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The Role of Sensor Based Insole as a Rehabilitation Tool in Improving Walking among the Patients with Lower Limb Arthroplasty: A Protocol for Systematic Review

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Authors' contributions

This work was carried out in collaboration among all authors. Authors SR and AS wrote the protocol and performed statistical analysis. Authors SM and GK designed the study and supervised in writing the first draft of the manuscript. Author AA managed the literature searches. All authors read and approved the final manuscript.

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Systematic Review Article

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ABSTRACT

Objectives: The purpose of this review protocol is to assess the role of sensor based insole in improving walking in patients with lower limb arthroplasty and to rule out the demand and advantage of sensor based insole in utilizing such types of problems at clinical setup.
Methodology: A systematic review will be conducted by two independent reviewers who will search articles using electronic search for publications in seven databases: Google Scholar, Index Copernicus, JSTOR, PubMed/Medline, Science Direct, Scopus and Web of Science. After applying the selection criteria, study papers published between the years 2001 to 2019 will be selected. Studies of human participants of 45-75 years of age having history of lower limb arthroplasty will be

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eligible. All the study papers will be analyzed using Modified Downs and Black scale and scores will be awarded for the items selected on a 27 point scale.
Findings: The findings of this review will be disseminated through presentations and peer-reviewed publication. The systematic review will direct the attention of the physiotherapists to assess and evaluate the patient's walking pattern, as alterations in the biomechanics of joints of lower limb can produce far-reaching effects in the ideal or normal gait. The results of this review will provide evidence regarding changes in gait parameters in patients with lower limb arthroplasty and this information will be useful in planning for rehabilitation in improving walking of patients after lower limb arthroplasty.
Novelty: Many studies have been carried on sensor insole technology for monitoring gait. However, there is scarcity of literature based on the systematic reviews on the use of smart sensor insole in improving walking among patients with lower limb arthroplasty.

Keywords: Arthroplasty; sensor insole; gait; rehabilitation.

1. INTRODUCTION

Arthroplasty is a more common surgical procedure performed on weight bearing joints such as knee and hip joints aimed to reduce symptoms and minimize disability and optimize the physical function [1]. Arthroplasty is often recommended for various musculoskeletal or bone related disorders and joint disorders [2]. It is estimated that over 1,20,000 total knee replacements(TKRs) are performed in India annually [3]. Post-surgery, recuperating the normal walking pattern is the most significant factor in recovery [4]. Phases such as, toe off or heel strike are the proven and validated methods for assessing the temporal parameters of gait and are precursors for measuring other temporal variables such as swing time, stride time and step time [5]. Evaluating temporal variables is very critical, because they play a major role in determining the risk of falling in the elderly population [6]. For the assessment of gait biomechanics, a well-equipped, expensive and complex biomechanical laboratory is mostly needed. To date, the gold standard assessment of ground reaction forces is by detecting initial contact and toe using force plate [7].

From last few years, there has been a high demand for wearable sensors integrated with smartphone-based devices used for gait analysis outside the laboratory setting [8]. Sensor based insoles helps in monitoring the gait impairments and thus helps in changing the walking patterns [9]. In the absence of regular motion capture based camera, Inertial Measurement Units (IMUs) can be used [10]. IMUs are portable and battery-powered sensors consisting of a gyroscope, an accelerometer and a magnetometer, and they are also small and powerful [11]. Previous work has shown that IMU is a true and accurate instrument for determining gait parameters. The accelerometer is primarily used to test the gait parameter but now the researchers are showing interest in the gyroscope as well [12]. The validity and reliability of gyroscope-based approaches to detect anomalies in the gait parameters becomes an important criteria [13].

Diverse work has been carried out on the creation and use of wearable devices to examine the human gait. Tao Liu et al. proposed a 3-axis accelerometer and gyroscope mobile gait analysis system [14]. Xu et al. developed an algorithm based on compressed sensing with one accelerometer for accurate detection of human behavior [15]. Usage of insoles affects the gait parameters in patients with various neuromuscular disorders and has effect on preventing gait related abnormalities [16]. However, no research has been carried out on the use of smart sensor insole in improving walking among patients with lower limb arthroplasty. The systematic review will focus on the role of a smart sensor based insole as a rehabilitation tool in patients with arthroplasty in the lower limbs in order to improve the walking.

2. OBJECTIVES

Sensor-based insole in lower limb arthroplasty- there might not be enough literature which is already published on this topic.

Key review question:

1. What is the effect of sensor-based insole on improving gait parameters in patients with arthroplasty in lower limbs?

   P= adult patients having 45-75 years of age with arthroplasty of lower limbs.

I= any sensor-based insole provided to patients with lower limb arthroplasty as part of a walking enhancement rehabilitation programme.
C= any comparator such as gait labs, wearable sensors
O= outcome measure relevant to the evaluation of the gait parameters such as temporal and spatial parameters of gait e.g. step length, step time, cadence, stride length and stride time
S= any form of setting in any region / country

Secondary review questions:

1. When assessing gait parameters in patients with lower limb arthroplasty, what precautions and contraindications should be taken into account?

   To answer the secondary review question the papers selected from the search results for the main review question will be further reviewed. Selected papers will be reviewed for further information.

2. What challenges will the researcher face when testing the gait parameters of patients with a lower limb arthroplasty?

3. MATERIALS AND METHODS

3.1 Participants

Studies may include only human participants between 45-75 years of age undergone arthroplasty in the lower limbs. Lower limb involvement will not be limited unilaterally or bilaterally. It will include both the genders, i.e. males and females. Excluded from the study are experiments involving animals as participants. Studies involving patients suffering from other serious acute / chronic illness will be excluded from the study. The study would also restrict research concerning mentally challenged or psychosocially deficient patients.

3.2 Included Study Designs

Any form of study design that takes into consideration the role of sensor-based insole in arthroplasty of the lower limbs.

3.3 Interventions and Comparators

Devices or tools that provide any form of exposure to sensor based insoles and shoes will be included. Interventional and evaluation based study will be considered if validated outcome measures were measured at least two visits including baseline, follow-up and on completion of intervention. We'll include any comparator in terms of comparison with the other standard validated sensor based device to measure the outcomes.

3.4 Outcomes

Outcomes Measures for assessing gait variables such as spatiotemporal variables (e.g. step length, step time, cadence, stride length and stride time).

3.5 Language

We will only consider full text articles published in English.

3.6 Search Strategy

The library of Lovely Professional University (LPU) and the library of Swami Vivekanand Subharti University (SVSU), Meerut, will conduct a thorough search during the span of 6-9 months. All bibliographic databases of readily accessible published research papers will be assessed. All required databases will be checked from the year 2001 to 2019. The electronic database includes Google Scholar, Copernicus Index, JSTOR, PubMed / Medline, Science Direct, Scopus and the Web of Science.

Table 1. Search terminologies used in this review protocol

Keywords	Alternative words
Knee Arthroplasty	Knee joint replacement, total knee joint replacement (TKR), total hip joint replacement (THR)
Physiotherapy	Physical therapy, rehabilitation, physical medicine
Biomechanics of Knee	Kinetics of knee joint, kinematics of knee joint Arthrokinematics of knee joint, dynamics of lower limb
Walking	Gait, normal gait, locomotion, gait cycle, gait phases
Gait parameters	Gait variables, spatial-temporal parameters of gait
Sensor based insole	Sensor based shoe, smart insole, wearable sensor insole

3.7 Study Records

All the searched results will be combined using 'Mendeley' information management software. The results of online searches will also be saved to the PUBMED account of the researcher. A shared folder on 'Google drive' will be developed by the principal investigator / researcher to promote and facilitate collaboration among reviewers and make it accessible by all researchers. The physical backup will be preserved by keeping all the screened papers in printed copies of the summaries.

3.8 Selection and Data Collection of Studies

Two reviewers 'SR' and 'AS', both physiotherapists, will separately search the databases and screen for eligibility titles and abstracts. The checked titles and abstracts will be carefully reviewed and the irrelevant papers will be deleted. The full text of selected potentially relevant articles will be obtained; to minimize duplication, multiple articles from the same study will be linked on different database. Both reviewers must extensively analyze full text articles to verify their conformity according to the requirements for inclusion and exclusion. The correspondence will be conducted among the author and co-authors to explain whether there is any misunderstanding. The judgment of the third reviewer 'SM' will be considered final in the event of difference between the researchers. Reviewer 'SR' will do the data analysis / synthesis of the articles meeting the eligibility criteria. The reviewer will also manually search the articles for references to be included in data extraction.

3.9 Assessment of (Risk Bias and Quality) Individual Studies

Cochrane communication method would be used to determine the possibility of bias. Modified Downs and Black 27 point scale will be used to determine the content of the literature. The cut-off to select or reject a particular manuscript is 19; the manuscripts below this range will be rejected. As per the interpretation of Modified Downs and Black 27-point scale: excellent (26-28); good (20-25); fair (15-19); and poor (less than=14). This scale determines the quality of the content of literature on the basis of its parameters such as reporting, internal validity, external validity and power.

3.10 Best Evidence Synthesis

Due to the possible heterogeneity of the outcome measures a narrative synthesis of the selected studies from the search results will be given. Population and outcome measures for patients will be described in a summary narrative. Information on protocol adherence, resources used, compliance monitoring and expenditure will, where available, be extracted from the selected studies. The meta-analysis will be performed using 'Revman' software. The model employed to aggregate and analyse the data into a meta-analysis will be the 'random effects' model.

4. RESULTS AND DISCUSSION

Literature evidences suggest that very few studies are available which provide experimental evidence relevant to evaluating the role of sensor based insole in patients with lower limb arthroplasty, as far as we are aware. This study will provide an answer to the question about the impact of sensor based insole in improving gait parameters in patients with the lower limbs arthroplasty. This will provide information on the safety precautions taken during the procedure to avoid adverse events. Subsequent review of the evaluation information published in the included literature should include previously inaccessible information on evaluation elements as to whether such elements are related to evidence of substantial benefits and whether best practices can be determined for the use of sensor insole to assess gait parameters and track patients' walking with lower limb arthroplasty.

Relevant details on safety measures considered to address the risk of adverse effects during the evaluation of gait parameters using the sensor insole for patients with lower limb arthroplasty will be highlighted. Where information on this evaluation is available that is relevant in low-income countries for patients with lower limb arthroplasty, the authors will compile evidence-informed guidance for the safe use of sensor-based insole in these settings.

5. CONCLUSION

This is a systematic review protocol to conduct a systematic review and meta-analysis for assessing the role of sensor based insole in improving gait parameters in patients with lower limb arthroplasty. All the articles will be selected on the basis of inclusion and exclusion criteria

and the random effects model will be employed to aggregate and analyze the data into the meta-analysis. For assessing the quality and risk of bias, Modified Downs and Black 27 point scale will be used. The systematic review will direct the attention of the physiotherapists to assess and evaluate the patient's walking pattern, as alterations in the biomechanics of joints of lower limb can produce far-reaching effects in the ideal or normal gait. This review will provide evidence regarding changes in gait parameters in patients with lower limb arthroplasty and this information will be useful in planning for rehabilitation in improving walking of patients after lower limb arthroplasty.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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