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Human-device interface pressure measurement in prosthetic, orthotic and exoskeleton applications: A systematic review

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Abstract

This study aimed to investigate normal and shear load sensor technology that has been characterised and used at the human-device interface in prosthetic, orthotic and exoskeleton applications. In addition to taking a cross-disciplinary view, this study expands on previous reviews by considering recently published papers, clinical translation of sensors, and development of the sensor technology itself. A search of MEDLINE, INSPEC, SCOPUS and Web of Science was performed up to 26 January 2021. A total of 33 studies were assessed for quality and their data extracted. The review found variable quality of published papers, with normal load being most commonly measured, and resistive sensor technology most commonly used. The translation to clinical environments was indicated in most studies, though the study population was not always made up of the target users. Studies could benefit from more direct comparison with clinically relevant load thresholds and by ensuring clinical testing is performed in the most realistic and representative way possible. Additionally, more focus on developing sensors that measure shear loads would enable further insights into conditions at the human-device interface. Finally, all researchers would benefit from better and more widespread anonymous data sharing practices to facilitate further experimentation.

Title: Human-device interface pressure measurement in prosthetic, orthotic and exoskeleton applications: A systematic review

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Abstract:

This study aimed to investigate normal and shear load sensor technology that has been characterised and used at the human-device interface in prosthetic, orthotic and exoskeleton applications. In addition to taking a cross-disciplinary view, this study expands on previous reviews by considering recently published papers, clinical translation of sensors, and development of the sensor technology itself. A search of MEDLINE, INSPEC, SCOPUS and Web of Science was performed up to 26 January 2021. A total of 33 studies were assessed for quality and their data extracted. The review found variable quality of published papers, with normal load being most commonly measured, and resistive sensor technology most commonly used. The translation to clinical environments was indicated in most studies, though the study population was not always made up of the target users. Studies could benefit from more direct comparison with clinically relevant load thresholds and by ensuring clinical testing is performed in the most realistic and representative way possible. Additionally, more focus on developing sensors that measure shear loads would enable further insights into conditions at the human-device interface. Finally, all researchers would benefit from better and more widespread anonymous data sharing practices to facilitate further experimentation.

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Background:

Several categories of external medical devices are used to support or replace parts of the body that are not functioning effectively. In a general sense, prosthetics replace function, orthotics support function and exoskeletons can support or augment function. The interface between humans and wearable medical devices is important for the long-term suitability of devices and should minimise the risk of damage to the underlying anatomical structures and maximise comfort [1]. A device that is uncomfortable or ill-fitting risks further medical complications, or alters natural loading patterns that may in turn limit compliance with the device and cause other long-term health issues [2–7]. Although the prosthetics, orthotics and exoskeleton research and application fields are generally distinct, the mechanical state of the interfaces is similar, thus yielding similar clinical implications.

A number of literature reviews have been performed over the last decade summarising existing sensing technology, albeit with a limited focus on prosthetic applications [8–11]. The last of these occurred 5 years ago, and since then several emerging technologies have been presented in literature. With the rapid development of orthotic and exoskeleton technology in recent years, there is a lack of studies that synthesise pressure measurement in orthotic applications or include human-exoskeleton interfaces. This information will provide an important addition to the current body of knowledge given the similarity of the mechanical state of the interfaces, with the potential for cross-disciplinary application of knowledge and technology. In particular, quantitative information about the interfaces is useful for understanding the clinical relevance of findings, especially if related to thresholds of clinical importance, e.g. the load at which skin breakdown starts. The current review then addresses this gap in literature by adopting a cross-sectional view, covering pressure sensing at the human-device interface in prosthetics, orthotics and exoskeletons. A particular focus is on studies that show potential for clinical application in relevant experimental tests, and evaluating the clinical translation of such technologies, both in terms of relevant clinical thresholds and the technologies themselves.

Various load metrics have been used in literature. Forces, measured in Newtons (N) either perpendicular to or parallel with the surface of interest are commonly measured as normal or shear forces, respectively. Pressure or stress, defined as force per unit area, is also a common metric and can also be quantified in the normal or shear directions. Both normal and shear forces are important to consider in the interface environment due to their potential negative consequences, however, there is a consensus that shear forces (often due to friction) are the greatest contributor to skin breakdown [5,12,13]. For the purpose of this review, *load* is used as a blanket term to describe both force and stress metrics. Where relevant, force or stress will be referred to directly.

There are several critical contributing factors to the maintenance of long-term health when using these devices, in particular, normal and shear forces, moisture and temperature [14] are important for maintaining skin health. Despite the importance of these factors, literature does little to highlight the clinical relevance of these quantitative measures, demonstrated by a lack of standard clinical threshold values. As the devices work by transmitting forces to the body, the location of these load points on the underlying anatomy is also important. Mechanical load or stress, both normal and shear, between the user and the device can be the most difficult to adapt to, as only specific parts of the human anatomy have evolved to bear sustained high loads, e.g. the uncut distal surfaces of the femur, the calcaneal fat pad on the heel. Most soft tissue, which often serves as the body's interface with wearable medical devices, is not accustomed to high stress. Skin breakdown and pressure sores are therefore not uncommon when skin is subjected to pressure [15]. Understanding the mechanics of the interaction between the human and the device is a major ongoing challenge in these areas of research [11].

Sensing technology may be utilised to effectively monitor the environment at the interface of the body and an external medical device. The use of sensors to measure normal and shear load can provide information that would not otherwise be available about the interface. Areas of high stress can be identified, allowing for the potential avoidance of skin damage in these regions. The

quantitative understanding of stress at the device-human interface may allow for further insight into one of the factors that cause negative consequences for individuals. The information could be used to determine clear thresholds across cohorts or individuals. Combined with user and clinician feedback, the quantitative data may be used to enhance clinical decision making. Measuring the stress at device-human interface sites also provides the means to gain a better understanding of the relationship between stress, sensation at the interface, and control of active systems that the user is wearing. Understanding these stresses could allow for a proactive design approach, combined with everyday monitoring, where modification could occur before users develop issues, and can give an indication of the threshold above which discomfort or damage is likely. To incorporate the value of stress measurement into clinical practice, first the clinical utility and value of the technology must be established. The technologies should be validated and tested in the clinical environment. This will be the focus area of this review. Subsequent engagement with feedback from clinicians and service users to optimise technology must then be pursued. Priorities may differ between the research and clinical perspectives, and acceptability criteria should be established to inform technology development. Applications outside the clinic may also be considered, opening opportunities for longer term remote and daily monitoring of loads as well as user health self-management.

The measurement of load at the interface between a user and a prosthetic, orthotic or exoskeleton is typically limited by the need for a low profile, safety and reliability. Factors such as temperature variation at the interface, curved surfaces and large ranges of loading add further complexity [9]. Commercially available load sensors are available as pads for multi-application use, with some developed for specific applications (e.g. prosthetic sockets, insoles). Commercial options are typically associated with high costs, restricted software compatibility and minimal information about their detailed structure. It is in this context that the ongoing development and reporting of sensor systems for this application occurs.

There is also no one definitive technology that has been developed to meet the diverse needs of researchers and users within or across prosthetics, orthotics and exoskeleton applications. Therefore, there is ongoing research into custom made sensor systems for specific use in these fields. Much of the published research is focused on sensor development and property characterisation through benchtop testing, with little demonstration of use in the intended application. For instance, Armitage et al. have described the fabrication and bench testing process of a normal and shear fiber Bragg grating sensor system, embedded in a prosthetic liner material, however, no testing with either residual limb models nor human participants has been reported in the study [16]. This makes it difficult for others to infer whether they will be appropriate for use clinically without the need for a larger scale clinical study.

An alternative to a large-scale clinical study is to present preliminary results based on a few participants, with the main purpose being to bridge the gap between benchtop testing and the clinical implementation. Participant testing is important to determine whether the sensors are fit for their clinical application, the requirements of which vary between applications. It is also important to demonstrate that the sensors add value to the clinical application being targeted. The gap between benchtop testing and clinical application should be minimised to ensure the technologies developed add the intended value. Ideally, the technology would be designed in collaboration with end users, both clinicians and device users, to minimise wasted resources and to achieve the required results.

The stage of development between benchtop testing and preliminary assessment of the device in the clinic will be the focus of this study. We seek to identify methods and technologies in the literature that will assist researchers in taking promising technology from the laboratory into the clinic.

This review focuses on translational studies of normal and shear load sensor technology that have been developed, characterised and used in preliminary clinical assessment at the human-device

interface in regions of the body that do not usually bear loads. Plantar pressure measurement was excluded from this review as we deemed the foot a region of usual load bearing, and there is a significant body of literature and reviews pertaining directly to this type of pressure measurement already.

This study has three aims. Firstly, to understand and report how interface pressure is currently measured in prosthetic, orthotic and exoskeleton applications. Secondly, to evaluate the methods used for clinical translation of the technologies in terms of testing and performance. Finally, to assess the quality of the reporting of these studies with a view to providing authors with guidance on improving the quality of the overall body of knowledge available to the community.

Methods:

Study selection

The protocol of this systematic review was registered with PROSPERO (registration number CRD42020181809). Methods have been developed and presented in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [17]. Studies that investigated the use of load (normal or shear) sensors at an interface between a human or limb model or phantom, that does not usually bear loads, and a prosthetic, orthotic or exoskeleton device were considered. Only journal articles published in English were included. A full list of inclusion and exclusion criteria is available in Appendix 1.

Data Sources and Search

A search strategy for MEDLINE, Web of Science, Inspec and Scopus was developed in consultation with a librarian at the XXXX. The search strategies have been included in Appendix 2. The databases were searched up until 26 January 2021. 2 assessors (L.A. and M.S.) independently screened titles and abstracts for eligibility, followed by full text articles. Personal libraries and reference lists of included studies were also screened for relevant articles. Any discrepancies between selections were

resolved via discussion between assessors and where necessary, the involvement of a third assessor (S.T.).

Data Extraction

2 assessors (L.A. and S.T) independently extracted study characteristics using standardised forms. These data included study aims, application field, sensor type, range, number and locations, validation or calibration procedures, experimental protocols, and pressure thresholds for clinical significance. A full list of the items collected has been included in Appendix 3. These items were included as they provide useful guidance to other researchers as to the experimental protocols for interface sensor testing.

Quality Assessment

There are several existing quality rating scales with items relevant to our study [18–21], however, no single quality rating scale previously used in the literature covered all items we wished to assess in this review. For example: items pertaining directly to sensor calibration are not routinely included in clinical studies, and items referring to the diagnostic ability of clinical tools are not relevant to our study. Therefore, a combination of the items used in the other reviews was developed. It included items pertaining to reporting of aims, methods, limitations and conclusions, characteristics of the anatomical landmarks, sensor configuration, sample size and demographic, usage of appropriate statistical analysis, availability of raw data and comparison to existing clinical data. Each item was scored with 'Yes' = 2, 'Unclear' = 1 or 'No' = 0. All items were equally weighted, and the total score was calculated across 13 items to give a total out of 26. Studies were considered high quality if they achieved a score of 17/26 or higher, moderate quality if they achieved a score between 9/26 and less than 17/26 and low quality if they achieved a score of less than 9/26. Prior to completing the quality assessment, 3 assessors attended a quality rating scale training session to ensure fairness of assessment. 2 assessors (S.T. and M.S) then independently completed the quality assessment. Where discrepancies were present, a third assessor (L.A.) assisted in resolution.

Results:

Eligible studies

An initial search was performed on 5 June 2020 and resulted in 11501 articles being identified. After removal of duplicates 8316 remained. Title and abstract screening removed 8280 articles that did not meet the inclusion criteria. 36 full text articles were screened, from which a further 7 were excluded. A final re-run of the search was performed on 26 January 2021 which resulted in an additional 1175 titles and abstracts from June 2020 and January 2021. After screening and removal of duplicates 797 remained. From this group, an additional 5 relevant papers were identified and included.

At the end, a total of 33 articles were included in the review, of which 17 pertained to prosthetic devices, 7 to orthotic devices and 9 to exoskeletons. A PRISMA flowchart presenting the total number of studies at each stage has been included in Figure 1 and an outline of general study characteristics is included in Table 1.

[Insert Figure 1 here]

[Insert Table 1 here]

Data extraction

Interface Stress Measurement

Data were extracted from 17 prosthetic studies [22–38], 7 orthotic studies [39–45] and 9 exoskeleton studies [46–54], with the characteristics summarised in Table 1 and results summarised in Table 2. Prosthetics studies included sample sizes from 1 to 4 with a total of 23 participants (Table 1). 3 of the prosthetic studies also used limb phantoms instead of human subjects. Orthotics studies included sample sizes ranging from 1 to 44, with a total of 110 participants (Table 1). Studies pertaining to exoskeletons included sample sizes ranging from 1-8 with a total of 29 participants (Table 1).

The most popular sensor types used in the studies across the 3 application areas were resistive (11 studies). Fiber Bragg Grating technology (5 studies) was also explored in prosthetic and exoskeleton applications (Item 2, Table 2). Normal force or stress was the dominant type of load that was measured (28 studies) (Item 3, Table 2).

Clinical Translation

Parameters relating to clinical translation included anatomical locations of sensors, testing on human subjects rather than phantoms only, the types of movements measured and the inclusion of clinical thresholds with respect to safe loads.

There was a wide range of approaches with respect to the location of sensors, with some studies measuring at specific anatomical points, particularly in exoskeleton (9 studies) and prosthetic applications (14 studies). Others, predominantly orthotic applications (6 studies), used large surface pressure measurements systems across the whole interface (Item 4, Table 2). Prosthetic applications saw the most diversity in the number and location of sensors. Lower limbs and locations on the trunk were most common, with only 4 studies investigating interface stress on the upper limb (Item

5, Table 2). Sensors were designed with a variety of normal and shear force or pressure ranges (Items 6 and 7, Table 2). 31 studies outlined their calibration process in the paper (Item 8, Table 2).

31 studies performed their translational testing on human subjects rather than phantoms (Item 9, Table 2). As a result of the large number of studies on human subjects, a broad range of human movements were examined (Item 10, Table 2). Of note when considering translation of this technology into a clinical setting is the ability for functional movements to be performed without restriction. In the context of lower limb devices, 22 studies reported data related to walking, 2 with respect to turning and 1 with respect to stairs. This would suggest these devices are portable, which is an important feature if longer term monitoring in daily life is also a consideration. Inferences about the portability of devices used for movements not involving ambulation were not made.

Nine studies reported clinical thresholds with respect to safe loads and used these to compare to their data (Item 11, Table 2). Clinical load thresholds used in the exoskeleton papers included a general reference to various pain pressure thresholds [47,50]. We noted that studies used 4.7 kPa for the onset of ischaemia [49], 40-50 mmHg (5.3 - 6.7 kPa) for tissue oxygenation and 30-35 mmHg (4 – 4.7 kPa) for adequate circulation [52]. There was also reference to the graphical representation of thresholds with different durations of exposure [54]. Pressure thresholds used as references in the orthotics papers included 40-60 mmHg for pressure sores [43]. Clinical thresholds that were used as references in the prosthetics papers included 8 kPa for ischaemia [22], pressures greater than 100 kPa potentially being dangerous [23] and pressures greater than 20 kPa leading to prosthetic tightness [29].

[Insert Table 2 here]

Quality Assessment

The quality assessment of the papers has been summarised in Table 3. 17 of the studies were considered to be of high quality [22,25,26,32–38,40,42–44,50,52,54], 13 of moderate quality [23,27–

31,39,45–48,51,53], and 3 of low quality [24,41,49]. Of the 9 exoskeleton papers, 3 were rated as high quality, 5 as moderate and 1 as low. Of the 7 orthotic papers, 4 were rated as high quality, 2 and moderate and 1 as low. Of the 17 prosthetics papers, 10 were rated as high quality, 6 as moderate and 1 as low.

Most studies provided good information on aims, participant details, findings and conclusions and included measurements from all participants. Common limitations included lack of detailed information about the interface where the sensor was acting; and lack of details about sample size calculations and statistical measures, if they were performed. There was also limited comparison of results to existing pressure or shear stress benchmarks in the literature. Only 1 study provided access to raw or processed data [38]. Figure 2 shows the breakdown of scores by item for each application area.

[Insert Table 3 here]

[Insert Figure 2 here]

Discussion:

The results of this review showcase an inter-disciplinary approach to measuring interface pressure across prosthetic, orthotic and exoskeleton applications. Existing technologies have been identified through a systematic review with a focus on studies providing initial clinical translation of the technologies, demonstrating both sensor development and the direct application of the sensors on human participants or phantoms. It is important to note that the review did not distinguish whether the studies were implemented in a clinical setting (i.e. hospital or practice). Rather, the definition of translation to a clinical environment focused on the use of the sensor system in an experiment that mirrored conditions that may occur in the clinic. This was a necessary distinction to make as the review focused on studies that documented the translation from non-clinical benchtop tests to preliminary human or phantom testing rather than studies implementing existing sensor systems in a clinical study.

It is significant that, despite a stringent exclusion criterion, 33 recent studies were identified that went beyond benchtop testing and achieved some aspect of the translation to clinical environments by completing initial testing with target users or on a limb phantom. As a vital step towards full clinical testing, these efforts should be acknowledged. However, we also noted several avenues for improvement across the studies. In the following we discuss our findings with the perspective to find synergies between approaches used in prosthetic, orthotic and exoskeleton research, as well as common challenges.

Data extraction

The majority of studies examined aimed to determine an absolute load that may be applied at a desired location. The nature of the device, particularly its flexibility and shape (e.g. curvature), are known to impact its characterisation and consequently the measured values. While some characterisation protocols do account for the effect of curvature or calibrate the sensors in situ, the flexibility of the material was not typically discussed. It is therefore likely that for more flexible

surfaces, e.g. the prosthetic socket or hand orthoses, relative rather than absolute pressure was being recorded.

Assessment of the diverse sensor technologies investigated in the reviewed studies found no definitive system that clearly outperformed others across applications. In many of the studies, there was a clear focus on normal rather than shear load measurement. However, it is important to note that shear loading is thought to be responsible for 40% of pressure ulcers [55]. While some state-of-the-art systems are beginning to address simultaneous normal and shear measurement (e.g. [56]) , our results clearly indicate that further research and development of shear sensing technology is needed [11,57]. As the true loading state is made up of combined normal and shear load, development of sensors capable of measuring both types of stress simultaneously would be ideal.

There was substantial variation in the values used as clinical indications for pressure tolerance. This is not a negative finding, as it is likely that different anatomical landmarks and applications have different requirements [52,58]. It does, however, highlight a general lack of consensus in the literature as to 'safe' thresholds for interface loads when using these devices. Furthermore, a key aspect of user acceptance of an external device is the perception of comfort, a subjective metric that a sensor will not be able to measure. Our appraisal of the studies in this review suggests that it is unlikely that sensors and load recordings alone could be an effective tool to assess the suitability of use of a sensor system in a given device or of the device itself. Therefore, the use of sensor technology in studies would benefit from correlations between the objective pressure readings and user and clinician preferences. This is a potential area of future research for the sensors systems that have high quality studies to back up their use. This research may also benefit from borrowing methods and approaches used in ergonomics (e.g. [59]) and modelling (e.g. [60]).

A particularly encouraging finding from this review was that the majority of studies used human subjects to perform preliminary testing. It should be acknowledged that it is challenging to replicate the complex loading state at the human-device interface with a phantom, which may affect sensor

performance. Most studies employed sensors at discrete anatomical landmarks rather than instrumenting the entire interface. This was perhaps due to the translational nature of the work, where authors were testing feasibility at discrete points before developing more complex networks to measure over larger areas. It may also indicate that the clinical focus in these applications tends to be towards 'trouble areas' where discrete stress measurement is adequate. Regardless, there were several high and moderate quality studies that support either approach, with orthotics applications tending to favour large area pressure mapping and prosthetic and exoskeleton applications focusing on discrete points.

Quality assessment

No trends were identified in the study quality across different types of sensors or for the application areas (i.e. prosthetics, orthotics, exoskeletons). The quality of the studies was mixed across these categories, with the majority of studies being of moderate or high quality. The lowest scored category across all disciplines was the provision of raw data by authors from their conducted experiments. This was particularly discouraging considering the easy availability of free online data repositories such as GitHub, Zenodo etc., some of which also allow for tagging datasets with DOIs (thus allowing formal acknowledgement of data re-use and improving citation counts). Of the 33 papers reviewed, only 1 prosthetics paper published their raw data for readers to access [38]. The availability of anonymised raw data is good practice as it allows readers to understand the conclusions made and perform analyses themselves to replicate and extend the methods. The publication of the raw data also allows the amalgamation of data sets which could lead to more robust investigations, particularly beneficial for areas with low participation numbers.

There was a relatively even distribution of study quality across different sensor types. The highest numbers of moderate and high quality studies covered resistive sensors, Fiber Bragg gratings and strain gauges. This does not exclude the merit of the other technologies that were explored, but highlights the need for further studies to provide more robust evidence for use.

We noted a particular lack of reporting of clinically relevant thresholds for acceptable load levels, either normal or shear. While this can make it difficult to understand whether the measured levels of load in the studies pose a clinical problem, it is not an unexpected omission. Literature has reported various acceptable load thresholds, with no specific range universally accepted [58,61]. The acceptable levels of load vary across the body of an individual, and across different individuals. It may also significantly vary with the size of the interface and the duration of the loading. Many of the papers included in the review do not outline the assessment of acceptable pressure in clinical applications as an aim, rather they outlined the manufacture and testing of the sensor technologies to understand if they were fit for purpose. Future research using the technologies outlined in the included studies would be beneficial to evaluate the clinical relevance of the sensor devices.

The translation from sensor fabrication and characterisation to clinical use is a vital step in the successful integration of new technology into the clinic. Studies demonstrating the details required for clinicians to select, build, calibrate and run published technology open opportunities for increased clinical use in similar and different contexts.

Strength of conclusions was a particular issue when studies did not include many participants, or the tests were conducted on a convenient population (e.g. healthy adults, male) rather than the target demographic of the technology. Sample size was generally small, with only a few papers explicitly stating that they were conducting preliminary or pilot testing. It was noteworthy that in some instances, none of the participants tested were representative of the intended end users, and yet conclusions were drawn about the suitability of the technology for them. Based on the review, we would encourage authors to consider highlighting the next steps required to continue to ensure technology is fit for purpose in the specific demographic.

Based on titles and abstracts that were reviewed but not included in this study, it was common for studies to report that newly developed sensors were appropriate for use in a clinical context without including any data on clinical testing having been performed. In order to ensure that the most

clinically and technically appropriate sensors can be selected for a specific application, it would be highly beneficial that the additional steps of including details of preliminary clinical testing and experimental protocols are taken, and that it is demonstrated that the technology is fit for purpose.

This review selected papers positioned between the traditional benchtop and full clinical testing. As a result, sample sizes were generally smaller, and focused on showing the feasibility of the sensor systems rather than answering clinical questions. This also meant that statistical measures were not widely utilised. Studies were also generally completed in a laboratory. Therefore, it is important to note that the conclusions about the studies here will not necessarily apply to studies conducting more robust clinical testing. Rather, the purpose is to provide authors with some guidance on pertinent reporting guidance for studies that fit in this context and summarise existing technology that may lead to innovation across disciplines. It is clear that once a sensor has been deemed fit for purpose, the next steps would involve the move to formal clinical testing. If the aim is to determine pressure tolerance or a particular pressure distribution for individuals in activities of daily living, a relative pressure reading may be adequate with testing in the home environment instead of the laboratory or clinic. However, if trends and comparisons are sought for multiple users, relative pressure may be too subjective. Further development and testing of the sensors may be required to characterise sensors in wider applications to minimise the error of absolute values and ensure robust readings for comparison. The questions to be answered should be directed by those who use and fit the devices; collaboration with relevant clinicians, device users and researchers should be at the centre of determining the appropriate use of the sensors and future testing to allow for robust interpretation of values. Another aspect of development is the ease of use in the desired environment, with development of user interfaces and fabrication methods to allow this and quick interpretation of values without the need for engineering specific expertise.

Considerations for Clinical Translation

Clinical use for sensor systems may be broadly divided into use at the time of device fitting, i.e. in the clinic, with a health professional, and, secondly, for longer term monitoring of loads during normal daily life, i.e. outside the clinic, in the community. Deciding whether a particular sensor system is appropriate for use in a given application requires consideration of a combination of parameters reported in the data extraction section (for example pressure range of interest and anatomical location) as well as parameters reported in the quality rating of the study (for example, whether the sensors are validated, and whether there was enough information reported to allow the system to be implemented effectively). Considerations such as portability of the device for applications where participants need to move around, or ensuring that the prosthesis, orthosis or exoskeleton does not need to be permanently modified to integrate sensors will also be relevant depending on the application. In thinking about further translation into systems to be used for longer term monitoring outside the clinic, considerations such as portability, data recording and security and power requirements, user comfort and preference are also essential.

The studies included in the review did not explore further possibilities for clinical translation, including seeking feedback from users (clinicians and service users) on preferences for the technologies or how they could be used to complement routine practice. There was also no indication that the application of the sensors would be modified for ease of use without specialised engineering knowledge. For instance, it has been demonstrated that various sensors including, temperature, pressure, shear and humidity sensors can be incorporated into a wearable devices, such as a prosthetic liner [62,63]. The advantage here is the relative ease of use in the clinical environment, which makes it suitable for application without need for specialist knowledge of the technology. Additional studies (not included in the current review due to the inclusion criteria) complete testing with service users using commercial sensor technologies; Tekscan sensors, in particular, are a frequently used product in this context [64–66].

It is also important to consider how the information from the sensing technologies is going to be understood by clinicians and service users, a crucial part of ensuring the hardware adds value to the

clinical environment. Software development can be an asset for this, with the creation of an easy-to-understand user interface making complex technologies and extensive data comprehendible and useful. This has been demonstrated in previous studies, both with and without the use of sensors to inform data presented [67–69].

Due to the translational nature of the reported studies, a vital aspect of clinical translation was missing: i.e. the engagement with the end-users, both the clinicians and users of the devices. From the methods outlined in the reviewed studies, whilst some indicated awareness of clinical issues (e.g. the need for stress monitoring or clinical thresholds), most did not integrate feedback from target users. This presents an exciting area for future work.

Study limitations

Our review focused on a subset of studies within the identified application areas, and can be associated with the following limitations. First, studies not published in English were not considered. Second, we only included peer reviewed journal articles. By excluding conference proceedings, we may have overlooked initial translational research that tends to get published in the relative faster review process associated with conferences. Third, the reliability and validity of the quality rating scale was not assessed. Although every attempt was made to develop the scale based on established quality rating scales, consistency of interpretation of the scale and studies by researchers outside of the study have not been performed. Finally, studies included in this review needed to include both sensor development and benchtop calibration as well as preliminary clinical tests to meet the inclusion criteria. This meant that any studies detailing only sensor development or only clinical testing have not been included. It is also worth noting that as a field of ongoing research, new technologies and solutions are being constantly developed. For example, the recent study by Dejke et al. [63] showcases relevant pressure sensor technology for prosthetic applications. However, this

study was published after the inclusion period specified for our current review and hence not included in the results.

In summary, the results of the review showed that the quality of papers in the prosthetic, orthotic and exoskeleton areas was variable. While different sensing technologies were tested across the disciplines, there was no one accepted as universally appropriate. The measurement of normal load was more common than shear despite it being accepted as a key factor in comfort and skin breakdown. Most studies started the process of understanding the acceptability of translating the sensing technologies into the clinical environment by conducting some initial testing with a study population, with some also comparing their results to significant clinical thresholds. However, study populations were generally small and were not always made up for the target users and reported clinical thresholds were not consistent. In general, studies could be strengthened by performing clinical testing with target populations in relevant environments and shared progress and understanding could be achieved by sharing de-identified data.

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454

455

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