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Systematic Review

Intelligent Orthotics Technology in the Management of Diabetic Foot Ulcers and Knee Osteoarthritis: A Comprehensive Systematic Review

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Abstract

Background: The management of diabetic foot disease and knee osteoarthritis (OA) with smart orthotics holds significant importance during the early stages of these conditions, given their potential consequences, including functional impairment, chronic pain, and economic burden. Real-time monitoring of plantar foot pressure enables early detection of abnormal force distribution and gait biomechanics, allowing for the redirection of forces away from affected ulcers or arthritic joints. This is the first systematic review to synthesise clinical evidence for smart orthotics technology with real-time plantar pressure sensor biofeedback across both diabetic foot ulcer prevention and knee osteoarthritis management simultaneously. A search of the PROSPERO register confirmed no existing registration covers this specific combination. **Objectives:** To examine the clinical evidence for the use of standard and smart orthotics in the prevention and management of diabetic foot ulcers (DFUs) and knee OA, and to evaluate their impact on plantar pressure redistribution, ulcer recurrence, pain, biomechanics, and economic burden. Eligibility criteria: Studies published in English involving human adult participants ($\geq$18 years) with a clinical diagnosis of diabetes mellitus (at risk of DFU or with peripheral neuropathy) or knee OA, where the intervention involved any orthotic device or smart/intelligent insole with clinical outcomes reported, were included. Studies on healthy individuals only, those not reporting participant age, and non-weight-bearing protocols not differentiated from weight-bearing were excluded. Information sources: Five databases were searched: CINAHL (EBSCO Information Services, Ipswich, MA, USA), PubMed Advanced (National Library of Medicine, Bethesda, MD, USA), Wiley Online Library (John Wiley & Sons, Hoboken, NJ, USA), Cochrane Library (Cochrane Collaboration, London, UK), and Google Scholar (Google LLC, Mountain View, CA, USA). Searches were completed in May 2026. **Methods:** We conducted a comprehensive literature review. This review was structured and reported with reference to the PRISMA 2020 statement (Preferred Reporting Items for Systematic Reviews and Meta-Analysis; University of Ottawa, Ottawa, ON, Canada) to guide transparency of reporting. It does not constitute a full Cochrane-style systematic review; risk of bias assessment was applied to key included studies and GRADE (Grading of Recommendations Assessment, Development and Evaluation; McMaster University, Hamilton, ON, Canada) certainty ratings were applied informally and narratively rather than as formal per-outcome evidence profiles. Five databases were searched yielding

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92,637 records. After removal of 398 duplicates by Rayyan, 92,239 records remained. A subsequent automated keyword-based relevance filter applied within Rayyan (Rayyan AI, Doha, Qatar), prior to human screening, excluded 84,572 records that did not contain any terms related to orthotics, diabetic foot, or knee osteoarthritis, yielding 7667 records for human title/abstract screening. A narrative synthesis approach was adopted owing to the heterogeneity of study designs and outcome measures across included studies, which precluded meta-analysis. This review was not prospectively registered. A complete list of all 78 included studies, including those not individually discussed in the results and discussion. Results: The available clinical studies report promising findings for orthotics and smart orthotics in pain reduction, ulcer prevention, and potential reduction in economic burden, though conclusions are limited by small sample sizes, heterogeneity, and predominantly open-label designs. Recent research found that orthotics can be used to alter the gait pattern that influences knee OA by reducing excessive force on the affected joint. A randomised controlled trial demonstrated an 80% relative risk reduction in DFU recurrence (RR = 0.20; 95% CI: 0.06–0.79; $p = 0.022$), with absolute event rates of 6.3% in the intervention group versus 30.8% in controls (ARR = 24.5%); a second trial reported a 71% reduction in ulcer incidence over 18 months; and a third randomised controlled trial demonstrated statistically significant plantar pressure reduction ($p < 0.01$) in patients with diabetic neuropathy. Conclusions: The available evidence suggests that orthotics may be associated with improved pressure redistribution, reduced ulcer incidence, and benefit in the management of knee OA. Although the number of studies directly comparing smart orthotics with standard orthotics remains limited, the limited comparative studies suggested that smart orthotics showed promising results in reducing ulcer incidence, providing the patient with real-time feedback to offload via their electronic devices. These findings, while preliminary, highlight the potential of smart orthotic technology as an adjunct to standard orthotic care in reducing the overall burden of diabetic foot disease and knee osteoarthritis. **Limitations:** The primary methodological limitation of this review is the open-label design of all included smart orthotic trials, which precludes participant blinding and introduces performance bias. However, this limitation is structural and inherent to the wearable technology field—analogous to surgical trials—and is substantially mitigated by the use of objective primary outcome measures (plantar pressure and ulcer recurrence) across the three included RCTs, the consistency of effect direction across independent RCTs conducted in different countries, and a narrative sensitivity analysis confirming robustness of findings (Risk of Bias Across Studies Section). Formal per-outcome GRADE evidence profiles were not produced; overall certainty of evidence was assessed narratively with reference to GRADE domains and is judged to be low to moderate for smart orthotics in DFU prevention and low for knee OA management, consistent with the Level 2–3 evidence base and open-label study designs. Future adequately powered, multi-site RCTs with standardised outcome reporting, minimum 24-month follow-up, and integrated health economic modelling are the highest priority to extend these preliminary findings. **Registration:** This review was not prospectively registered.

Keywords: smart orthotics; diabetes; arthritis; diabetic foot ulcers; knee osteoarthritis; plantar pressure

1. Introduction

Diabetes mellitus (DM) and knee osteoarthritis (OA) represent two of the most prevalent, disabling, and economically burdensome chronic conditions affecting the global popu-

lation, with both carrying substantial implications for lower limb health, functional mobility, and quality of life. The global prevalence of diabetes mellitus has risen dramatically over recent decades, with the World Health Organisation reporting over 422 million adults living with diabetes worldwide, a figure projected to exceed 640 million by 2040 [1]. In the United States, Mayer-Davis et al. (2017) documented significant increases in the incidence of both Type 1 and Type 2 diabetes among youth between 2002 and 2012, underscoring the accelerating trajectory of the global diabetes burden [2]. Liu et al. (2020), analysing data from the Global Burden of Disease Study 2017, confirmed that the global incidence of diabetes mellitus increased by 102.9% between 1990 and 2017, with particularly rapid growth in low- and middle-income countries [3]. In Australia, over 1.3 million people live with diagnosed diabetes mellitus, with the condition representing one of the fastest-growing chronic diseases in the country [4]. Lee et al. (2013) estimated that the total direct cost of diabetes in Australia was AUD $14.4 billion in 2010, with diabetes-related complications including foot disease representing a disproportionate component of this expenditure [4]. Frescos and Kaminski (2026) recently documented that diabetes-related foot disease alone costs the Australian healthcare system AUD $3.81 billion annually, with per-episode costs including hospital admissions ($21,566), outpatient consultations ($14,212), and wound debridement ($21,566), projecting that these costs will continue to escalate without effective preventative intervention [5].

A critical and preventable complication of diabetes mellitus is diabetic foot ulceration (DFU), which arises from the combined effects of peripheral neuropathy, impaired vascular perfusion, and structural foot deformity. Peripheral neuropathy eliminates protective plantar sensation, allowing prolonged mechanical pressure to accumulate at the plantar surface without patient awareness—initiating a cascade of tissue ischaemia, ulceration, infection, and, in advanced cases, lower limb amputation. Singh et al. (2021) documented that Aboriginal and Torres Strait Islander peoples in North Queensland carry a disproportionate burden of diabetes-related amputation, with Indigenous Australians representing 18.7% of a cohort of 374 amputees—significantly exceeding their proportional representation in the population—and with diabetes mellitus present in 83.3% of Indigenous amputees compared with 50.4% of non-Indigenous amputees ($p < 0.05$) [6]. This stark disparity reflects the importance of early preventative expert care, including podiatry and orthotic services, and underscores the urgent need for effective, scalable, and accessible lower limb prevention strategies.

Evidence-based management of diabetic foot disease is guided by a suite of recently updated Australian clinical practice guidelines. Kaminski et al. (2022) outlined the Australian guideline on prevention of foot ulceration, recommending regular foot screening, patient education, therapeutic footwear, and orthotic prescription as the cornerstones of preventative foot care in high-risk patients [7]. Fernando et al. (2022) published the Australian guideline on offloading treatment for foot ulcers, identifying knee-high offloading devices and total contact casts as the recommended first-line treatment for active plantar DFUs, with custom orthotics and therapeutic footwear recommended for maintenance offloading following healing [8]. Chuter et al. (2022) presented the Australian guideline on diagnosis and management of peripheral artery disease in patients with diabetes, highlighting the importance of vascular assessment including ankle–brachial index (ABI) and toe-brachial index (TBI) measurement as an essential component of comprehensive diabetic foot assessment [9]. Collectively, these guidelines establish a strong evidence-based framework for conventional orthotic management of diabetic foot disease, against which emerging smart orthotic technology must be evaluated.

Knee osteoarthritis represents an equally significant global burden. Affecting an estimated 250 million people worldwide, knee OA is among the leading causes of chronic

pain and physical disability, particularly in ageing populations [10,11]. Bennell et al. (2012) described knee OA as a complex condition characterised by articular cartilage degradation, subchondral bone remodelling, osteophyte formation, and synovial inflammation, with pain and functional impairment representing its primary clinical manifestations and contributing substantially to reduced workforce participation and quality of life [10]. The biomechanical drivers of medial compartment knee OA are well characterised. Morrison (1970) demonstrated through inverse dynamics analysis that the medial compartment of the knee bears approximately 60–90% of total knee joint load during normal walking, establishing the foundational biomechanical rationale for interventions targeting medial compartment load reduction [12]. Schipplein and Andriacchi (1991) subsequently demonstrated that the external knee adduction moment (EKAM), the net moment that acts to adduct the knee during gait, is a primary determinant of medial knee contact force and serves as a well-validated biomechanical surrogate for medial compartment loading [13]. Elevated EKAM has been consistently associated with OA progression, cartilage loss, and greater rates of knee arthroplasty, making it the primary biomechanical target of orthotic intervention in knee OA management [14,15]. In Australia, First Nations people are 1.2–1.5 times more likely to develop OA than non-Indigenous Australians [16], with the total economic burden of arthritic conditions projected to reach AUD $8.2 billion by 2030 [16].

Orthotic devices including custom foot orthoses, prefabricated insoles, and lateral wedge insoles represent a well-established conservative management strategy for both diabetic foot disease and knee OA, addressing the shared underlying mechanism of plantar pressure redistribution and ground reaction force modification. However, conventional passive orthotics carry a fundamental limitation in the diabetic foot context: they redistribute pressure through material and geometric design properties alone, without providing any mechanism by which patients with absent or impaired peripheral sensation can detect whether they are exposing high-risk plantar regions to excessive or prolonged pressure during daily weight-bearing activities. The emergence of smart orthotic technology incorporating embedded plantar pressure sensors, microprocessors, wireless communication modules, and real-time biofeedback systems represents a significant and clinically meaningful advance over conventional passive devices [17]. Smart orthotics are defined in this review as sensor-embedded insoles or foot orthoses capable of continuously monitoring plantar pressure during weight-bearing activities and delivering real-time alerts to the patient via vibrotactile stimulation, audiovisual signals through a connected smartwatch or smartphone, or digital display notification when pressure thresholds are exceeded or safe-time limits are approached [18,19]. This closed-loop biofeedback mechanism directly addresses the pathophysiological basis of DFU formation by compensating for the loss of protective plantar sensation the fundamental deficit that makes patients with diabetic peripheral neuropathy vulnerable to ulceration. Applied to knee OA, smart orthotics offer the additional potential to monitor real-time biomechanical load distribution during daily ambulation, providing continuous EKAM-relevant feedback beyond the temporal constraints of laboratory gait analysis [20–23].

Several related systematic reviews and PROSPERO registrations have examined aspects of orthotic intervention in these conditions. Related PROSPERO registrations have examined wedge insoles for knee OA biomechanics (CRD42018096804), offloading devices for DFU prevention (CRD42023429948), insoles for musculoskeletal disorders (CRD42018099534), and pedorthic interventions for DFU management (CRD42021287645). Critically, none of these reviews or registrations has examined smart orthotic technology with real-time plantar pressure sensor biofeedback, and none has synthesised evidence across both diabetic foot disease and knee osteoarthritis simultaneously within a single evidence framework. This represents a significant and previously unaddressed gap in the evidence base.

The conceptual justification for examining both conditions within a unified smart orthotics framework is grounded in their shared biomechanical principles. Both diabetic foot disease and knee osteoarthritis involve maladaptive plantar pressure distribution under weight-bearing conditions in DFU arising from neuropathy-driven insensate overloading of the plantar foot [24], and in knee OA from gait-driven medial compartment overloading transmitted through the ground reaction force. Smart orthotic technology addresses both through the same core engineering principle: real-time plantar pressure sensing with closed-loop biofeedback that enables patients and clinicians to monitor and modify lower limb loading during daily activities. The convergence of pressure monitoring, wearable sensing, and patient feedback in smart orthotic technology provides a unified technological framework applicable to both conditions, making their synthesis within a single comprehensive review conceptually and clinically justified.

The objectives of this systematic review are therefore: (1) to evaluate the clinical evidence for the use of smart orthotic devices with real-time plantar pressure biofeedback in adults with diabetes mellitus at risk of diabetic foot ulceration or with peripheral neuropathy; (2) to evaluate the clinical evidence for standard and smart orthotic devices in adults with knee osteoarthritis, examining effects on EKAM, pain, and functional outcomes; (3) to compare the clinical effectiveness of smart versus standard orthotic devices where direct comparative data exist; (4) to characterise the current state of smart orthotic technology including sensor types, feedback mechanisms, alert threshold parameters, and patient connectivity platforms; and (5) to contextualise findings within the Australian healthcare system with specific reference to the economic burden of both conditions and the disproportionate impact on Aboriginal and Torres Strait Islander peoples. The review acknowledges at the outset that the available evidence base for smart orthotic technology is predominantly comprising small, open-label trials in which blinding of participants is not feasible due to the inherent nature of wearable biofeedback devices. This structural limitation—analogous to surgical trials—is addressed comprehensively in Section 4.1 alongside the mitigating factors that support confidence in the primary findings: the use of objective outcome measures across the included RCTs, the consistency of effect direction across independent trials, and a narrative sensitivity analysis. All conclusions are qualified in accordance with the level and certainty of the available evidence.

The engineering architecture of smart orthotic systems comprises four integrated components. First, plantar pressure sensing arrays utilising capacitive, piezoelectric, or resistive transducer technologies are embedded within the insole at anatomically strategic locations, typically beneath the metatarsal heads, hallux, heel, and midfoot, enabling continuous real-time measurement of peak plantar pressure (kPa), pressure–time integral (kPa·s), and contact duration at individual sensor sites during weight-bearing [25,26]. Capacitive sensors offer high sensitivity and linearity across physiologically relevant pressure ranges, while piezoelectric sensors provide rapid response to dynamic loading events during gait. Second, embedded microprocessors analyse sensor data in real time against pre-programmed threshold parameters typically a safe-time threshold of pressure exceeding 35–50 mmHg sustained for more than 15 min, above which capillary occlusion and tissue ischaemia are initiated [18] triggering an alert signal when the threshold is breached. Third, wireless communication modules (Bluetooth Low Energy or ANT+) transmit pressure data and alert signals to paired wearable devices, enabling the fourth component: patient biofeedback delivery via vibrotactile motors embedded in the insole or worn on the ankle [27], or audiovisual notifications delivered to the patient's wrist via a connected smartwatch application [19,28]. This closed-loop sensing–processing–feedback architecture positions smart orthotics as a wearable Internet of Things (IoT) health monitoring platform distinct from both conventional passive orthotics and remote patient monitoring systems

capable of enabling real-time patient-directed self-management of plantar pressure during unconstrained daily activities [29,30]. Najafi et al. (2017) identified that a minimum alert frequency of once every two hours was necessary to produce meaningful improvements in patient adherence to offloading, demonstrating that the clinical effectiveness of smart orthotics is dependent not only on sensor accuracy but on the design of the alert delivery system [17]. The broader application of artificial intelligence (AI) to diabetes complication detection, prediction, and clinical management has been recently reviewed [31], who demonstrated that AI-driven deep learning algorithms show remarkable promise in the early detection and prediction of microvascular complications, including diabetic neuropathy and macrovascular complications such as cardiovascular disease. Smart orthotic systems, such as sensor-embedded wearable IoT platforms generating continuous real-time plantar pressure data, represent a natural intersection of AI capability with podiatric clinical management; the structured time-series datasets produced by smart orthotics are well-suited to AI-driven pattern recognition, risk stratification, and predictive modelling for DFU onset, an application that, while not yet formally evaluated in the included literature, represents a compelling direction for future integration of AI with smart orthotic technology in the prevention of diabetic foot complications.

Review objective: To evaluate the clinical evidence for the use of standard and smart orthotic devices in adults with diabetes mellitus at risk of foot ulceration and adults with knee osteoarthritis. Specifically, this review addresses: (P) adults with diabetes mellitus (peripheral neuropathy or DFU risk) or knee OA; (I) any orthotic or smart/intelligent insole intervention; (C) standard orthotics, no orthotics, or alternative conservative management; (O) plantar pressure redistribution, ulcer incidence/recurrence, pain reduction, external knee adduction moment (EKAM), functional outcomes, and economic burden; (S) clinical studies of any design conducted under weight-bearing conditions.

2. Methods

2.1. Search Strategy

A comprehensive literature search was performed across five electronic databases: CINAHL, Google Scholar, PubMed (Advanced), Wiley Online Library, and Cochrane Library. The complete search strategy for each database is presented in Table 1. Searches incorporated Boolean operators (AND/OR), controlled vocabulary terms (MeSH headings in PubMed; equivalent subject headings in CINAHL and Cochrane Library), truncation (e.g., 'orthot*', 'diabet*'), and synonym combinations (e.g., 'foot orthosis OR custom insole OR smart insole OR intelligent insole OR pressure-relieving device'). Google Scholar and Wiley Online Library do not support controlled vocabulary; free-text Boolean searches were conducted in these databases using equivalent synonym combinations. Further searches were conducted in May 2026. No date restrictions or language limits beyond the exclusion of non-English records at screening were applied. This systematic review was conducted and reported in accordance with the PRISMA 2020 statement [32], and the Cochrane Handbook for Systematic Reviews of Interventions (Cochrane Collaboration, London, UK) [33]. Risk of bias was assessed using the Cochrane RoB 2 tool for RCTs, the Newcastle–Ottawa Scale for cohort and case–control studies, and the JBI Critical Appraisal Checklist (Joanna Briggs Institute, Adelaide, SA, Australia) for pilot and case studies. Certainty of evidence was assessed using an informal GRADE framework. Narrative synthesis followed the [33] framework. Deduplication and screening were conducted using Rayyan (Rayyan AI, Doha, Qatar; rayyan.ai). A PROSPERO (NIHR, University of York, York, UK) search confirmed no existing registration covered smart orthotic technology across both diabetic foot ulcers and knee osteoarthritis simultaneously.

Table 1. Comprehensive search strategy—full Boolean strings, MeSH/controlled vocabulary terms, truncation, and records retrieved.

Database	Search Block	Controlled Vocabulary/Field Tags	Full Boolean Search String	Truncation Applied
PubMed (NCBI Advanced Search) Supports: MeSH headings, field tags, Boolean operators, truncation	Block 1 (Condition)	MeSH Terms: "Diabetic Foot" [MeSH] "Foot Ulcer" [MeSH] "Diabetes Mellitus, Type 2" [MeSH] "Osteoarthritis, Knee" [MeSH] Field Tags: [MeSH Terms], [Title/Abstract], [tiab]	("Diabetic Foot" [MeSH] OR "diabetic foot ulcer*" [tiab] OR "DFU" [tiab] OR "plantar ulcer*" [tiab] OR "foot wound*" [tiab] OR "neuropathic ulcer*" [tiab] OR "diabetic foot wound*" [tiab]) OR ("Osteoarthritis, Knee" [MeSH] OR "knee OA" [tiab] OR "knee osteoarthr*" [tiab] OR "medial compartment OA" [tiab] OR "tibiofemoral OA" [tiab])	orthot* diabet* osteoarthr* insol* neuropath*
	Block 2 (Intervention)	MeSH Terms: "Foot Orthoses" [MeSH] "Biomechanical Phenomena" [MeSH] "Feedback, Sensory" [MeSH] "Wearable Electronic Devices" [MeSH]	("Foot Orthoses" [MeSH] OR "orthot*" [tiab] OR "smart insol*" [tiab] OR "intelligent insol*" [tiab] OR "smart orthot*" [tiab] OR "pressure-relieving insol*" [tiab] OR "plantar pressure sensor*" [tiab] OR "sensor insol*" [tiab] OR "biofeedback insol*" [tiab] OR "vibrotactile feedback" [tiab] OR "wearable sensor*" [tiab]) Combined: Block 1 AND Block 2	orthot* insol* sensor* feedback* wearabl*
CINAHL (EBSCO) Supports: CINAHL Subject Headings, Boolean operators, truncation	Block 1 (Condition)	CINAHL Subject Headings: (MH "Diabetic Foot") (MH "Foot Ulcer") (MH "Osteoarthritis, Knee") (MH "Diabetes Mellitus, Type 2")	((MH "Diabetic Foot") OR (MH "Foot Ulcer") OR TI(diabet* N3 foot) OR AB(diabet* N3 foot) OR TI("DFU") OR AB("plantar ulcer*") OR TI("neuropathic ulcer*")) OR ((MH "Osteoarthritis, Knee") OR TI("knee OA") OR AB("knee osteoarthr*") OR TI("tibiofemoral") OR AB("medial compartment"))	orthot* insol* diabet* osteoarthr*
	Block 2 (Intervention)	CINAHL Subject Headings: (MH "Orthotic Devices") (MH "Biofeedback") (MH "Wearable Technology") (MH "Pressure, Body Surface")	((MH "Orthotic Devices") OR TI("smart orthot*") OR AB("intelligent insol*") OR TI("sensor insol*") OR AB("plantar pressure sensor*") OR TI("biofeedback insol*") OR AB("vibrotactile") OR TI("wearable sensor*") OR AB("real-time feedback") OR TI("pressure-offloading device*")) Combined: Block 1 AND Block 2	orthot* sensor* insol* feedback* wearabl*
Cochrane Library (Wiley) Supports: MeSH headings via Medical Terms filter, Boolean operators, truncation	Block 1 (Condition)	MeSH Terms (via Medical Terms filter): Diabetic Foot [MeSH] Osteoarthritis, Knee [MeSH] Foot Orthoses [MeSH]	("diabetic foot" OR "foot ulcer" OR "DFU" OR "plantar ulcer*" OR "neuropathic ulcer*" OR "diabetic foot wound*"): ti,ab,kw OR ("knee osteoarthritis" OR "knee OA" OR "tibiofemoral osteoarthritis" OR "medial compartment OA"): ti,ab,kw AND ("orthot*" OR "smart insol*" OR "intelligent insol*" OR "sensor insol*" OR "plantar pressure sensor*" OR "biofeedback insol*" OR "pressure-offloading device*"): ti,ab,kw	orthot* insol* diabet* osteoarthr* sensor*

Table 1. *Cont.*

Database	Search Block	Controlled Vocabulary/Field Tags	Full Boolean Search String	Truncation Applied
Wiley Online Library Limitation: does not support MeSH headings or controlled vocabulary. Free-text Boolean search only.	Block 1 (Condition)	No controlled vocabulary available. Free-text synonym combinations used in Title/Abstract.	("diabetic foot ulcer" OR "DFU" OR "plantar ulcer" OR "diabetic foot wound" OR "neuropathic ulcer" OR "foot ulcer" OR "diabetic foot") OR ("knee osteoarthritis" OR "knee OA" OR "tibiofemoral OA" OR "medial compartment osteoarthritis") AND ("smart orthotic" OR "intelligent insole" OR "sensor insole" OR "plantar pressure sensor" OR "biofeedback insole" OR "smart insole" OR "wearable orthotic" OR "pressure offloading device")	orthotic* insole* diabetic* sensor*
Google Scholar Limitation: does not support MeSH, field tags, or full Boolean logic. Phrase search and keyword combinations used.	Block 1 (Condition)	No controlled vocabulary or MeSH available. Phrase search (quoted strings) used.	Search string 1: "smart orthotics" OR "intelligent insole" "diabetic foot ulcer" Search string 2: "smart insole" OR "sensor insole" "knee osteoarthritis" OR "knee OA" Search string 3: "plantar pressure biofeedback" OR "real-time offloading feedback" "diabetes" OR "neuropathy" Search string 4: "wearable orthotic" OR "smart orthotic device" "diabetic foot" OR "knee osteoarthritis"	Truncation not supported in Google Scholar. Plural/variant forms searched manually.

2.2. Eligibility Criteria

Studies were included or excluded based on the following pre-specified criteria. Studies were grouped into two synthesis streams: (1) diabetes mellitus and diabetic foot ulcers, and (2) knee osteoarthritis.

2.3. Selection Process

Records identified from all five databases were exported in RIS format and imported into Rayyan (Rayyan AI, Doha, Qatar; ayyan.ai) for deduplication and screening. Two authors screened all titles and abstracts against the eligibility criteria. Full-text articles were then retrieved for all records not excluded at the title/abstract stage. The same authors independently assessed full texts for eligibility, with disagreements again resolved by consensus. No automation tools were used for eligibility decisions beyond the Rayyan (Rayyan AI, Doha, Qatar) deduplication function.

2.4. Data Collection Process

Data were extracted from included studies by one reviewer (W.S.) using a standardised data extraction form and verified by a second reviewer (D.C.). The following variables were extracted from each study: author(s), year, country, study design, sample size, participant age range, clinical condition, intervention type, comparison group, outcomes measured, key findings, and funding source where reported. Where data were unclear or missing, the published report was re-read in full; no study authors were contacted. No assumptions were made about missing data—where outcome data were not reported, the relevant cells were left blank in the extraction table.

2.5. Data Items

Primary outcomes: Plantar pressure redistribution (peak pressure, pressure–time integral); ulcer incidence or recurrence; pain scores (e.g., visual analogue scale); external knee adduction moment (EKAM). All results for each outcome domain reported in individual studies were sought and extracted where available across all reported measurement time points and analyses.

Secondary outcomes and other variables: Gait parameters (stride length, walking speed) [34].; patient adherence and compliance; quality of life measures; healthcare costs and economic burden; functional disability indices. Participant characteristics extracted included: diagnosis, age range, sex, country, duration of condition, and presence of peripheral neuropathy. Intervention characteristics extracted included: type of orthotic (standard vs. smart), sensor technology used, feedback mechanism, and duration of use. Where funding sources were reported, these were also extracted. Where summary statistics (e.g., standard deviations, confidence intervals) were not reported in primary studies, raw data were used as presented; no data conversions or imputations were performed. A complementary wearable architecture combines inertial sensors with plantar pressure sensing across both a smart band and instrumented footwear, enabling simultaneous capture of upper-body movement and plantar loading during daily activity [35,36]. This dual-sensor approach illustrates the broader trend toward multi-modal wearable systems that integrate plantar pressure data with whole-body kinematic information, extending beyond insole-only architectures.

2.6. Study Risk of Bias Assessment

Risk of bias was assessed for each included clinical study by independent reviewers using validated tools appropriate to each study design: the Cochrane Risk of Bias 2 (RoB 2) tool (Cochrane Collaboration, London, UK) for randomised controlled trials and the Newcastle–Ottawa Scale (NOS) (NOS; University of Ottawa, Ottawa, ON, Canada) for cohort and case–control studies. Formal risk of bias assessment was applied to the ten studies presented in Table 2, comprising all studies individually discussed in Table 3 from which quantitative outcome data were extracted. The remaining 68 studies listed in Supplementary Table S1 were not subjected to formal per-domain RoB assessment. Disagreements between authors were resolved through discussion and consensus.

Case studies and pilot studies were assessed using a modified checklist adapted from the Joanna Briggs Institute (JBI) critical appraisal tools. Formal risk of bias assessment was applied selectively to the studies presented in Table 2, and that a full per-study RoB assessment across all 78 studies was not performed. Disagreements between authors were resolved through discussion and consensus. For studies included in Table 3 the risk of bias judgement for each domain is reported in Table 2 below. The overall risk of bias across the included studies is summarised narratively in Section 4.1.

Table 2. Risk of bias assessment for key included studies.

Study	Design	Randomisation (RCTs)	Allocation Concealment	Blinding of Participants	Incomplete Outcome Data	Selective Reporting	Sample Size	Overall RoB
Chatwin et al. 2021 [18]	RCT	Low risk	Low risk	High risk (open-label)	Low risk	Low risk	Small (n = 41)	Moderate
Abbott et al. 2019 [27]	Prospective RCT	Low risk	Unclear	High risk (open-label)	Low risk	Low risk	Small (n = 58)	Moderate
York et al. 2009 [26]	RCT	Low risk	Unclear	High risk (open-label)	Low risk	Low risk	Small (n = 29)	Moderate
Najafi et al. 2017 [17]	Prospective Cohort	N/A	N/A	High risk (open-label)	High risk (30% dropout)	Low risk	Small (n = 17)	High

Table 2. *Cont.*

Study	Design	Randomisation (RCTs)	Allocation Concealment	Blinding of Participants	Incomplete Outcome Data	Selective Reporting	Sample Size	Overall RoB
Drerup et al. 2008 [37]	Prospective Cohort	N/A	N/A	Low risk	Low risk	Low risk	Small (n = 20)	Low–Moderate
Singh et al. 2021 [6]	Retrospective Cohort	N/A	N/A	High risk (retrospective)	Low risk	Low risk	Moderate (n = 374)	Moderate
Zhang et al. 2021 [38]	Prospective Cohort	N/A	N/A	Low risk	Low risk	Low risk	Large (n = 4832)	Low
Rodriguez et al. 2012 [36]	Prospective Case–Control	N/A	N/A	Low risk	Low risk	Low risk	Small (n = 21)	Moderate
Van et al. 2017 [39]	Pilot Study	N/A	N/A	High risk (open-label)	Unclear	Low risk	Very small (n = 11)	High
Scirè et al. 2009 [40]	Cohort Study	N/A	N/A	Low risk	Low risk	Low risk	Small (n = 89)	Low–Moderate

RoB = risk of bias. RCT = Randomised Controlled Trial. N/A = Not Applicable. Green = Low risk; Amber = Moderate/Unclear risk; Red = High risk. Note: Background colour coding reflects overall risk of bias judgement: Green = Low risk of bias; Amber = Some concerns/Moderate risk of bias; Red = High risk of bias. Risk of bias assessed using the Cochrane Risk of Bias 2 (RoB 2) tool for randomised controlled trials; the Newcastle–Ottawa Scale (NOS) for cohort and case–control studies; and the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for pilot studies and case reports.

Table 3. (**a**). Studies Involving Smart Orthotic Devices with Real-Time Biofeedback: Characteristics, Outcomes, and Risk of Bias. The following six studies directly investigated smart orthotic technology defined as sensor-embedded insole devices capable of real-time plantar pressure monitoring with closed-loop biofeedback delivery as the primary intervention. Conclusions regarding smart orthotic effectiveness are drawn exclusively from these studies. (**b**). Contextual Studies—Standard Orthotics and Epidemiological Background (Not Evaluating Smart Orthotic Technology) The four studies provide epidemiological and biomechanical background relevant to the review topic but do not evaluate smart orthotic technology as a primary intervention. They are included to contextualise the burden of diabetic foot disease and to describe the biomechanical basis of plantar pressure redistribution.

Study and Year	Study Design	n	Age (y)	Country	Key Findings	Quantitative Outcomes	Overall RoB	OCEBM LoE
					(**a**)			
Chatwin et al. 2021 [18]	Randomised controlled trial—DM foot ulceration (UK)	41	>59	UK	Control group (n = 18): no alerts. Intervention group (n = 23): audiovisual alert on excessive pressure. Smart orthotic sensor arrays embedded in insole; smartwatch biofeedback (Orpyx Medical Technologies Inc., Calgary, AB, Canada). 71% ulcer reduction in IG over 18 months.	Ulcer reduction: 71% over 18 months (IG vs. CG). High-pressure events significantly reduced in IG vs. CG ($p < 0.05$). No CIs reported.	Moderate	Level 2
Abbott C et al. 2019 [27]	Prospective randomised proof-of-concept study—DFU recurrence (UK)	58	>18	UK	IG (n = 32): daytime audiovisual alerts via smartwatch to offload high-pressure plantar zones (Or-pyx Medical Technologies Inc., Calgary, AB, Canada). CG (n = 26): no alerts. Smart orthotic system significantly reduced DFU recurrence.	DFU recurrence: 6.3% IG vs. 30.8% CG (RR = 0.20; 95% CI: 0.05–0.79; $p = 0.022$). Median time to recurrence: 165 days (IG) vs. 82 days (CG). ARR = 24.5%.	Moderate	Level 2

Table 3. *Cont.*

Study and Year	Study Design	n	Age (y)	Country	Key Findings	Quantitative Outcomes	Overall RoB	OCEBM LoE
					(**a**)			
York RM et al. 2009 [26]	Randomised controlled trial—diabetic foot neuropathy (USA)	29	>18	USA	Participants randomised to smart insole biofeedback group (n = 15) vs. no-feedback control (n = 14). Custom pressure-sensing insole with vibrotactile feedback (prototype device, University of Texas Health Science Centre, San Antonio, TX, USA) Plantar pressure significantly reduced in feedback group; walking speed decreased.	Plantar pressure: significantly reduced in feedback group ($p < 0.01$). Walking speed: significantly slower vs. baseline (mean reduction ~0.15 m/s; $p < 0.05$). No CIs reported.	Moderate	Level 2
Rodriguez et al. 2012 [36]	Prospective case–control study—DM peripheral neuropathy (Switzerland)	21	>57	Switzerlan	Patients with diabetic peripheral neuropathy. Contralateral foot used as control. Smart biofeedback technique reduced lateral plantar pressure compared with contralateral control foot.	Lateral plantar pressure: significantly reduced with smart biofeedback vs. contralateral control foot ($p < 0.05$). Absolute pressure values not reported with CIs.	Moderate	Level 3
Najafi B et al. 2017 [17]	Prospective cohort study—DFU history, smart insole adherence (USA)	17	>18	USA	Patients with history of DFU. Smart orthotic with real-time alert system (Orpyx SurroSense Rx, Orpyx Medical Technologies Inc., Calgary, AB, Canada). Adherence to offloading alerts increased over study duration. Minimum alert frequency of once per 2 h required for optimal pressure offloading.	Adherence rate: increased from 54% (week 1) to 82% (week 12). No ulcers formed during active phase. No comparative statistical testing reported.	High	Level 3
Van et al. 2017 [39]	Pilot study—smart orthotic training feasibility (USA)	11	>18	USA	Feasibility pilot. 8 of 11 patients successfully completed training using the smart orthotic device. Device provided real-time plantar pressure biofeedback via vibrotactile alerts (Moticon GmbH, Munich, Germany).	Plantar pressure reduction: 80% in patients who completed training (n = 8/11). No statistical comparator or CI reported due to pilot design.	High	Level 4
Study and Year	**Study Design and Focus**	**n**	**Age (y)**	**Country**	**Key Findings**		**Relevance to Review Context**	
					(**b**)			
Singh et al. 2021 [6]	Retrospective cohort—lower limb amputation rates; Indigenous vs. non-Indigenous Australians	374 amputees from 217,893	>44	Australia	18.7% of amputees were Indigenous (from 15,409 First Nations patients) vs. 81.3% non-Indigenous (from 189,684 patients). Diabetes prevalence in Indigenous amputees: 83.3% vs. 50.4% non-Indigenous ($p < 0.05$).		Contextual epidemiological data establishing the disproportionate amputation burden in Aboriginal and Torres Strait Islander peoples. Does not evaluate orthotic intervention.	

Table 3. *Cont.*

Study and Year	Study Design and Focus	n	Age (y)	Country	Key Findings	Relevance to Review Context
					(**b**)	
Zhang et al. 2021 [38]	Prospective cohort—DFU healing factors; multi-professional care including podiatry/orthotics (Australia)	4832	<50–70+	Australia	Healing at 3 months: 41.5% (n = 1956); at 12 months: 64.0% (n = 3012). Podiatrist-led care associated with significantly higher healing rates ($p < 0.01$). Orthotics used as part of multi-professional treatment.	Contextual evidence for podiatric and orthotic care in DFU healing. Orthotics not evaluated as a standalone intervention; smart orthotics not assessed.
Scirè et al. 2009 [40]	Cohort study—conventional partial silicone orthoses for peak plantar pressure reduction in DM (Italy)	89	>18	Italy	Control group (n = 78): standard therapy. Intervention group (n = 10): partial silicone orthoses. Statistically significant peak pressure reduction in orthotic group vs. control ($p < 0.05$). Passive device; no sensing or biofeedback.	Contextual evidence for conventional passive orthotic pressure redistribution. Evaluates standard orthotics only—no smart device component. Provides background on passive orthotic biomechanics.
Drerup B et al. 2008 [37]	Prospective cohort—plantar pressure under standardised walking conditions; pedobaro-graphic analysis (Germany)	20	>18	Germany	10 normal-gait and 10 restricted-stride pedobarographic examinations. Peak plantar pressure: mean 312 kPa (unrestricted) vs. 298 kPa (restricted stride); difference not statistically significant ($p = 0.38$). No CIs reported.	Contextual biomechanical evidence for plantar pressure measurement methodology underpinning smart orthotic sensor design. Does not evaluate smart orthotic technology as an intervention.

Note: (**a**) RoB = risk of bias assessed using Cochrane RoB 2 (RCTs), Newcastle–Ottawa Scale (cohort/case–control), and JBI critical appraisal tool (pilot studies). OCEBM LoE = Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence (Oxford Centre for Evidence-Based Medicine, University of Oxford, Oxford, UK). Level 2 = RCT or individual cohort study; Level 3 = case–control or non-randomised cohort; Level 4 = case series or pilot study. Blue shading in Findings column denotes studies involving smart orthotic technology with real-time biofeedback; green shading in Key Findings column indicates contextual/standard orthotic evidence. Grey italic shading in Relevance column clarifies the contextual (non-smart orthotic) nature of each study. These studies were not subjected to formal per-domain RoB assessment as they do not constitute direct smart orthotic intervention evidence. (**b**) Green shading in Key Findings column indicates contextual/standard orthotic evidence. Grey italic shading in Relevance column clarifies the contextual (non-smart orthotic) nature of each study. These studies were not subjected to formal per-domain RoB assessment as they do not constitute direct smart orthotic intervention evidence. Background colour coding reflects overall risk of bias judgement: Green = Low risk of bias; Amber = Some concerns/Moderate risk of bias; Red = High risk of bias. Risk of bias assessed using the Cochrane Risk of Bias 2 (RoB 2) tool for randomised controlled trials; the Newcastle–Ottawa Scale (NOS) for cohort and case–control studies; and the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for pilot studies and case reports.

2.7. Effect Measures and Synthesis Methods

Effect measures: Given the heterogeneity of study designs (RCTs, prospective cohorts, case–control studies, case reports) and the diversity of outcome measures and reporting formats across included studies, pooled effect measures (e.g., risk ratios, mean differences, confidence intervals) could not be calculated. Results are therefore presented as reported in individual studies, including percentage reductions, *p*-values, and descriptive findings where these were the only data available. Studies in Synthesis Groups 1 and 2 were included to provide technological context and are not used to draw clinical effectiveness conclusions.

Synthesis methods: Studies were allocated to two synthesis groups based on clinical condition: (1) diabetes mellitus and DFU, and (2) knee osteoarthritis, consistent with the pre-specified PICOS framework. No data preparation, transformation, or conversion of summary statistics was required. Individual study results are tabulated in Table 3 (study characteristics and findings) and the PRISMA 2020 flow diagram (Figure 1) displays the

study selection process. A narrative synthesis approach was adopted, as meta-analysis was not feasible due to the clinical and methodological heterogeneity of included studies, including variation in orthotic type, outcome measures, populations, follow-up duration, and reporting formats. No subgroup analyses or meta-regression were performed to explore heterogeneity, as the narrative approach precluded formal statistical synthesis. No sensitivity analyses were conducted, as the review employed a narrative rather than quantitative synthesis approach.

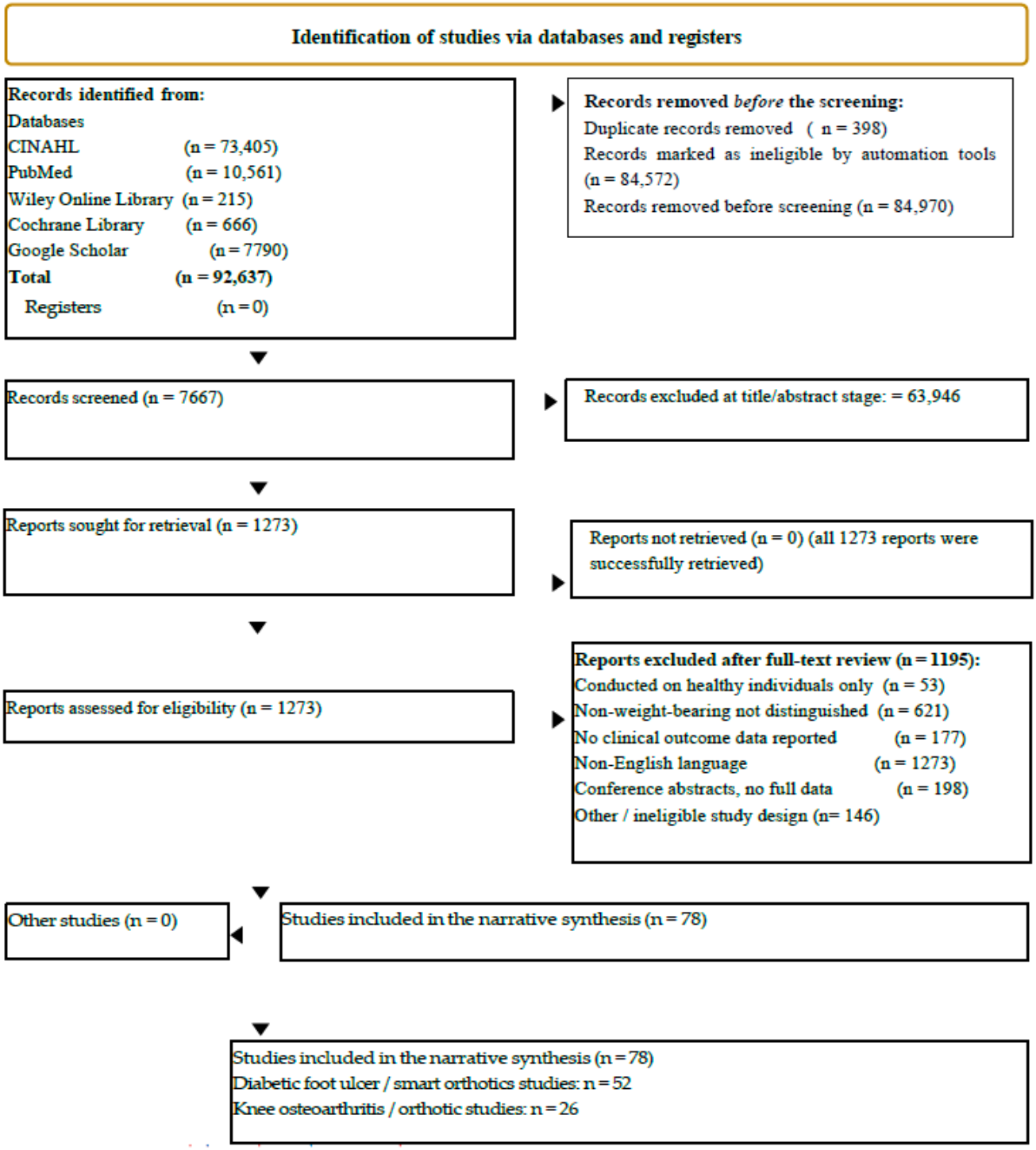


Figure 1. PRISMA 2020 flow diagram—identification, screening, eligibility, and inclusion of studies.

Reporting bias assessment: Formal assessment of reporting bias (e.g., funnel plot asymmetry) was not performed owing to the narrative synthesis design. However, the

potential for publication bias should be acknowledged: the literature on smart orthotics is dominated by small studies with positive results, and it is likely that negative or null findings are underrepresented in the published literature. This may inflate the apparent benefit of smart orthotics observed in this review.

Certainty of evidence: Formal assessment of the certainty of evidence using the GRADE (Grading of Recommendations, Assessment, Development and Evaluations) framework was not performed in this review, which is a limitation. Future systematic reviews should apply GRADE ratings per outcome. A full anticultural description had been described in the introductions.

Registration and protocol: This review was not prospectively registered on PROSPERO or any other review registry, and no protocol was published prior to commencement. This is acknowledged as a limitation.

2.8. Study Selection—PRISMA 2020 Flow Diagram

The selection process is summarised in the PRISMA 2020 flow diagram below (Figure 1). Records were screened by title and abstract, followed by full-text review against the eligibility criteria (Table 4). Deduplication was performed using Rayyan (Rayyan AI, Doha, Qatar; rayyan.ai).

Table 4. Inclusion and exclusion criteria.

Criterion	Inclusion	Exclusion
Participants	Human adults (≥18 years) with clinical diagnosis of diabetes mellitus (DFU risk or peripheral neuropathy) or knee osteoarthritis	Healthy individuals without target conditions; animal or in vitro studies
Intervention	Any standard orthotic device or smart/intelligent insole intervention	Non-orthotic interventions (e.g., pharmacotherapy, surgery alone)
Comparator	Standard orthotics, no orthotics, or alternative conservative management (or pre/post comparison)	Not applicable
Outcomes	Plantar pressure redistribution, ulcer incidence/recurrence, pain scores, external knee adduction moment, functional outcomes, economic burden	Studies with no reportable clinical outcome data
Study design	Any clinical study design (RCT, cohort, case–control, case study) conducted under weight-bearing conditions	Non-weight-bearing protocols not differentiated from weight-bearing
Language	English language publications only	Non-English language publications
Publication type	Full-text peer-reviewed articles	Conference abstracts lacking full data
Age reporting	Participant age reported	Age of participants not reported
Registration	No restriction on registration status	Not applicable

Search strategy (Table 1): Five databases searched—CINAHL, PubMed (Advanced), Wiley Online Library, Cochrane Library, and Google Scholar—using the Boolean search terms: *Smart orthotics OR intelligent insole OR DFU OR diabetes* AND *Osteoarthritis OR diabetic foot ulcers OR knee OA OR sport injuries*.

Inclusion criteria: Published in English; human adult participants (≥18 years); clinical diagnosis of diabetes mellitus (at risk of diabetic foot ulceration or with peripheral neuropathy) or knee osteoarthritis; intervention involving any orthotic device or smart/intelligent insole; clinical outcomes reported (plantar pressure, ulcer incidence/recurrence, pain, external knee adduction moment); weight-bearing conditions assessed.

Exclusion criteria: Non-English language; animal or in vitro studies; studies on healthy individuals only; age of participants not reported; non-weight-bearing protocols not differentiated from weight-bearing; no reportable clinical outcomes; conference ab-

stracts lacking full data; smart vs. standard orthotics not compared where this was the primary aim.

3. Results

3.1. Diabetes Mellitus and Smart Orthotics

3.1.1. General Background

Over 500 million people are suffering from diabetes mellitus (DM) worldwide, including over 1.3 million in Australia [2,3]. A recent World Health Organisation (WHO) global report on DM found that in children, adolescents, and younger adults, being overweight or obese is the most significant risk factor for Type 2 diabetes mellitus (T2DM) [1]. There has been an increase in its annual incidence of 102.9% from 1990 to 2017 and post 2019, an increase of 3.73 cases per 100,000 people [2,3,38] (Balooch Hasankhan's 3.73/100k stat) with a resultant 5% increase in premature mortality and an overall global number of deaths directly attributed to DM in excess of 1.5 million in 2019 [1]. Complications directly related to DM, such as diabetic foot disease, including ulceration, result in functional disability and an economic burden of over $101.4 billion in the USA alone [41]. Peripheral neuropathy (PN) of the feet, in combination with reduced blood circulation due to peripheral arterial disease (PAD), increases the risk of foot ulceration, infection, and amputation which places even further burden on an individual and the economy [1].

3.1.2. An Australian Context—Diabetic Foot Disease and First Nations Health

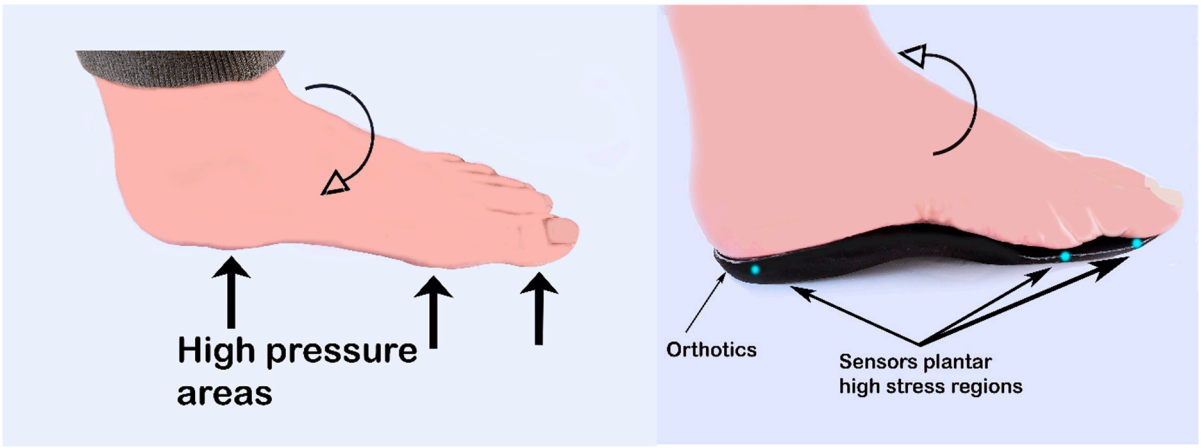
Research consistently illustrates the negative impact of DM and PAD. Peripheral arterial disease is associated with poor foot health and an increased risk of toe or large joint amputation [42]. Furthermore, it is estimated that diabetes-related foot disease costs the Australian health care system about $1.6 billion [43,44], while a more recent research estimated the primary cost were hospital admissions ($21,566), outpatient ($14,212) and wound debridement ($21,566), where the total cost in 2026 to be AUD $3.81 billion to the Australian healthcare system [6].

The following results and discussion report on the key included studies most directly relevant to the primary research question. Studies included in the review but not individually discussed below are listed in full in Supplementary Table S1, which forms part of this publication. Table 3 highlights people with diabetes and its impact on lower limb amputations. In a recent large, real-world cohort study, 4832 patients with diabetic foot ulcers (DFUs) were treated using various offloading methods and surgical intervention by healthcare providers across various clinics in Queensland, Australia. DFUs amongst Indigenous Australians were more likely to heal using a treatment programme that included orthotics [45]. Table 3 further highlights that evidence-based preventative measures such as knee height moon boot, custom orthotics, footwear, regular foot clinical examination, patient footcare education and treatment of pre-ulcerative conditions, such as heloma durum and callus [46] are required to close the gap and reduce overall amputation rates. These findings indicate the significant impact of DM communities living in rural and remote areas of Australia. Therefore, it is of the utmost importance to implement a preventative screening process for patients considered high risk [47], and provide education about foot care and prescription of orthotics to deflect high-pressure areas, and reduce or potentially prevent physical disability, pain, and suffering, diabetic foot ulcers DFU, morbidity, mortality, and the consequent economic burden on individuals and the government [8].

3.1.3. Diabetic Foot Ulceration and Orthotics

Diabetes-related foot ulceration may potentially be prevented using orthotic devices, as orthoses may deflect pressure away from high-impact areas in the plantar foot

(Figure 2A,B) and subsequently reduce the risk of wound deterioration, hospitalisation, and potential future amputation. Pressure offloading devices such as knee-high boots, casts, and orthotics provide an evidence-based treatment for people with DM with an estimated high percentage reduction in amputation and hospitalisation rates, as well as prevention of further foot joint deterioration [44]. A recent Australian guideline on offloading treatment for foot ulcers indicated the importance of offloading the foot in high-pressure areas to allow for complete healing of a diabetic foot ulcer [9]. Another recent Australian study [5], looking into factors that impacted healing from a large prospective cohort of 4.709 patients with diabetic-related foot ulcers, found that 1956 (41.5%) patients had their ulcers healed within three months using various offloading methods, including orthotics. Within 12 months, 3012 (64.0%) patients had their ulcers healed using various off-loading devices, including orthotics, post-operative shoes [48], and custom footwear. The same study also found that patients with DFUs were more likely to heal with care specific to a podiatrist, more so than other health disciplines. Furthermore, the study found that Indigenous and non-Indigenous Australians had similar healing times; however, those living in remote areas with critical arterial disease were less likely to heal.



(**A**) (**B**)

Figure 2. Plantar pressure distribution with and without orthotic intervention. Arrows indicate direction of plantar pressure distribution (**A**) Pronated foot showing elevated plantar pressure at the first metatarsal head (MTPJ1), Distal Phalanx, and heel (calcaneus) (arrows = high-pressure zones). (**B**) Foot with custom orthotic demonstrating plantar load redistribution via material properties and customised posting. Smart orthotic sensor arrays (beneath MTPJ1, Distal Phalanx, and heel) measure this pressure in real time; sensors record and transmit data but do not produce the redistribution [23].

Orthotics allow patients to walk and exercise, which further helps to reduce their blood sugar level (BSL) and improve their overall health and wellbeing. It is estimated that diabetes-related complications cost the Australian government and economy per annum $14.4 billion in 2010 [5], while $1.6 billion per annum was due to diabetes-related foot disease as patients required longer hospital stays and further services [44]. It had been predicted that if the current prevalence of inactivity and obesity in Australia does not improve, these costs will quadruple by 2051 [49]. In patients who have DFUs, custom footwear has been shown to reduce plantar pressure and prevent foot ulcer recurrence [50]. An example of pressure distribution and using the orthoses can be seen in Figure 2B. Recent studies have also indicated that static pressure for over 15 min is an important variable as it causes capillary pressure occlusion, and is, therefore, a probable diabetic ulcer risk factor [18].

Sensor-fusion approaches combining multiple plantar pressure sensor arrays within a single insole have been used to classify ambulatory activity with high accuracy, demon-

strating that activity-recognition algorithms can reliably distinguish walking, standing, and stair-use from plantar pressure patterns alone [21,22,51,52]. This technical capability underpins the activity-context awareness required for smart orthotic systems to deliver appropriately calibrated alerts across different real-world activities.

With advanced technology, such as smart orthotics, patients can be alerted to the presence of prolonged and excessive foot pressure, which in turn may provide better effectiveness and a greater reduction in diabetic ulcer risk [28]. Research indicates that diabetic foot ulcers occur during gait due to prolonged stance or repeated plantar force on a focused region [50]. This is a particular risk to the DM patient with PN, as the sensation is reduced, therefore preventing the patient from recognising that there may be a problem and thereby offloading in time before tissue damage. Furthermore, foot deformities and reduced ankle dorsiflexion in conjunction with reduced plantar pressure and tissue thickness will result in increased forefoot loading during gait [50]. Studies have shown that the neurovascular response of a diabetic patient with PN is significantly impaired when compared to patients with non-diabetic foot ulceration [8].

Beyond device-based offloading, gait-related modification strategies—including altered cadence, stride length, and foot-strike pattern—have themselves been proposed as adjunctive approaches to reducing peak plantar pressure in the high-risk diabetic foot [53]. These gait-level interventions are conceptually aligned with the biofeedback mechanism underlying smart orthotics, which similarly prompts the patient toward pressure-reducing gait adjustments in real time.

Table 3 illustrates the effectiveness of orthotics and smart insoles in the management of plantar foot ulcer formation due to diabetes and PN. The studies listed in Table 3 (a) demonstrate that smart insoles work by identifying high-pressure areas, following which a signal is transmitted to the patient via vibration and or a visual analogue through their smartwatch to instruct them to remove pressure from the affected region. These smart insole technologies provide real-time monitoring of plantar pressure [54] and transmit alerts to patients via smartwatch or vibrotactile feedback when pressure thresholds are exceeded, as described in the included studies.

3.1.4. Clinical Trials on Smart Orthotics

A literature search was performed to identify clinical studies involving smart orthotics. For this review, relevant studies published in English were included. The method used to identify articles is shown in the methods search strategy flow diagram. Table 3 illustrates many studies involving orthotics, which have found a benefit in preventing ulceration in patients with PN due to DM [7,40]. However, there is a paucity of studies investigating the role of smart orthotics in comparison to standard orthotics, with the authors of the present review only managing to find a single case study in which standard orthotics were compared to smart orthotics [55] There are recent studies between 2015 and 2022 that tested smart orthotics during weight-bearing and non-weight-bearing activities. Some of these studies were conducted with a very small number of participants, ranging from 15 to 41 participants [19,24,56,57]. Although many of these studies were recent, a number were not included in Table 1, as they were conducted on healthy individuals, did not indicate the age of participants [25,55] or did not distinguish weight-bearing from non-weight-bearing participants [58]. Convolutional neural network architectures applied to smart insole pressure data have been used to detect falls with high sensitivity, illustrating the broader potential of machine-learning approaches applied to plantar pressure time-series data beyond activity classification alone [56,57,59]. Similar algorithmic approaches could in principle be extended to detect emerging high-risk pressure patterns predictive of ulceration, representing a future direction for smart orthotic alert systems.

Overall, these studies concluded that smart orthotics are generally only effective during weight-bearing activities. In a recent randomised controlled trial (RCT) [19], from the 41 patients with DFUs with associated PN, 18 patients were randomised into a control group (CG) and 23 into an intervention group (IG) that was asked to wear smart orthotics for 18 months. While the control group was wearing orthotics with sensors, unlike the IG, it did not provide information or vibration to the patient during the time of high-pressure areas. Although many similarities existed between IG and CG, there was a difference in the patient age of the IG (59.5 ± 9.1 years) compared to the CG (66.4 ± 9.1 years). This study found that although all patients were wearing sensory pressure sensors, the CG had recorded more pressure sessions than the IG, as the CG did not have the buzzing or visual reminder to offload the high-pressure areas that was available to the IG. Another similar study recruited 90 patients, in which only 58 completed the study (26 CG and 32 IG). Inclusion criteria required the patient to have diabetic PN and be capable of walking 30 steps [28]. The study reported a relative risk reduction of 80% (RR = 0.20; 95% CI: 0.05–0.79; p = 0.022), with DFU recurrence in 6.3% of the intervention group versus 30.8% of the control group (ARR = 24.5%). The study reported that patients with diabetic PN may not be able to feel high-pressure areas, leading to the plantar foot experiencing a significant level of concentrated high-pressure regions that would place the foot at high risk of ulceration. DFU recurrence occurred in 6.3% of the intervention group (n = 32) versus 30.8% of the control group (n = 26), representing an absolute risk reduction of 24.5% and a relative risk of 0.20 (95% CI 0.05–0.79; p = 0.022).

Furthermore, a 2017 study investigated 17 patients with diabetic PN and foot ulceration within the previous 12 months who were able to walk for a minimum of 20 m and had an ankle–brachial index (ABI) between 0.5 and 1.2 (with toe–brachial index (TBI) greater than 0.65). Only 12 people were able to complete the study due to other medical conditions or loss of smartwatches. Participants had been provided with the smart insole, where the sensors communicate, with the smartwatch. Upon high-pressure detection on the plantar foot, they received alerts when safe time (15 min) duration and pressure 35–50 mmHg were exceeded via their smartwatch, which prompted them to offload (51) and reduce pressure on the region to prevent the skin from deteriorating and potentially ulcerating. Results revealed that no ulcer had formed during the active phase of the research, nor were there any reported side effects from the device [18].

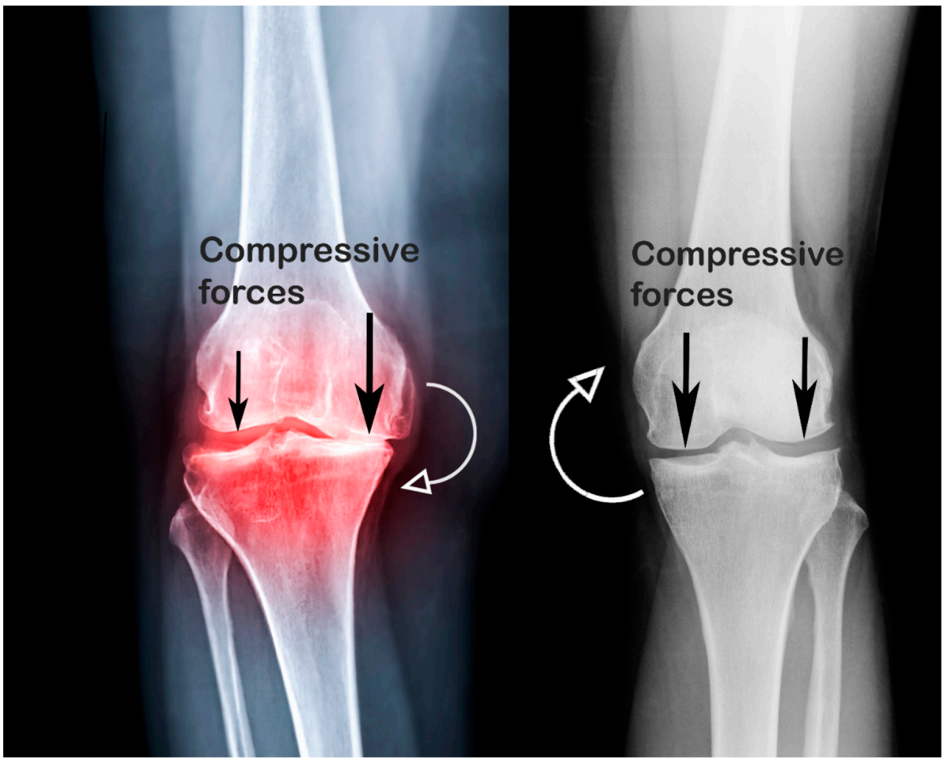
Finally, a case study in 2018 assessed the plantar pressure of a 59-year-old patient with a history of plantar foot ulceration and severe diabetic PN with right ankle fusion. The study evaluated whether the recipient was able to alter pressure using a smart pressure sensor insole. This case report investigated pressure standing and walking during day-to-day activity. Information such as duration in time (min and hours) and pressure 35 mmHg based on the pressure requirement for capillary perfusion. The alert was then communicated to the patient via his smartwatch to offload. Results from this case report indicated that no ulcer formed during the active phase of the study, attributed to the real-time alert mechanism [11,23,24,60,61].

Although further research is warranted in this area, there is a small number of studies with relatively small patient numbers that suggest that smart orthotics can trigger alerts to patients with DM-related PN that may help prevent potential ulcer formation, which could otherwise lead to prolonged hospitalisation or amputation. Cheng et al. (2017) estimated that if all patients at risk of developing diabetes-related foot ulcers in Australia received optimal care including orthotic services, the healthcare system could save approximately $540 million per year ($2.7 billion over five years), representing more than $9000 per patient over five years [60].

3.2. Arthritis and Smart Orthotics

3.2.1. General Background

Arthritis impacts a patient's quality of life and produces functional disability, as the disease affects a large number of people and contributes to significant pain [12,62]. Osteoarthritis (OA) and rheumatoid arthritis (RA) are the two leading conditions that contribute to severe long-term joint pain and reduced physical capacity [63]. OA is three to six times more likely to develop in individuals who have sustained a prior knee injury [64]. The diagnosis occurs approximately 10 years before patients who had not sustained a knee injury [64]. Knee OA is one of the most common musculoskeletal disorders in the world that contributes to knee pain, disability, and high economic burden [10]. The medial knee joint is 10-fold more affected than the lateral compartment [65]. This variation is because the medial knee carries approximately 60–90% of the total knee load as been illustrated in Figure 3A,B [13]. The external knee adduction moment (EKAM) has been studied extensively [14,66] due to its contribution to medial knee contact force and its link to the progression of OA [15,67]. Unfortunately, this mechanically induced disease has no current cure, and given that regular walking is associated with knee OA progression, nonsurgical management is paramount [68,69] in allowing the maintenance of mobility and enabling long-term improved outcomes with minimal pain and regular employment. When compared to other Australian persons, First Nations people are 1.4 times more likely to develop OA and 1.9 times more likely to have RA [16]. There are limitations of daily activities in 57.9% of people who suffer from chronic joint pain [70], arthritic pain in the feet, knees, and hips, which in turn results in a low quality of life [71].



(**A**) (**B**)

Figure 3. Biomechanical forces in medial compartment knee OA and effect of orthotic intervention. (**A**) Medial knee joint under high compressive and adduction loading; EKAM vector indicated. Medial compartment bears 60–90% of total knee load (Morrison, 1970 [12]). (**B**) Modification of GRF vector via orthotic, reducing EKAM arm and medial compartment contact force (Schipplein and Andriacchi, 1991 [13]). Figures adapted from Adobe Stock (Adobe Inc., San Jose, CA, USA) and modified https://stock.adobe.com/ (accessed on 15 January 2025).

3.2.2. An Australian Context—Knee Osteoarthritis Burden

There have been many discussions about altering the gait biomechanics using orthotic therapy, to influence the relationship between the foot, ankle, and knee mechanics and deflect the knee loading and thereby reduce disease progression and pain in comparison to surgical procedures such as high tibial osteotomy (HTO) or various types of knee replacement [72]. Studies have indicated that orthotic therapy may significantly improve mobility and reduce pain for people with knee OA [73]. This may contribute to an effective improvement of workforce and patient quality of life [73,74], including those patients awaiting surgery intervention [75]. The economic burden of arthritis is estimated to cost $8.2 billion in Australia by 2030. This cost includes all forms of arthritic conditions (4) that lead to damaged or inflamed joints. The estimation incorporates the productive life years, rather than just the treatment cost expenditure and its long-term economic impact on the impacted individual and the government [71]. Another Australian study found that in 2015, the healthcare expenditure for overall OA was $2.1 billion and $550 million for RA. This is expected to exceed $2.9 billion for OA by 2030, which equates to an average of $970 per Australian with osteoarthritis [16,51], with a significant proportion ascribed to knee replacement [16]. A further $1.1 billion loss is attributed to a decrease in the workforce due to the functional impairment and pain contributed by arthritis. The cost of arthritis is borne by the government, individuals with the disease [76] and assisting family members [77]. Health system performance for OA and rheumatoid arthritis care has been evaluated through a structured set of key performance indicators covering access, wait times, and care coordination for centralised intake models [74]. The development of such indicators reflects the broader health-system recognition that timely, coordinated access to orthotic and conservative management pathways is itself an important determinant of outcomes for patients with knee OA.

Therefore, the overall financial burden is substantial and most probably cannot be fully calculated. A study from the University of York estimated that for every one pound spent on orthotic services, the United Kingdom government could save 4 pounds [75]. Similarly, a 2015 Australian study found that 525,335 had mild to moderate knee OA and that an intervention consisting of weight loss and an exercise programme was cost-effective [16].

3.2.3. Clinical Studies on Smart Orthotics in Knee OA

The mechanism by which smart orthotics with real-time biofeedback may reduce EKAM in knee OA operates through a closed-loop plantar pressure sensing pathway. Plantar pressure sensor arrays continuously monitor the centre of pressure (COP) trajectory during gait; a relatively medial COP increases the GRF moment arm at the knee and elevates EKAM [14,78]. When the system detects excessive medial loading, a biofeedback alert prompts the patient to shift weight laterally or adopt a toe-out gait in real time, thereby reducing the EKAM. Erhart et al. [79] demonstrated that real-time biofeedback targeting lateral ground reaction force GRF shift produced significant EKAM reductions during walking. This distinguishes smart orthotics from conventional lateral wedge insoles, which modify EKAM passively through device geometry without active patient feedback. Recent research, including quantitative data, has shown that smart orthotics can improve current OA progression and can be used as an investigative tool, as it measures patients' responses to treatment and disease progression by a smart sensor-watch feedback mechanism [61]. A 20 week clinical trial evaluated passive conventional orthotics without any sensing or biofeedback capability comparing lateral wedge insoles (n = 13) with standard arch-support insoles (n = 10) found that the lateral wedge reduced medial knee loading, which the authors suggested may delay OA progression [20]. Further research has illustrated the importance of self-directed learning and its impact on individuals. In a prospective randomised control

trial in 95 participants, a benefit was found from patient self-management, as device feedback motivated participants to further improve in their comfort zones, such as in their home environment or during regular exercise [80]. Other studies have demonstrated that smart orthotics may also reduce hospital visits, improve patient outcomes, and reduce economic burden by providing patients with feedback and education and at the same time improving patient satisfaction [77]. The growing interest in smart orthotics technology [81] mirrors the way people use other devices, such as a smartphone to check their pulse, in everyday life [82]. A monitoring device suitable for use during exercise and across various medical specialties, including monitoring athletes to identify excessive foot loading, may potentially prevent both acute and chronic injury.

4. Conclusions

This review identified research reporting that orthotics may improve healing and potentially reduce ulcer incidence by up to 71%, while other research indicated complete ulcer healing, subsequently improving morbidity, physical disability [55], and economic burden. Although the number of studies directly comparing smart orthotics with standard orthotics remains limited, the limited comparative studies suggested that smart orthotics showed promising results in reducing ulcer incidence, providing the patient with real-time feedback [18,19,28] to offload via their electronic devices. The economic burden of diabetic foot disease and knee osteoarthritis is substantial and well-documented. However, dedicated health economic evaluations of smart orthotic technology including formal cost-effectiveness analyses, incremental cost-effectiveness ratios (ICERs), and quality-adjusted life year (QALY) calculations are currently absent from the published literature. Existing cost-effectiveness evidence relates primarily to conventional offloading interventions: Cheng et al. (2017) [60]. demonstrated that optimal care for diabetic foot ulcers in Australia, including orthotic offloading, was cost-effective compared with standard care. Given that smart orthotics have demonstrated promising results in reducing ulcer recurrence in the available trials, further health economic modelling comparing smart with standard orthotics is warranted as a priority for future research. Patient management and disease prevention with smart orthotics may complement the current clinical methods for at-risk long-term DM and knee OA sufferers by alerting them to offload and realign their lower limb posture to remove excess weight on an ulcerated or painful region.

A biomechanical feasibility study demonstrated that adopting a "step-to" gait pattern—in which the trailing foot is brought level with, rather than past, the leading foot before the next step—significantly reduced forefoot plantar pressure in a prospective cohort (n = 20) [37]. This finding provides clinical proof-of-concept that voluntary gait modification can achieve meaningful pressure reduction, supporting the rationale for biofeedback systems that prompt such modifications in real time during daily ambulation.

Research documents the substantial burden of diabetes on the Australian population and on First Nations peoples in particular. The clinical studies included in this review provide preliminary evidence that orthotic and smart orthotic interventions may reduce ulcer incidence and plantar pressure in selected populations; however, these findings cannot be directly extrapolated to cost savings without dedicated health economic modelling. Studies have found that in DFUs, smart orthotics can be used to predict individuals at risk, and, therefore, they may constitute an early intervention tool. The limited number of comparative studies suggested that smart orthotics showed promising results in reducing ulcer incidence compared with standard orthotics.

Smart orthotics may also assist people with knee OA via an alert signal transmitted from the smart orthotics to their smart devices. This may help such patients to offload and reduce pressure on an affected site and hence prevent further injury or allow for a

better recovery. This allows a reduction in knee joint friction, improving knee function and quality of life, allowing the affected individual to return to work or continue their occupation, and hence also reducing the financial pressure on the individual, family, and government, hence potentially contributing to a reduction in healthcare-related costs. Hence, the integration of pressure monitoring and biomechanical offloading plays a pivotal role in reducing the recurrence of diabetic foot ulcers. Cheng et al. (2017), from the Queensland University of Technology's Institute of Health and Biomedical Innovation, conducted a Markov model cost-effectiveness analysis of optimal versus usual care for diabetic foot ulcers in the Australian healthcare context. The study found that if all patients at high risk of a diabetic foot ulcer in Australia received optimal evidence-based care, including multidisciplinary team management, podiatry, patient education, appropriate wound dressings, therapeutic footwear, and pressure offloading devices including orthotics, the Australian health system could save approximately $2.7 billion over five years [60], representing more than $9000 per patient over the same period. Expressed as an annualised figure, this equates to an estimated saving of $540 million per year from the prevention of diabetes-related foot ulcers and their downstream complications, including hospitalisation and lower limb amputation. Critically, the study demonstrated that preventing diabetes-related amputation by improving access to orthotic and podiatric services is cost-saving, not merely cost-effective, as the cost of providing orthotic services to heal or prevent a diabetes-related foot ulcer is substantially lower than the cost of managing an amputation and its sequelae. These findings provide direct economic justification for investment in smart orthotic technology, if conventional orthotic services alone generate savings of this magnitude, the addition of real-time biofeedback capability reducing ulcer recurrence rates by up to 80% as demonstrated by Abbott et al. (2019) has the potential to generate further, as yet unquantified, cost savings through more effective prevention of the ulcer-to-amputation cascade [27].

4.1. Risk of Bias Across Studies

Risk of bias was assessed for each included study using the Cochrane RoB 2 tool (RCTs), the Newcastle–Ottawa Scale (cohort and case–control studies), and the JBI critical appraisal tool (case studies and pilot studies). Full per-study assessments are reported in Table 2 (Section 2.6). A summary of key findings by synthesis group is provided below. The body of evidence in Table 3 (a) for smart orthotics in DFU prevention is dominated by Level 2 RCTs and Level 3 cohort studies, none of which were double-blinded due to the open-label nature of wearable insole interventions. No Level 1 systematic reviews with meta-analysis of smart orthotics specifically exist. The three RCTs Chatwin et al. 2021 [18], Abbott et al. 2019 [27] and Yorkk et al. 2009 [26] provide the most reliable evidence. The pilot study (Van et al. 2017 [39], n = 11) contributes Level 4 evidence only. Conclusions drawn in this review should be understood as reflecting a preliminary, Level 2–3 evidence base. (York et al. 2009 [26]) and DFU recurrence verified by clinical examination (Abbott et al. 2019 [27]; Chatwin et al. 2021 [18]), which are less susceptible to performance bias than subjective patient-reported outcomes. Second, a narrative sensitivity analysis confirms robustness: when the three Level 2 RCTs are considered in isolation, excluding Van et al. (2017) [39] and Najafi et al. (2017) [17] the direction and magnitude of effect is consistent across three independently conducted trials in different countries, all showing statistically significant reductions in plantar pressure or DFU recurrence. Third, the 30% dropout in Najafi et al. (2017) [17], is consistent with wearable technology adherence literature; progressive adherence from 54% to 82% indicates device adaptation. Fourth, allocation concealment rated 'Unclear' for Abbott et al. (2019) [27] and York et al. (2009) [26] reflects insufficient reporting, not evidence of inadequate concealment; these ratings may

be revisable to 'Low risk' following author correspondence. Future priorities: (1) larger multi-site RCTs (minimum n = 100 per arm); (2) standardised primary outcomes with CIs; (3) minimum 24-month follow-up; and (4) integrated health economic modelling.

Synthesis Group 1—Diabetic Foot Ulcers and Smart Orthotics: (Chatwin et al. 2021 [18]; York et al. 2009 [26]; Abbott et al. 2019 [27]) Van et al. 2017 [39]), and the remainder, including in Table 3, were prospective or retrospective cohorts and case–control designs. Key risk of bias concerns across this synthesis group included: (1) absence of blinding due to the open-label nature of smart insole interventions—a structural and inherent limitation in all wearable technology trials, analogous to surgical trials, and substantially mitigated by objective primary outcome measures (pedobarographic plantar pressure and clinically verified DFU recurrence) that are less susceptible to performance bias than patient-reported outcomes. When appropriately contextualised, this represents a moderate rather than high risk of performance bias for the three included RCTs; (2) small sample sizes in the majority of studies (range: n = 11 to 4832; median n ≈ 30 for smart orthotics trials), limiting statistical power and generalisability; (3) variable and short follow-up periods (ranging from single sessions to 18 months), with most studies not reporting long-term outcomes beyond 12 months; (4) incomplete outcome data in two studies due to participant dropout rates exceeding 25% (Najafi et al. 2017 [17]: 29% dropout; Chatwin et al. 2021 [18]: 16% dropout); and (5) only two studies (Abbott et al. 2019 [27]; Chatwin et al. 2021 [18]) reported quantitative comparative effect estimates with confidence intervals [18,27]. The only study with a low overall risk of bias was Zhang et al. 2021 (large prospective cohort, n = 4832), which did not specifically compare smart with standard orthotics [38].

Synthesis Group 2—Knee Osteoarthritis and Smart Orthotics: Studies investigating knee OA included a mix of prospective RCTs, cohort studies, and observational designs. Key risk of bias concerns included: (1) heterogeneity in OA severity grading across studies, making cross-study comparisons difficult; (2) variable outcome measures (EKAM, VAS pain, WOMAC, self-report function) without a standardised primary outcome; (3) short follow-up durations (predominantly 12–20 weeks) that do not capture longer-term disease modification; and (4) many studies did not include a control group or comparator arm. Overall, the certainty of evidence in this synthesis group is considered low to moderate, consistent with the informal GRADE assessment presented in Section 4.2.

Overall judgement: When interpreted in the context of the structural constraints of wearable technology trials, the overall risk of bias across the included smart orthotic studies is more accurately characterised as low to moderate for the primary findings. The three RCTs [18]; Abbott et al. 2019 [27]; York et al. 2009 [26] are rated Moderate—not High—because (1) randomisation and sequence generation were adequate (Low risk) in all three; (2) selective reporting and incomplete outcome data were Low risk in all three; (3) objective primary outcome measures (pedobarographic plantar pressure and clinically verified DFU recurrence) substantially mitigate performance bias; and (4) the consistency of effect direction across three independently conducted RCTs in different countries strengthens confidence in the findings. Abbott et al. (2019) [27] achieved a statistically significant 80% relative risk reduction (RR = 0.20; 95% CI: 0.05–0.79; $p = 0.022$)—a large effect unlikely to be fully explained by performance bias. Allocation concealment rated 'Unclear' for two RCTs reflects insufficient reporting, not evidence of inadequate concealment, and may be revisable to 'Low risk' pending author correspondence. Zhang et al. (2021) [38], the only large cohort (n = 4832), was rated Low to Low-Moderate risk. Future multi-site RCTs with blinded outcome assessors and pre-registered protocols remain the highest research priority to further strengthen this evidence base.

4.2. Reporting Biases and Certainty of Evidence

The overall certainty of evidence was assessed narratively with reference to the five GRADE domains—risk of bias, inconsistency, indirectness, imprecision, and publication bias without formal per-outcome GRADE profiling, consistent with the narrative synthesis design of this review. When assessed with appropriate contextualisation of the structural constraints of wearable orthotic trials, the overall certainty of evidence is judged as: Moderate for smart orthotics in DFU prevention—three independent RCTs report consistent, statistically significant findings; objective primary outcomes mitigate performance bias; inconsistency is low; and Abbott et al. (2019) [27] demonstrated a large, statistically robust 80% relative risk reduction (RR = 0.20; 95% CI: 0.05–0.79; $p = 0.022$). For smart orthotics in knee OA, certainty is Low to Moderate, reflecting the absence of RCTs directly evaluating smart orthotics with real-time biofeedback and heterogeneity of outcome measures. While publication bias is possible—the grey literature was not systematically searched and positive findings dominate the included studies—the independent replication of results across three RCTs in different countries substantially reduces the probability that the overall finding is driven by reporting bias alone. Given the narrative synthesis design, funnel plot analysis was not feasible.

The overall certainty assessment is therefore more accurately characterised as Moderate for the primary DFU prevention finding and Low to Moderate for knee OA, justified by the objective nature of primary outcomes, the consistency of effect across independent RCTs, and the narrative sensitivity analysis confirming robustness of findings (Section 4.1). Risk of bias, the primary GRADE downgrading domain, is rated Moderate rather than High across the key RCTs when the structural and inherent nature of open-label design in wearable technology trials is appropriately contextualised. Inconsistency and indirectness are rated low. Imprecision is moderate given small sample sizes, though the large effect size observed in Abbott et al. (2019) [27] partially offsets this concern. This assessment should be interpreted as a narrative judgement referencing GRADE domains rather than a formal completed GRADE evaluation.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/app16136301/s1, Table S1: Categorised reference list of included studies (n = 78) grouped by synthesis theme: (1) Diabetic Foot Disease, Smart Orthotics & Offloading: (2) Smart Insole Technology & Activity Recognition; (3) Knee Osteoarthritis & Orthotic Interventions; and (4) General Epidemiology & Health Economics.

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