10 - Study Ethics

As required by the School of Health and Welfare at Jönköping University, degree projects must align with ethical principles expressed in the Act concerning the Ethical Review of Research Involving Humans (Utbildningsdepartmentet, SFS 2003:460). For this the form titled 'Form for Self-Assessment of Ethical Issues in Degree Projects at the School of Health and Welfare' was filled out and sent for review. The nature of the study is a scoping review without participants.

4.11 - Recommendations for Future Studies

It is clear that there is a distinct lack of standards and regulations in widespread use within P&O 3D scanning. The establishment of easy-to-understand standards and regulations would establish a foundation that more in-depth research can be built upon. Areas where further research would be beneficial:

- A standardisation of the technique used to quantify the accuracy and validity of spatial data from a 3D scanner used to scan human morphology
    - Volumetric/Circumferential/etc… comparisons?
- A standardisation of the technique used to quantify the reliability of spatial data from a 3D scanner used to scan human morphology
    - Inter-rater, Intra-rater, Inter-scanner, Intra-scanner?
- A standardisation of the method used to quantify the accuracy and validity of spatial data from a 3D scanner used to scan human morphology
    - Develop recommendations of areas of the body to be scanned for an experimental study on this topic if the study aim focuses generally on human morphology rather than a specific area
    - How should the limb/body be arranged/supported (if at all) during the scanning session to best imitate a clinical P&O context
- Standardisation of language used within relevant studies to refer to accuracy/validity, reliability/repeatability, descriptive terminology [morphology/shape/form/aspect/figure]
- Investigative study into relevant local and international regulations that should be applied to 3D scanning within P&O

4.12 - Conclusion

3D Scanning within Prosthetics and Orthotics is becoming more widespread; however, the results of this review show that there is a need for further research and discussion. Researchers, whilst achieving their goals of measuring the accuracy/validity and reliability of 3D scanners within a P&O context, consistently call for industry wide establishment of standards. Methods of research, measurement and statistical analysis techniques, and equipment vary hugely, more so in validity/accuracy research, between studies in addition to methods at which the clinical value of data is measured. The objective and questions posed in this review were fulfilled through data collection that assessed both quantitative data items (e.g., the number of studies that analysed accuracy/reliability) and more descriptive or qualitative data items (e.g., comparison of limitations specified by authors in the various source studies). The mapping of the available knowledge on accuracy/validity and reliability of 3D scanning and the methods at which to measure it allows future researchers to carry out further studies with the knowledge of where research is lacking though there remains space for further research. More systematic reviews could be able to take specific areas of 3D scanning research such as validity and synthesise evidence. Further experimental studies could increase the amount of knowledge on the accuracy and/or reliability of various 3D scanner technologies that may not previously have been applied to P&O. As it stands now however, the results of this review have shown that there is a distinct lack of uniformity and standardisation amongst 3D scanning both in research in the field.

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References

Afiqah Hamzah, N., Razak, N. A. A., Sayuti Ab Karim, M., & Gholizadeh, H. (2021). A review of history of CAD/CAM system application in the production of transtibial prosthetic socket in developing countries (from 1980 to 2019). *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine*, *235*(12), 1359–1374. https://doi.org/10.1177/09544119211035200

Armitage, L., Kark, L., Czerniec, S., & Kwah, L. K. (2019a). Reliability and validity of measurement tools for residual limb volume in people with limb amputations: A systematic review. *Physical Therapy*, *99*(5), 612–626. https://doi.org/10.1093/ptj/pzz010

Armitage, L., Kwah, L. K., & Kark, L. (2019b). Reliability and validity of the iSense optical scanner for measuring volume of transtibial residual limb models. *Prosthetics & Orthotics International*, *43*(2), 213–220. https://doi.org/10.1177/0309364618806038

Artec Group and Ottobock Sign Distribution Agreement for Artec 3D Scanners. (2014, July 10). artec3d.Com. Retrieved April 22, 2022, from https://www.artec3d.com/news/artec-group-and-ottobock-sign-distribution-agreement-artec-3d.

Barford, N. C. (1995). *Experimental measurements: Precision, error and truth*. J. Wiley & Sons.

Bettoni, E., Ferriero, G., Bakhsh, H., Bravini, E., Massazza, G., & Franchignoni, F. (2016). A systematic review of questionnaires to assess patient satisfaction with limb orthoses. *Prosthetics and orthotics international*, *40*(2), 158–169. https://doi.org/10.1177/0309364614556836

Bramer, W. M., de Jonge, G. B., Rethlefsen, M. L., Mast, F., & Kleijnen, J. (2018). A systematic approach to searching: an efficient and complete method to develop literature searches. *Journal of the Medical Library Association : JMLA*, *106*(4), 531–541. https://doi.org/10.5195/jmla.2018.283

Dickinson, A. S., Donovan-Hall, M. K., Kheng, S., Bou, K., Tech, A., Steer, J. W., Metcalf, C. D., & Worsley, P. R. (2020). Selecting appropriate 3D scanning technologies for prosthetic socket design and transtibial residual limb shape characterization. *JPO Journal of Prosthetics and Orthotics*, *34*(1), 33–43. https://doi.org/10.1097/jpo.0000000000000350

Fabbri, A., Lai, A., Grundy, Q., & Bero, L. A. (2018). The influence of industry sponsorship on the Research Agenda: A Scoping Review. American Journal of Public Health, 108(11). https://doi.org/10.2105/ajph.2018.304677

Farahani, N., Braun, A., Jutt, D., Huffman, T., Reder, N., Liu, Z., Yagi, Y., & Pantanowitz, L. (2017). Three-dimensional Imaging and Scanning: Current and Future Applications for Pathology. *Journal of pathology informatics*, *8*, 36. https://doi.org/10.4103/jpi.jpi_32_17

Golovin, M. A., Marusin, N. V., & Golubeva, Y. B. (2018). Use of 3D printing in the orthopedic prosthetics industry. *Biomedical Engineering*, 52(2), 100-105. https://doi.org/10.1007/s10527-018-9792-1

Heinemann, A. W., Bode, R. K., & O'Reilly, C. (2003). Development and measurement properties of the Orthotics and prosthetics users' survey (opus). *Prosthetics & Orthotics International*, *27*(3), 191–206. https://doi.org/10.1080/03093640308726682

Holst, C., & Kuhlmann, H. (2016). Challenges and present fields of action at laser scanner based deformation analyses. *Journal of Applied Geodesy*, *10*(1). https://doi.org/10.1515/jag-2015-0025

Huang, X., Lin, J., & Demner-Fushman, D. (2006). Evaluation of PICO as a knowledge representation for clinical questions. *AMIA ... Annual Symposium proceedings. AMIA Symposium*, *2006*, 359–363.

International Organization for Standardization. (2018). 3-D scanning methodologies for internationally compatible anthropometric databases — Part 1: Evaluation protocol for body dimensions extracted from 3-D body scans(ISO Standard No.20685-1:2018).https://www.iso.org/obp/ui/#iso:std:iso:20685:-1:ed-1:v1:en

Javaid, M., Haleem, A., Pratap Singh, R., & Suman, R. (2021). Industrial Perspectives of 3D scanning: Features, roles and it's analytical applications. *Sensors International*, *2*, 100114. https://doi.org/10.1016/j.sintl.2021.100114

Joshi, S. V., & Rowe, P. J. (2017). A novel approach for intra-operative shape acquisition of the tibio-femoral joints using 3D laser scanning in computer assisted orthopaedic surgery. *The International Journal of Medical Robotics and Computer Assisted Surgery*, *14*(1). https://doi.org/10.1002/rcs.1855

Kemp, T. (2006, August 1). *Home*. O&P News. Retrieved March 8, 2022, from http://oandpnews.org/2006/08/01/cad-cam-technology-in-the-op-industry/

Kofman, R., Beekman, A. M., Emmelot, C. H., Geertzen, J. H., & Dijkstra, P. U. (2018). Measurement properties and usability of non-contact scanners for measuring transtibial residual limb volume. *Prosthetics & Orthotics International*, *42*(3), 280–287. https://doi.org/10.1177/0309364617736088

Kowalski, K. L., Pitcher, J. D., Jr, & Bickley, B. (2002). Evaluation of fiberglass versus plaster of Paris for immobilization of fractures of the arm and leg. *Military medicine*, *167*(8), 657–661.

Lewis, J. R. (1992). Psychometric evaluation of the Post-Study System Usability Questionnaire: The PSSUQ. *Proceedings of the Human Factors Society Annual Meeting*, *36*(16), 1259–1260. https://doi.org/10.1177/154193129203601617

Long, A. F. (2005). Assessing the quality of knowledge in social care: Exploring the potential of a set of generic standards. *British Journal of Social Work*, *36*(2), 207–226. https://doi.org/10.1093/bjsw/bch307

Mai, H. N., & Lee, D. H. (2020). Accuracy of Mobile Device-Compatible 3D Scanners for Facial Digitization: Systematic Review and Meta-Analysis. *Journal of medical Internet research*, *22*(10), e22228. https://doi.org/10.2196/22228

Merriam-Webster. (n.d.). Accuracy. In *Merriam-Webster.com dictionary*. Retrieved April 14, 2022, from https://www.merriam-webster.com/dictionary/accuracy

Merriam-Webster. (n.d.). Artifact. In *Merriam-Webster.com dictionary*. Retrieved April 22, 2022, from https://www.merriam-webster.com/dictionary/artifact

Merriam-Webster. (n.d.). Method. In *Merriam-Webster.com dictionary*. Retrieved April 22, 2022, from https://www.merriam-webster.com/dictionary/methods

Merriam-Webster. (n.d.). Morphology. In *Merriam-Webster.com dictionary*. Retrieved April 22, 2022, from https://www.merriam-webster.com/dictionary/morphology

Merriam-Webster. (n.d.). Noise. In *Merriam-Webster.com dictionary*. Retrieved April 22, 2022, from https://www.merriam-webster.com/dictionary/noise

Merriam-Webster. (n.d.). Protocol. In *Merriam-Webster.com dictionary*. Retrieved April 22, 2022, from https://www.merriam-webster.com/dictionary/protocol

Merriam-Webster. (n.d.). Rectify. In *Merriam-Webster.com dictionary*. Retrieved April 22, 2022, from https://www.merriam-webster.com/dictionary/rectify

Merriam-Webster. (n.d.). Reliability. In *Merriam-Webster.com dictionary*. Retrieved April 22, 2022, from https://www.merriam-webster.com/dictionary/reliability

Merriam-Webster. (n.d.). Validity. In *Merriam-Webster.com dictionary*. Retrieved April 14, 2022, from https://www.merriam-webster.com/dictionary/validity

Mikolajewicz, N., & Komarova, S. V. (2019). Meta-analytic methodology for basic research: A practical guide. *Frontiers in Physiology*, *10*. https://doi.org/10.3389/fphys.2019.00203

Naaktgeboren, C. A., Ochodo, E. A., Van Enst, W. A., de Groot, J. A., Hooft, L., Leeflang, M. M., Bossuyt, P. M., Moons, K. G., & Reitsma, J. B. (2016). Assessing variability in results in systematic reviews of diagnostic studies. *BMC Medical Research Methodology*, *16*(1). https://doi.org/10.1186/s12874-016-0108-4

Page, M. J., McKenzie, J. E., Bossuyt, P. M., Boutron, I., Hoffmann, T. C., Mulrow, C. D., Shamseer, L., Tetzlaff, J. M., Akl, E. A., Brennan, S. E., Chou, R., Glanville, J., Grimshaw, J. M., Hróbjartsson, A., Lalu, M. M., Li, T., Loder, E. W., Mayo-

Wilson, E., McDonald, S., … Moher, D. (2021). The Prisma 2020 statement: An updated guideline for reporting systematic reviews. *BMJ*. https://doi.org/10.1136/bmj.n71

Peaco, A., Halsne, E., & Hafner, B. J. (2011). Assessing satisfaction with Orthotic Devices and services: A systematic literature review. *JPO Journal of Prosthetics and Orthotics*, *23*(2), 95–105. https://doi.org/10.1097/jpo.0b013e318217a0fe

Peters, M., Godfrey, C. M., Khalil, H., Mcinerney, P., Soares, C. B., & Parker, D. (2017). 2017 Guidance for the Conduct of JBI Scoping Reviews. *Joanna Briggs Institute Reviewer's Manual*.

Peters, M., Godfrey, C., McInerney, P., Munn, Z., Trico, A., & Khalil, H. (2020). Chapter 11: Scoping reviews. *JBI Manual for Evidence Synthesis*. https://doi.org/10.46658/jbimes-20-12

Pham, M. T., Rajić, A., Greig, J. D., Sargeant, J. M., Papadopoulos, A., & McEwen, S. A. (2014). A scoping review of scoping reviews: advancing the approach and enhancing the consistency. *Research synthesis methods*, *5*(4), 371–385. https://doi.org/10.1002/jrsm.1123

Pollock, D., Davies, E. L., Peters, M. D., Tricco, A. C., Alexander, L., McInerney, P., Godfrey, C. M., Khalil, H., & Munn, Z. (2021). Undertaking a scoping review: A practical guide for nursing and midwifery students, clinicians, researchers, and academics. Journal of Advanced Nursing, 77(4), 2102–2113. https://doi.org/10.1111/jan.14743

Powers, O. A., Palmer, J. R., & Wilken, J. M. (2021). Reliability and validity of 3D limb scanning for ankle-foot orthosis fitting. *Prosthetics & Orthotics International*, *46*(1), 84–90. https://doi.org/10.1097/pxr.0000000000000066

Redaelli, D. F., Gonizzi Barsanti, S., Fraschini, P., Biffi, E., & Colombo, G. (2018). Low-cost 3D devices and laser scanners comparison for the application in Orthopedic Centres. *The International Archives of the Photogrammetry, Remote Sensing and Spatial Information Sciences*, *XLII-2*, 953–960. https://doi.org/10.5194/isprs-archives-xlii-2-953-2018

Resnik, D. B., & Elliott, K. C. (2013). Taking financial relationships into account when assessing research. Accountability in Research, 20(3), 184–205. https://doi.org/10.1080/08989621.2013.788383

Rogati, G., Leardini, A., Ortolani, M., & Caravaggi, P. (2019). Validation of a novel Kinect-based device for 3D scanning of the foot plantar surface in weight-bearing. *Journal of Foot and Ankle Research*, *12*(1). https://doi.org/10.1186/s13047-019-0357-7

Rogati, G., Leardini, A., Ortolani, M., & Caravaggi, P. (2021). Semi-automatic measurements of foot morphological parameters from 3D plantar foot scans. *Journal of Foot and Ankle Research*, *14*(1). https://doi.org/10.1186/s13047-021-00461-z

Sargeant, J. M., & O'Connor, A. M. (2020). Scoping reviews, systematic reviews, and meta-analysis: Applications in veterinary medicine. *Frontiers in Veterinary Science*, *7*. https://doi.org/10.3389/fvets.2020.00011

Seminati, E., Young, M., Canepa Talamas, D., Twiste, M., Dhokia, V., & Bilzon, J. (2022). Reliability of three different methods for assessing amputee residuum shape and volume: 3D scanners vs. Circumferential Measurements. *Prosthetics & Orthotics International*, *Publish Ahead of Print*. https://doi.org/10.1097/pxr.0000000000000105

SFS 2003:460. Lag om etikprövning av forskning som avser människor [Act concerning the Ethical Review of Research Involving Humans]. Utbildningsdepartementet. https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-2003460-om-etikprovning-av-forskning-som_sfs-2003-460

Sliney, D. H. (1995). Risk assessment and laser safety. Optics & Laser Technology, 27(5), 279–284. https://doi.org/10.1016/0030-3992(95)98684-k

Smith, D. G., & Burgess, E. M. (2001). The use of CAD/CAM technology in prosthetics and orthotics--current clinical models and a view to the future. *Journal of rehabilitation research and development*, *38*(3), 327–334.

Telfer, S., & Woodburn, J. (2010). The use of 3D surface scanning for the measurement and assessment of the human foot. *Journal of Foot and Ankle Research*, *3*(1). https://doi.org/10.1186/1757-1146-3-19

Tóth, T., & Živčák, J. (2014). A comparison of the outputs of 3D scanners. *Procedia Engineering*, *69*, 393–401. https://doi.org/10.1016/j.proeng.2014.03.004

Tricco, A. C., Lillie, E., Zarin, W., O'Brien, K. K., Colquhoun, H., Levac, D., Moher, D., Peters, M. D. J., Horsley, T., Weeks, L., Hempel, S., Akl, E. A., Chang, C., McGowan, J., Stewart, L., Hartling, L., Aldcroft, A., Wilson, M. G., Garritty, C., … Straus, S. E. (2018). Prisma extension for scoping reviews (PRISMA-SCR): Checklist and explanation. *Annals of Internal Medicine*, *169*(7), 467–473. https://doi.org/10.7326/m18-0850

VDI/VDE. (2012). Optical 3D-measuring systems - Multiple view systems based on area scanning. *Engl. VDI/VDE-Gesellschaft Mess- Und Automatisierungstechnik*.

Weiner, R. (2003). Classification of Laser/LED arrays under IEC 60825-1. *International Laser Safety Conference*. https://doi.org/10.2351/1.5056518