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A Systematic Review on Smart Insole Prototypes: Development and Optimization Pathways

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Santos, VM; Gomes, B; Neto, MA.; Amaro, AM.

Corresponding author:
Vítor Miguel Santos

vmfsantos@student.dem.uc.pt

Author Affiliation:
University of Coimbra.

ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - The work is on the final stages. At the moment minor corrections are being done.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 6 February 2025 and was last updated on 6 February 2025.

INTRODUCTION

Review question / Objective What methodologies are used to assemble smart insoles prototypes, preferable the ones with a wireless/bluetooth communication/transmission system and AI integrated?

Rationale The rationale of the study is based on the increasing importance of smart insole technology in biomechanics, healthcare, and athletic performance, particularly with the integration of artificial intelligence (AI) and wireless communication systems.

Condition being studied Diabetic foot monitoring, fall risk assessment, rehabilitation monitoring, musculoskeletal disorders and even injury prevention in sports through the gathering and analysis of gait patterns, plantar pressure distribution and ground reaction forces.

METHODS

Search strategy The electronic bases included in the investigation were the Web of Science, Scopus and PubMed databases.

Participant or population There isn't addressed a specific type of participant in the respective review.

Intervention This systematic review evaluates smart insole prototypes and their technological advancements, specifically focusing on interventions that enhance their design, functionality, and optimization.

Comparator The comparative intervention consists of evaluating different smart insole prototypes and technologies against each other based on various criteria such as sensor type, AI integration, wireless connectivity, material composition, and practical applications.

Study designs to be included Experimental & Observational Studies like Randomized Controlled Trials, Quasi-Experimental Studies, Cohort Studies; Systematic Reviews and Meta-Analyses; Cross-Sectional and Case Studies; Technological and Engineering Studies; and Conference Papers and Industry Reports.

Eligibility criteria Experimental & Observational Studies like Randomized Controlled Trials, Quasi-Experimental Studies, Cohort Studies; Systematic Reviews and Meta-Analyses; Cross-Sectional and Case Studies; Technological and Engineering Studies; and Conference Papers and Industry Reports.

Information sources This systematic review gathered information from electronic databases, including PubMed, Scopus, and Web of Science. It also includes conference proceedings. A manual search and reference tracking was also made to identify additional relevant studies.

Main outcome(s) This systematic review evaluates AI-powered smart insoles' development, optimization, and effectiveness, focusing on technological advancements, clinical applications, and performance improvements in biomechanics, healthcare, and sports. It examines the evolution of sensor technologies, the integration of machine learning for gait analysis, and the impact of wireless systems on real-time monitoring. Comparisons include AI-enhanced vs. traditional insoles, wireless vs. wired systems, and different machine learning models for movement classification. Key outcomes include gait analysis accuracy, diabetic foot monitoring, injury prevention, rehabilitation progress, and sports performance tracking. Short- and long-term effects are analyzed using classification accuracy, root mean square error, reliability, usability, and battery efficiency. The findings highlight trends, challenges, and pathways to enhance accuracy, efficiency, and user experience, guiding future research and innovation in smart insole technology.This systematic review evaluates the development, optimization, and effectiveness of AI-powered smart insoles, focusing on technological advancements, clinical applications, and performance improvements in biomechanics, healthcare, and sports. It examines the evolution of sensor technologies, integration of machine learning for gait analysis, and impact of wireless systems on real-time monitoring. Comparisons include AI-enhanced vs. traditional insoles, wireless vs. wired systems, and different machine learning models for movement classification. Key outcomes include gait analysis accuracy, diabetic foot monitoring, injury prevention, rehabilitation progress, and sports performance tracking. Both short-term and long-term effects are analyzed using classification accuracy, root mean square error, reliability, usability, and battery efficiency. The findings highlight trends, challenges, and pathways to enhance accuracy, efficiency, and user experience, guiding future research and innovation in smart insole technology.

Additional outcome(s) This systematic review is a comprehensive exploration that goes beyond technological advancements, focusing on material innovation, sensor optimization, AI integration, power efficiency, real-time data transmission, and clinical applications. It evaluates the impact of 3D-printed insoles, carbon fiber composites, and biocompatible materials on durability and comfort, emphasizing the importance of precise sensor placement and calibration for accurate plantar pressure and gait analysis. The study compares piezoresistive, capacitive, triboelectric, and IMU sensors, assessing their effectiveness in real-world applications. Machine learning models, including Support Vector Machines, Neural Networks, and Decision Trees, are analyzed for their role in gait pattern recognition and abnormal movement detection, focusing on improving accuracy through data augmentation techniques. Additionally, the review explores energy-efficient solutions, such as self-powered sensors and low-power electronics, to enhance battery life. Wireless communication systems like Bluetooth, BLE, and ZigBee are evaluated for their role in real-time data transmission, considering factors like latency and cloud-based storage. The study further assesses the effectiveness of smart insoles in healthcare for diabetic foot monitoring, fall-risk assessment, and rehabilitation, alongside their applications in sports biomechanics for injury prevention and performance tracking. Challenges related to cost, data privacy, and commercialization are identified, with recommendations for open-source AI models, standardized datasets, and IoT integration to enhance future smart insole technologies. These findings provide a comprehensive roadmap for optimizing smart insoles, ensuring higher accuracy, usability, and impact in medical, sports, and industrial applications, and instilling confidence in the robustness of the review.

Data management Studies were retrieved from electronic databases such as PubMed, Scopus, and Web of Science using predefined keywords and Boolean operators. All search results were imported into reference management software (Mendeley) to organize citations. The filtering and the duplicates was done manually, while a PRISMA flow diagram tracks the inclusion and exclusion process. Screening is conducted by two independent reviewers, first by evaluating titles and abstracts, then by performing a full-text assessment based on inclusion and exclusion criteria. Quantitative outcomes such as sensor accuracy, machine learning performance, and battery efficiency were analyzed using statistical measures, while qualitative data, including usability and future challenges, undergoes narrative synthesis. Extracted data was stored in Excel software and backed up securely.

Quality assessment / Risk of bias analysis Four elements of the group selected and filtered the studies. High-quality studies must have clearly defined objectives, robust methodology, adequate sample size, validated AI models, properly calibrated sensors, and transparent reporting of results and limitations. Studies with high bias or methodological flaws are excluded or addressed in the limitations section. This quality assessment ensures that only methodological studies contribute to the review's conclusions, enhancing the credibility and impact of the findings.

Strategy of data synthesis Key performance metrics such as sensor accuracy, machine learning model score, battery life, and data transmission speed are extracted and summarized in text to make it understandable. Statistical measures such as mean differences, confidence intervals, and standard deviations highlighted the smart insole prototypes, AI models, and sensor technologies that presented the best results.

For qualitative data, a narrative synthesis approach is applied to interpret trends, usability, technological advancements, and practical applications. Studies were grouped, allowing for an in-depth comparison of AI integration, wireless transmission, material composition, and power efficiency. Importantly, bias assessments and methodological quality ratings play a crucial role in guiding the weighting of findings, ensuring that higher-quality studies contribute more significantly to the conclusions and instill confidence in the research process.

Subgroup analysis It was conducted a comprehensive subgroup analysis to examine variations in the performance, effectiveness, and optimization of AI-powered smart insoles based on key factors. Studies were categorized by technological features, including sensor type (piezoresistive, capacitive, triboelectric, IMU) and AI integration (machine learning models, supervised vs. unsupervised learning). The comprehensive nature of this subgroup analysis helps identify performance variations, optimization challenges, and best practices, ensuring a thorough understanding of smart insole advancements across different applications.

Sensitivity analysis The sensitivity analysis in this investigation assesses the robustness and reliability of the findings by examining how variations in study quality, methodology, and sample characteristics impact the overall conclusions. Additionally, the review evaluates the effect of different machine learning models, sensor types, and wireless transmission methods to identify potential inconsistencies in results. If removing studies with methodological weaknesses or extreme results does not significantly alter the conclusions, the findings are considered robust and reliable. This sensitivity analysis ensures that only well-supported evidence contributes to the final recommendations, thereby strengthening the validity and applicability of the review's outcomes, which carry significant weight in the research community.

Language restriction Yes, only studies published in English were considered.

Country(ies) involved Portugal.

Keywords Smart Insole; Biomechanics; Artificial Intelligence; Machine Learning; Design; Prototype.

Contributions of each author

Author 1 - Vítor Miguel Santos - The author drafted the manuscript.
Email: vmfsantos@student.dem.uc.pt
Author 2 - Beatriz Branquinho Gomes.
Email: beatrizgomes@fcdef.uc.pt
Author 3 - The author read, provided feedback, gave several suggestions and approved the manuscript.
Email: augusta.neto@dem.uc.pt
Author 4 - Ana Martins Amaro - The author read, provided feedback, gave several suggestions and approved the manuscript.
Email: ana.amaro@dem.uc.pt