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Smart Insoles a Cutting Edge Technology in the Field of Orthotics: A Review

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ABSTRACT

Introduction: Smart insole is a biomechanical device which consist of sensors within the insole that can be used for evaluation of gait pattern, plantar pressure, centre of pressure, balance, monitoring of activity, and for performing a quantitative assessment of motor functions. Smart insoles are light in weight, results in minimally impacted gait, which make the measurements obtained to be more reflective of our natural gait. It can be used for assistive living, healthcare promotion, fitness monitoring/training, human-machine interactions, disease detection, rehabilitation which is also increasing day by day.
Aims: The aim of the study is to highlight the importance of smart insoles along with its advantages, limitations and future implications in the field of Orthotics.
Study design: literature review
Method: An electronic database search was conducted using Google Scholar, ScienceDirect, PubMed, Cochrane library and reference list from all the retrieved articles. The 15 articles have been reviewed using key words like smart insoles, pressure sensing, diabetes, flatfoot, stroke, Parkinson and foot ulcers. Further the articles have been reviewed on the evolution of smart insoles, their importance, how can it be a revolutionary device for the patients with common life style pathology like ulcers, flat foot etc. The articles were also reviewed on the advantages and disadvantages of the smart insole and their limitations.
Results: Studies had showed that the smart insole can be used to evaluate foot pressure measurements, gait spatiotemporal parameter extraction, and gait pattern of the wearer. It also includes applications for tracking gait abnormalities associated with neurological diseases, detecting walking abnormalities in adults and elderly, and patient rehabilitation. Additionally, it can be used for activity recognition, which is primarily supported by machine learning for clinical test translations, caloric estimation, daily activity tracking, and assistance for the safety and work environment in particular occupations. Furthermore, it aids in monitoring diabetic foot, foot gesture recognition for digital device management and human-machine interactions in gaming, and vibration insoles.
Discussion: During functional movement, the motion tracking sensor in the smart insole provides real-time input. Additionally, it supports the ideal movement pattern and follows the adhere rehabilitation protocol. The wireless transmission of this data to a health care professional's mobile application allows for real-time analysis of the gait pattern, pressure spots, and prospective problem region, which may improve the decision of treatment. When the sensors come into contact with the user's body, they also monitor the temperature and

humidity conditions. This additionally help for assessing comfort in identifying skin irritation or moisture accumulation, which aids in further improving the orthosis's construction and design.

Conclusion: Smart insoles are insoles that are seamless from the shoe, lightweight, adaptable to fit any shoe, and have a low cost of production due to their easy integration of small-sized electronics and can perform. Along with this, storage capacity and power usage will be an issue and it is inconvenient to constantly charge or replace batteries, few design have been done to overcome these problems. Therefore, in the near future, smart insoles could rank among the best wearable technology to analyse gait, balance, plantar pressure, posture and other characteristics. Thus, it is a useful tool for the field of Orthotics.

Keywords: smart insole, plantar pressure, gait analysis, foot ulcer

INTRODUCTION

Smart assistive devices are emerging as a beneficial technology for the person with any kind of disability, such as speech control of assistive devices for the physically disabled [1], interactive devices for deaf and dumb using atmega 328 processor [2], dual mode application of control system for people with several disabilities [3], smart canes for geriatric people [4], etc. In the last ten years, an extensive type of wearable technology has become available for use in our daily lives for assistive living [5], health promotion [6], fitness tracking and training [7], human-machine interactions [8], disease diagnosis [9], rehabilitation [10], and a host of other applications. For everyday usage, wearable technology must be small, light, discreet, portable, easy to use, reasonably priced, and have a long battery life. Fitting all the criteria, smart insoles are quickly emerging as the newest and most popular wearable technology for daily use. An insole that is undetectable from the shoes, portable enough to fit into any shoe, small enough to integrate small-size electronics with ease and at a low cost of manufacturing is referred to as a smart insole. As a result, in the near future, smart insoles might rank among the best wearables. Smart insoles can be used in daily life for activities such as activity detection, gait pattern analysis, gait spatiotemporal parameter extraction [12], and foot pressure measurement [11]. Apart from being employed as medical equipment in labs or clinics, smart insoles can also be used for fitness training, rehabilitation, health monitoring, support disease detection, and foot gesture recognition for human-machine interaction [13]. For everyday applications, data accuracy, power, wearability factor, connection, affordability, and robustness are essential. Over the past ten years, the offered insole devices have changed from being large and heavy to being lightweight and even invisible [14]. Therefore, the aim of the study is to highlight the importance of smart insoles along with its advantages, limitations and future implications in the field of Orthotics.

BACKGROUND

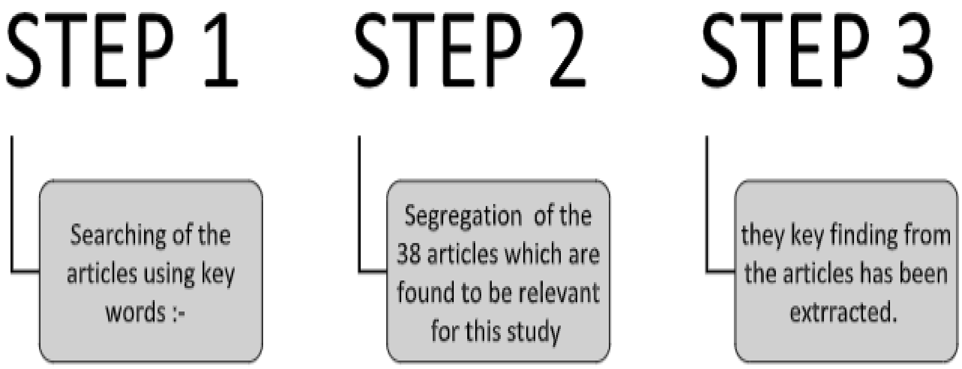
The concept of smart insoles, which emerged from the idea of smart shoes, which first appeared in the late 19th century when E.J. Marey investigated human gait by looking into pressure recording shoes, was the first attempt to measure human movement [15]. When the MIT Media Laboratory first investigated the piezoelectric and rotary magnetic generator inside the shoe to power small electronics and created self-powered Radio Frequency Identification (RFID) trainers, from 1998 to 2001, their groundbreaking work entered a new era for smart shoes. Micro electromechanical systems (MEMS) were introduced to the human shoe during the start of the twenty-first century. The proposed solution, known as GPDS, had a gyroscope fixed to the rear of the shoe and three force sensors integrated into the insole, providing additional data on human motions in addition to pressure readings. These sensors were provided by Pappas et al. In 2004, Pappas and colleagues made revisions to their design and presented the idea of a shoe insole that incorporates all sensors, known as a GPDS insole. Only a small number of research studies addressed the term "insole," despite the fact that prior to 2008, most studies concentrated on large but simple designs to demonstrate the principles [16].

2008 saw the emergence of flexible printed circuit boards (PCBs) and flexible electronics, which allowed smart insole devices to begin to gain popularity. Like the GaitShoe and Hermes, the majority of smart insole devices use multiple types of sensors to gather additional data, including human mobility, ambient context, and localization [17]. The enormous amount of sensor data processing was addressed by the advancement of sensor fusion and machine learning technology. The suggested prototypes at this time often had several sensors placed at various foot barriers. Hence, in contrast to the 2014–2021 timeframe, the majority of prototypes still have large designs with certain components fastened to the shoes, ankles, and thighs. In addition to extensive research on gait, rapid advancements were being made in other fascinating applications, including the detection and categorization of diseases, the identification of activity and posture, and assistance for dance. Prototypes of representative smart insoles, including SmartStep1.0, Smart Insole version 1, Elastomeric Insole, and Kinetic Insole, [18] were presented on stage and demonstrated significant promise for applications in everyday life.

Since 2014, several groups have shown a huge amount of interest in smart insole devices. The use of smart insoles in daily life has become more common because of a number of factors, including new sensor technologies, signal processing algorithms with cutting-edge machine learning technologies, and the mature technologies used in the last few years to continuously simplify smart insole designs [19, 20]. Additionally, in contrast to previous versions of smart insole designs, the suggested smart insole prototypes are designed to be lightweight, portable, and economical, with no visible components outside of the shoe, all in an effort to maximize user comfort. In contrast to the previous model, which had five force sensors and an electrical panel fastened to the rear of the shoe, the "SmartStep2.0" was introduced in 2014 and had three force sensors as well as an electrical board inserted in the middle foot [21]. It produced identical results for gait analysis and activity detection. In 2017, after a span of three years, the "SmartStep3.0" was created as a universally fitting insole that fits all shoe sizes [22]. The "Smart Insole" version 1 product has evolved into five variants at the same time. Significant improvements have also optimized each version's amount of pressure sensors incorporated for different application. Using a triboelectric-electromagnetic nanogenerator in conjunction with piezoelectric nanogenerators, Deng et al. (2018) created a pressure distribution monitoring insole that operates in real time. A smart insole with a triboelectric nanogenerator for gait anomaly detection was proposed a year later. The self-charging or battery-free option for everyday usage is one of the two benefits of these footstep energy collecting insoles. Moreover, the energy producers can be used as pressure sensors, eliminating the need for extra ones and bringing the smart insole-like gadgets even closer to common services. Beginning in 2017, polymer optical fiber (POF) is utilized in pressure-sensing smart insole-like devices. POF are a good option for long-term use in wearable devices since they are more resilient and flexible than the current pressure sensors (Force Sensing Resistors, Piezoelectric Sensors, and Capacitive Sensors) [23].

MATERIALS & METHODS

Various articles from following databases like Google Scholar, ScienceDirect, PubMed and Cochrane library were retrieved through a search by using keywords Smart insole, gait, plantar pressure, diabetic foot, foot ulcer, etc. Studies which includes gait analysis, plantar pressure, balance, as a parameter for the evaluation of the efficacy of smart insoles were included in the study. Total 20 articles were included in the study and based on their findings a review was made



RESULT

An orthotic insole creates a more practical connection between a patient's diagnosis and course of treatment. Smart insoles can be a convenient and alternative treatment for both patients and healthcare professionals [24]. In 2015, Mustufa et al., design and developed a smart insole that can measure temperature, acceleration, plantar pressure, and the foot's rotational angle. The system is designed to offer an easily accessible and invisible device platform that is simple to incorporate into current recreational footwear. In a free-living environment, the smart insole offers a potent research platform that is affordable and flexible, capable of recording and undertaking gait analysis. The research community can benefit from the smart insoles usage of wireless technology, which makes data transfer easier and can be conveniently integrated with cloud services [25]. In 2017 Bijan Najafi show that high-risk diabetic patients believe smart insoles to be useful and acceptable, and that they may improve adherence to recommended footwear when used in conjunction with an alert-based feedback system warns patients of dangerous plantar pressures. This study specifically indicates that users may improve their adherence to footwear over time, respond more favorably to alert-based feedback, and perceive the advantages of such a technology-based intervention if they receive at least one alert every two hours. Furthermore, a low frequency of daily warnings can deter diabetic patients from wearing smart insoles. Furthermore, smart insoles can be a useful supplement to smartwatches and smartphones, which are usually worn on the trunk or upper limbs, by giving extra data about the lower limbs to help expand body sensor networks. In particular, it is supposed to be small, low-powered actuators and sensors would play critical roles in smart systems and smart devices in the era of the internet-of-things (IoT) and internet-of-everything (IoE) [26]. Thus, plantar pressure, activity, gait pattern, and a quantitative evaluation of motor capabilities can all be tracked in real time with smart insole devices. considering that such a system is non-obtrusive, it also has a little impact on gait, which helps ensure that the measurements are more accurately reflective of human gait.

The details of the reviewed articles are tabulated in given table.

S.no	Authors & year	Title of the study	Conclusion
1.	Behzad Karimkhani & Sayed Hasan Mirtalaie 2023	Analysis of Orthotic Insoles Manufacturing for Treating Flatfoot Using Smart Orthotic Insole in Comparison with Traditional Methods	Used three technologies for the fabrication of modified insole for flatfeet patients and found smart insole as the most effective for the assessment & evaluation of plantar pressure of the patient.
2.	Amith Khandakar, et al. 2022	Design and Implementation of a Smart Insole System to Measure Plantar Pressure and Temperature	Showed that smart insole can be used to continuously monitor foot issues at home by comparing the temperatures and pressure patterns of the two feet. With the use of artificial intelligence, the created maps can be utilized for the early detection of diabetic foot complications.
3.	Chariklia Chatzaki, et al. 2021	The Smart-Insole Dataset: Gait Analysis Using Wearable Sensors with a Focus on Elderly and Parkinson's Patients	Proved the accepted beliefs about the gait characteristics of Parkinson's disease patients and the elderly, as well as the differentiation between the groups.
4.	Zhiming Lin, et. Al 2018	A Triboelectric Nanogenerator-Based Smart Insole for Multifunctional Gait Monitoring	Used smart insole for the purpose of evaluating rehabilitation, the smart insole may also be utilized to track abnormalities in gait. Furthermore, they also found that smart insole can serve as a vital fall detection device for patients or the elderly, among other crucial roles in healthcare applications.
5.	Caroline A Abbott, et al 2019	Innovative intelligent insole system reduces diabetic foot ulcer recurrence at plantar sites: a prospective, randomised, proof-of-concept study	demonstrate how a smart insole system's dynamic offloading guidance and ongoing plantar pressure monitoring can reduce the recurrence of diabetic foot ulcer sites.
6.	Hanatsu Nagano and Rezaul K. Begg 2018	Shoe-Insole Technology for Injury Prevention in Walking	Found that the use of shoe insoles as an intervention to promote safe walking has promise.
7.	Allyson R. Alfonso, et al 2017	Novel Pressure-Sensing Smart Insole System Used for the Prevention of Pressure Ulceration in the Insensate Foot	Found that in diabetic foot there is a tendency to develop pressure ulcers, the insensate foot presents difficulties for wound prevention.
8.	Mustufa, et al 2015	Design of a smart insole for ambulatory assessment of gait	developed a smart insole that can measure temperature, acceleration, plantar pressure, and the angle at which the foot rotates. It offers a potent, scalable, and inexpensive research platform that can record and then perform gait analysis in a free-living environment and the data transfer of the smart insole is facilitated by wireless technology, which may be seamlessly integrated with a cloud service to benefit the research community.
9.	Changwon Wang, Young Kim and Se Dong Min 2018	Soft-Material-Based Smart Insoles for a Gait Monitoring System	developed a wearable, soft-material-based, smart insole sensor that is affordable, easy to use, and has a real-time monitoring system.
10.	Adin Ming Tana, et al 2015	Centre of pressure detection and analysis with a high-resolution and low-cost smart insole	Developed a smart insoles that have the ability to detect macroscopic changes to the COP and also showed a high degree of correlation with the force plate.

DISCUSSION

Smart insoles have been used in studies [27, 28, 29] detect and identify a variety of abnormal gait patterns, including toe-in, toe-out, heel-walking, toe-walking, foot pronation, and supination. When abnormalities are recognized, users receive feedback. Few research has examined the variations in gait between stroke patients with abnormalities and healthy controls, except from identifications. According to few studies [30, 31, 32], diabetic foot ulcer monitoring can be done with smart insole devices. The severity of foot ulcers can be prevented and tracked in daily life by keeping an eye on variations in foot pressure, temperature, and humidity. For instance, Rescio et al. developed an insole for elderly persons with eight pressure and eight temperature sensors to demonstrate its usefulness in measuring foot pressure and temperature. However, diabetic patients were not used to test the insole's impact on foot ulcers. In addition to monitoring, a special kind of smart insole was developed that delivers specific oxygen to a diabetic on the insole's sole. Similar research tested a small number of diabetes individuals to demonstrate the effectiveness of pressure-sensing insoles in preventing pressure ulcers. Smart insole has the potential to accurately identify certain actions, as evidenced by low-cost systems such as Deepsole [33]. Furthermore, the work demonstrates that modest amounts of data acquired with low-cost, no calibrated sensors can be utilized to classify activities with comparable accuracy to data collected using other methods. These findings seem to indicate that the insole devices may be able to categorize the severe motor impairments that Parkinson's sufferers experience. In order to assess the effectiveness of the smart insole in identifying Parkinson's motor dysfunctions, Chariklia [34] employed a neurologist with expertise in movement disorders. By incorporating vibration motors (coreless DC motors) into the design, smart insoles are utilized for feedback in addition to sensing. GymSoles with vibration motors were created by Elvitigala to enhance users squatting performance [35]. According to Regueme, diabetic sensorimotor polyneuropathy may benefit from mechanical noises. In order to help with postural stability and to increase diabetic foot sensitivity, they devised a smart insole incorporating vibration motors [36].

Recently in 2023, Behzad Karimkhani and Sayed Hasan Mirtalaie found that for the fabrication of an insoles, more sophisticated method should be used due to the inefficiency and significant time required by the procedure based on this method. The utilization of data obtained from smart orthotic insoles is the central idea of this sophisticated approach. Due to its constant presence during normal motions and activities, the smart orthotic insole technique gathers accurate and real-time information regarding the subject's foot state in comparison to the traditional stamp-based and scanning-based methods. As such, the insole that was created using this data is quite accurate. Additionally, this process shortens the time needed to fabricating orthotic insoles [24].

CONCLUSION

In conclusion, it is anticipated that smart insoles would play a significant part in intelligent systems and smart devices in the era of the internet of things (IoT). Because of this, a smart insole equipped with pressure sensors or IMUs, along with fast processing and communication technologies, can be used to monitor an individual's activity in real time and provide a quantitative evaluation of their foot health based on their daily activities which allows for real-time analysis of the gait pattern, pressure spots, and prospective problem region, which may improve the decision of treatment. When the sensors come into contact with the user's body, they also monitor the temperature and humidity conditions. This additionally help for assessing comfort in identifying skin irritation or moisture accumulation, which aids in further improving the orthosis's construction and design.

Limitations

- As per as our best knowledge, we had not found any study from the developing countries because collecting data for research involving smart insole devices is costly and time-consuming.
- In our review, we found that only few studies gathered data from tests involving more than ten people. The majority of research solely enrolled college students; thus, the data are not diverse.

Future consideration

- More experimental researches are required to establish the effect or efficacy of smart insoles in the field of orthotics.

Declaration by Authors

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