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Review

An integrative review of therapeutic footwear for neuropathic foot due to diabetes mellitus

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ABSTRACT

Background: Therapeutic footwear is built on a model of patient's foot, for people with diabetes suffering with neuropathy. Can the footwear helps to improve plantar pressure in neuropathic foot? This study focussed on available data on therapeutic footwear as an intervention for improving and offloading plantar pressure in neuropathic diabetic foot.

Methods: Relevant scientific literature in PubMed, Medline and Google Scholar published between 2000 and 2017 were searched. The keywords searched were therapeutic footwear, plantar pressure, neuropathic foot, rocker sole, ulcer healing and offloading of plantar pressure. Articles on randomized controlled trials, observational, cohort, feasibility and factorial studies were reviewed.

Results: One hundred and twenty five (125) articles were identified. The article comprised of 6 randomized controlled trials, 2 observational, 1 cohort, 1 feasibility and 1 factorial study met the inclusion criteria and were critiqued with a total enrolment of 1380 study subjects.

Conclusions: The review of the collated literature demonstrated that, therapeutic footwear can improve the healing of neuropathic diabetic foot ulcer by redistributing plantar pressure. However, the efficacy of therapeutic footwear requires the inclusion of technical features that should not be compromised from the design to the production of the footwear.

1. Introduction

Diabetes mellitus (DM) is a physiological disorder characterized by hyperglycaemia, due to endogenous insulin deficiency, impaired efficiency of insulin action, or both with chronic complications which affects nearly all organs in the body [1–3]. The disease is a major challenge in developing countries like Nigeria and India [4]. Its prevalence is steadily increasing across the globe among all age groups [5,6], irrespective of gender, race, socioeconomic status [7] or ethnicity and this constitutes a global public health burden to everyone. According to the International Diabetes Federation (IDF), 425 million people worldwide, or 8.8% of adults 20–79 years are living with DM as at 2017. The value is four times more than what was documented in 1980. Regrettably, it is expected to increase to about 629 million by 2045 [8].

In Nigeria, DM has become a health scourge with long-term complications such as amputations, ulceration, Charcot deformity, neuropathy, nephropathy and retinopathy [9–11]. It was reported that, in every 30 s, a limb is lost somewhere in the world [12], while at least a person dies every 6 s due to DM or its consequence [8,13]. An estimated 5, 000,000 deaths were attributed to diabetes in 2015 globally (IDF 2015). In 2014 approximately 3,921,500 cases were reported in Nigeria alone with a prevalence rate of 4.99% [13].

Plantar pressures are forces exerted on the foot during gait cycle, which causes delay in the healing of diabetic foot ulcers (DFUs) [14–16]. Research findings had revealed that appropriate offloading devices such as total contact casting (TCC), short leg walkers, half shoes, felted foam dressings, bed rest, wheelchair, crutches and therapeutic shoes reduces the rate of DFU healing [15,17,18]. In spite of these various treatment techniques, only 60% of all DFUs are healed within one year of onset, and greater than 10% of those ultimately involve foot amputation [19]. Ahmed et al. [20], established that, about 49–85% of all foot amputations can be

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ameliorated, using appropriate therapeutic footwear. People suffering with diabetes need appropriate therapeutic footwear to offload and facilitate the healing of diabetes ulcers [21–23]. Offloading efforts of 30% reduction has been recommended to ameliorate DFU [24].

Therapeutic footwears (orthopaedic or bespoke) are medical devices used in the treatment of foot disorder [25]. They are built on a model of patient's foot to accommodate defect, improve healings, and offload pressure for at-risk sites on the plantar and dorsal surfaces of the foot. For people suffering with diabetes who have at-risk feet, therapeutic footwear that includes custom-made insole is recognized as one of the fundamental preventative interventions for reducing incidence of plantar ulcer [24].

Appropriate footwear refers to well fitted comfortable shoe which can protects the foot from injury and reduces plantar pressures as well as foot ulceration [25–28]. Neuropathic foot ulcers could be prevented by a combination of soft insole, with midsole and hard outsole with proper back counter and adjustable front and back straps [29]. The National Health and Medical Research Council (NHMRC) guidelines revealed that, appropriate therapeutic footwear is one of the key strategies in preventing foot ulceration [30]. Therefore, this study aimed at reviewing the technical requirements and efficacy of therapeutic footwear as an intervention for the amelioration and redistribution of mechanical pressure in the neuropathic foot particularly for people suffering with diabetes.

2. Methodology

2.1. Search strategy

This integrative review was conducted by searching relevant scientific articles from major databases to identify original research on therapeutic footwear. These original researches were those that focussed on the interventions to improve ulcer and redistribute plantar pressure on neuropathic foot. The following databases were searched: PubMed, Medline and Google Scholar. The major keywords for the search included diabetic shoe, therapeutic footwear, foot ulcer, neuropathy, diabetic ulcer, diabetic foot, custom made footwear intervention and diabetes. Our literature database search identified 125 articles, 55 of the articles were considered eligible after review of the title and abstract. From these, was identified 11 articles representing 6 randomized controlled trials (RCTs), 2 observational, 1 cohort, 1 feasibility and 1 factorial study (Fig. 1) with enrolment of 1380 study subjects having neuropathic diabetic foot ulcers due to DM and treated with an offloading technique that fulfilled our inclusion criteria.

2.2. Inclusion criteria

Original research articles were included which reported on therapeutic footwear interventions used in improving ulcer healing and offloading of plantar pressure. Studies that were considered were randomized controlled trials, cohort, feasibility, factorial and observational studies that enrolled patients with diabetes mellitus type 1 or 2 and published in English language.

2.3. Exclusion criteria

Excluded articles included, studies on individuals with neuropathy other than diabetes and articles like commentaries and letters.

3. Therapeutic footwear for neuropathic foot due to DM

Research findings about the function of therapeutic footwear in improving foot ulcer for those at-risk suffering with diabetes are

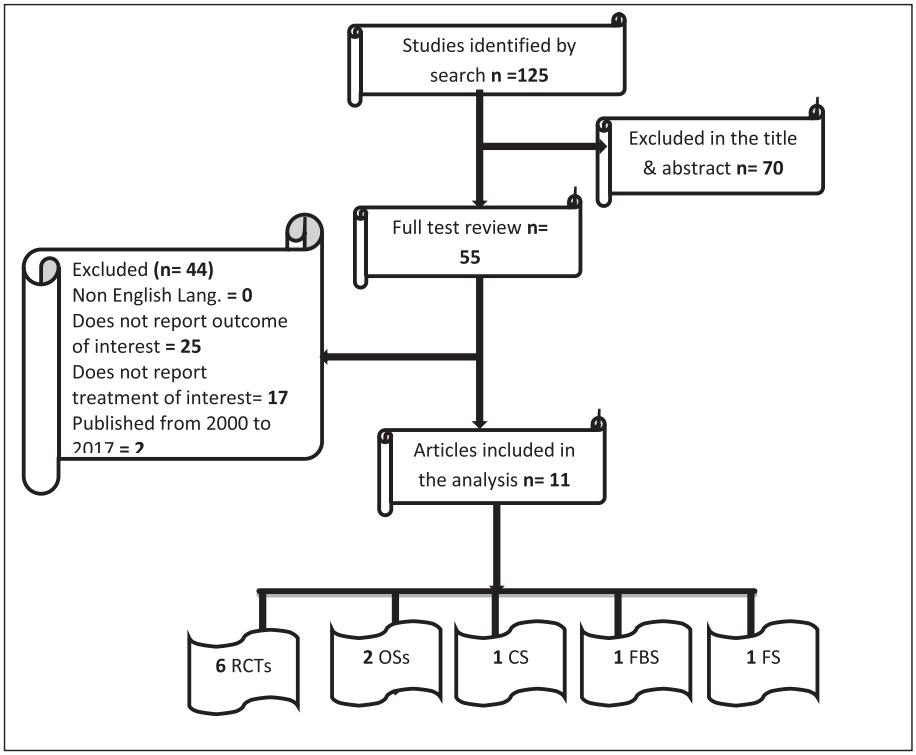

Fig. 1. Literature flow diagram of articles identified, screened, met inclusion criteria and utilized for footwear intervention. RCTs = Randomized controlled trails: OSs = Observational studies: CS = Cohort study: FBS = Feasibility study: FS = Factorial study.

deficient. It is known that, those at-risk with diabetes have high levels of mechanical plantar pressure during barefoot walking, which is an independent risk factor for foot ulceration [31,32]. In the literature search as presented in Table 1 [22], demonstrated that, therapeutic footwear was effective in off-loading plantar pressures with 100% healing of neuropathic ulcer at an average of 56 days. Rocker footwear with 15° and 20° rocker angle (RA) having mean optimal apex position of 52% of footwear length has a significant reduction in peak pressure when rocker angle was increased from 15 to 20°. Sixty six percent (66%) of patients experienced sufficient offloading with 15° rocker angle at a selected optimal apex position [33]. Sicco et al. [34], reported that, 79 (46%) of the total group of 171 patients, adhered to wearing their custom-made footwear. In this subcategory, 25.7% of the patients with improved footwear had an ulcer relapse which was significantly lower than that of the 47.8% patients in the usual care group [34].

Rizzo et al. [35], reveal that therapeutic footwear helps in reducing ulcer elapse than conventional footwear. The result from their study showed that the group with therapeutic footwear demonstrated significantly less ulceration incidence at first year, third year, and fifth-year (23.5% vs. 70%) (Table 1). The findings support the advantages of early therapeutic footwear intervention. Similarly, Busch & Chantelau [36], and Uccioli et al. [37], reported a reduction in ulceration rates among study subjects who wore therapeutic footwear compared to those who wore their own footwear.

Footwear as an intervention has shown a substantial role in the pathogenesis of foot problems in neuropathic foot [38,39]. Appropriate footwear and insoles for individuals suffering with diabetes will help minimize unusual pressure, reduce the development of callus and ulcers [40]. Therapeutic footwear redistribute the pressure that develop under the foot and can be used by patients to reduce ulceration on the foot [41].

Therapeutic footwear with insoles and elevated toe boxes are significant adjunctive intervention to reduce the manifestation of foot ulcer and possible amputation [37,42–44]. People suffering with neuropathy and foot defects should have therapeutic footwear that offer fitting with width depth [45,46]. Tagang [47] and Apelgvist et al. [38] have given a significant subjective proof and view to demonstrate ill-fitting footwears that are not appropriate. The scholars revealed that 21%–82% of foot ulcers are associated to pressure from footwear that is too narrow. Edmonds and Foster [48], emphasized that, footwear that is not of accurate size can continuously hurt the feet, and lead to callus defect and ulceration.

Reiber et al. [43], reported in a RCT of 400 patients (58% of patients with neuropathy) to therapeutic footwear having customized medium-density cork inserts, prefabricated polyurethane inserts, and to their own conventional footwear. The authors found no significant difference in ulcer relapse occurrence over a 2-year period between therapeutic footwear and control footwear (15% vs 14% and 17%). Off-loading plantar pressure of neuropathic foot ulcer enhances the healing of the wound with appropriate dressing of the wound because pressure is a contributory dynamic for neuropathic foot ulcers. A randomized control trail with great risk of prejudice by Uccioli et al. [37], in 69 study subjects established a significantly lesser number of participants with foot ulcer above one year period in individuals who had worn therapeutic footwear compared with individuals that constantly use their conventional

Table 1
Study report and assessment of the reviewed articles.

Study design	Types of diabetes	No. of patients	Duration	Intervention	Results	Outcome measure	Reference
Randomized controlled trial	NR	30	NR	Medical grade shoe & conventional shoe	Test shoe reduces pressure on the forefoot with greater comfort than conventional shoe	Forefoot pressure reduction	[25]
Randomized controlled trial	1 & 2	171	18 months	Custom made shoe	Among 85 patients, ulcer relapse occur in 38% improved shoe & 44.2% usual care ($p < 0.48$). For high adherence (79 patients), 25.7% with improved shoe & 47.8% with usual care	Ulcer relapse	[34]
Randomized controlled trial	NR	119	6 months	Custom made functional and prefabricated insole	Custom made = 30%, prefabricated insole = 24% ($p < 0.001$)	Pressure reduction	[50]
Randomized controlled trial	NR	299	Insole replace every 4 months	Shear insole & traditional insole	Shear reducing insole more effective than traditional insole	Ulcer healing	[51]
Randomized controlled trial	1 & 2	Intervention 1 = 121, Intervention 2 = 119, Control = 160	2 years	(1) 3 pairs of therapeutic shoe & 3 pairs of customized cork insole (2) 3 pairs of therapeutic shoe & 3 pairs of prefabricated, tapered PU insole (3)Participants own shoes	(1) 15% (2) 14% (3) 17%	Ulcer relapse	[43]
Randomized controlled trial	NR	50	30 days	Cloth footwear with rigid sole & unloading alkaform insole	8.3% increase of ulcer in 2 patients ($p < 0.0004$). For others, 5 (20.8%) ulcer heal ($p < 0.03$)	Plantar ulcer	[52]
Cohort study	1 & 2	102	NR	Footwear with rocker outsole	increase plantar pressure significantly as apex position was moved distally and rocker angle reduced ($p < 0.001$)	Offloading of plantar pressure	[53]
Feasibility study	2	7	56 days	Therapeutic shoe & custom made insole	Effective offloading & ulcer heal	Ulcer relapse	[22]
Factorial study	NR	87	NR	Custom made rocker footwear	Significant reduction in plantar pressure when rocker angle was increase from 15° to 20°	Plantar pressure reduction	[33]
Observational study	1 & 2	23	Optimization lasted for 53 min.	Custom made footwear	Peak pressure significantly reduced with 95kpa (30.2%) ($p < 0.001$)	Offloading of plantar pressure	[54]
Observational study	1 & 2	Intervention = 60, Control = 32	12 months	(1) Diabetic shoe (2) Participants own shoe	(1) 15% (2) 60% ($p < 0.001$)	Ulcer relapse	[36]

NR = Not reported. Cross-sectional study; type 1 and 2; Forty-one outpatients.

footwear (27.7% versus 58.3%, p = 0.009) [37]. Among patients in the neuropathy group who wore therapeutic footwear, 26% had ulcer relapse compared with 83% of the patients in the referent group (risk ratio 0.31, 95% CI 0.24–0.46). Among the ischemic ulcer follow-up group, 25% of those wearing therapeutic footwear had ulcer relapse compared with 83% of the referent group with retail footwear (0.30, 0.22–0.53) [49].

A RCT with very low risk of bias in 171 neuropathic patients compared an intervention group that receive therapeutic footwear that have been modified to reduce in-shoe plantar pressure at-risk positions to a group that receive the same type of custom-made footwear that did not undergo such modifications [27]. There was no significant difference in relapse of plantar foot ulcers at 18 months between the intervention and control group (38.8% vs. 44.2%, p = 0.48). Although, half of the study subjects who wore their therapeutic footwear for at least 80% of their measured activity, had a significant ulcer reduction among the intervention group than the control group (25.7% versus 47.8% [p = 0.045]).

A randomized controlled trial was conducted by Paton et al. [50], among 119 neuropathic participants suffering with diabetes. The participants were treated with custom-made functional or prefabricated insoles. The outcome of the study revealed that custom-made functional insole was slightly more effective than the prefabricated insole in reducing forefoot pressure time integral (27% vs. 22%), and was more effective at six month follow-up (30% vs. 24). Similarly, Tagang et al. [55], reported in their study that, 41 (91%) of the study subjects responded that foot ulcers could be connected to inappropriate footwear, 37 (82%) says ill-fitting footwear could be the most important problem that lead to foot amputation while 27 (60%) says they have come across patients that reported bad foot experience like blisters and ulcers.

A RCT with high risk of bias showed a clear trend, but no significant effect of shear-reducing insoles on preventing foot ulcers [51]. Also in a RCT at very low risk of bias, it shows that digital silicone orthoses can significantly reduce first ulcer occurrence in at-risk patients with pre-ulcerative lesions [56]. Carlo et al. [52], in a randomized study show that 20.8% of the study subjects were in the footwear group (P = 0.03) and ulcers healed at 30-day without any side effects.

One cohort study with high risk of bias with 241 study subjects found that the use of therapeutic sandals resulted in significantly lesser ulcers relapse in 9 months compared with wearing sandals that have a hard leather board insole [57]. However, Busch and Chantelau [36] in an earlier cohort study with great danger of bias, found 15% ulcer re-emergence over 12 months in 60 study subjects who were beneficiaries of prescribed diabetic footwear compared with 60% in 32 study subjects who were not compensated and for that reason put on their personal footwear (p < 0.001).

With respect to footwear intervention techniques in these studies, only Reiber et al. [43], provided 3 pairs of standardised therapeutic footwear for replacement throughout the study with footwear given to patients at interval. Some studies reported the inclusion of a rocker sole in their footwear but provided limited description of the rocker footwear. Wearing of appropriately close-fitting or prescribed footwear (with technical features) has been revealed to significantly reduced plantar foot pressures, and so lessening the chance of developing callus and in the end ulceration [26].

4. Technical requirements of therapeutic footwear

Appropriate design of therapeutic footwear will promote proper musculoskeletal movement and improve healing of health issues caused by neurological disorder. Therapeutic footwear requires the following features in other to enhance ulcer healing and redistribution of pressure within the plantar region.

i). Extra-depth, broad and squared toe-box to avoid irritation on the dorsum of clawed toes [58,59].
ii). Sensor technology to monitor musculoskeletal pressure and movement, as well as pronation and supination detection (Figs. 2 and 3)
iii). Custom-made functional insoles (Fig. 4) which reduces intrinsic risk factors to the foot, in particular peak pressure.
iv). Low heel, not higher than one inch to reduce load in the forefoot.
v). The footwear must be wide enough in the forefoot to prevent rubbing that could result in blisters
vi). The footwear should be of light weight with a seamless protection lining to prevent friction.
vii). Footwear should have visible laces or velcro (Fig. 5) and a broad sole to provide sufficient stability.
viii). Use of F-scan system is required to measure plantar pressures in order to offload excessive pressures [62].
ix). The uppers should be of high value kid leather or fabric material, which will permit the passage of water vapour from the patient's feet.
x). Required a rocker profile on the outsole geometry [63]. This has three design features: apex angle (orientation relative to the long axis of the footwear), apex position (percentage of footwear length where the outsole begins to curve upwards under the forefoot) and rocker angle (angle between the floor and sole under the toe area) [64] (Fig. 6). Apex angle of 95° was established to be appropriate for footwear designed to offload high risk regions of the forefoot [64] and should be used for all footwear.

5. Etiological factors associated with diabetic foot ulcer (DFU)

Foot ulcers are a frequent complication of diabetes mellitus, with a lifetime incidence between 19% and 34% with a 40% reappearance rate in the first year once an ulcer is in remission [65]. Approximately 50% of these ulcers are found at the plantar surface of the foot [66]. An important aspect of treatment to heal these ulcers is offloading treatment that aims to relieve mechanical stress on the ulcer [67,68]. One study on RCT that was performed on a subset of patients comparing three offloading devices [69]. With regard to clinical outcomes or adherence, there was no device effect found in this RCT [69].

The mechanism of injury of diabetic foot disease can be classified into intrinsic and extrinsic factors. The intrinsic factors are neuropathy, abnormal biomechanics, and peripheral vascular diseases. Motor, autonomic, and peripheral sensory neuropathy (Fig. 7) are the leading factors that causes neuropathic ulcerations due to DM [70,71].

It is estimated that 45%–60% of all ulcerations in patients with diabetes are mainly due to neuropathy, while 45% of the ulcers are due to neuropathic and ischemic factors (Fig. 8) [70,73,74].

Motor neuropathy can lead to foot deformities like hammer toes, equinus and prominent plantar metatarsal heads. These factors affect the patients biomechanic predisposing them to foot ulcerations. Autonomic neuropathy causes dry skin with cracking and fissuring, thus, creating possible entry of bacteria. Foot ulcerations is rarely cause by peripheral vascular disease but once ulceration develops, arterial insufficiency predisposes the patients to prolonged healing [75].

Extrinsic factors that cause diabetic foot ulcerations are trauma and social factors [70]. Trauma to the foot in the presence of peripheral sensory neuropathy is the cause of ulcerations, which

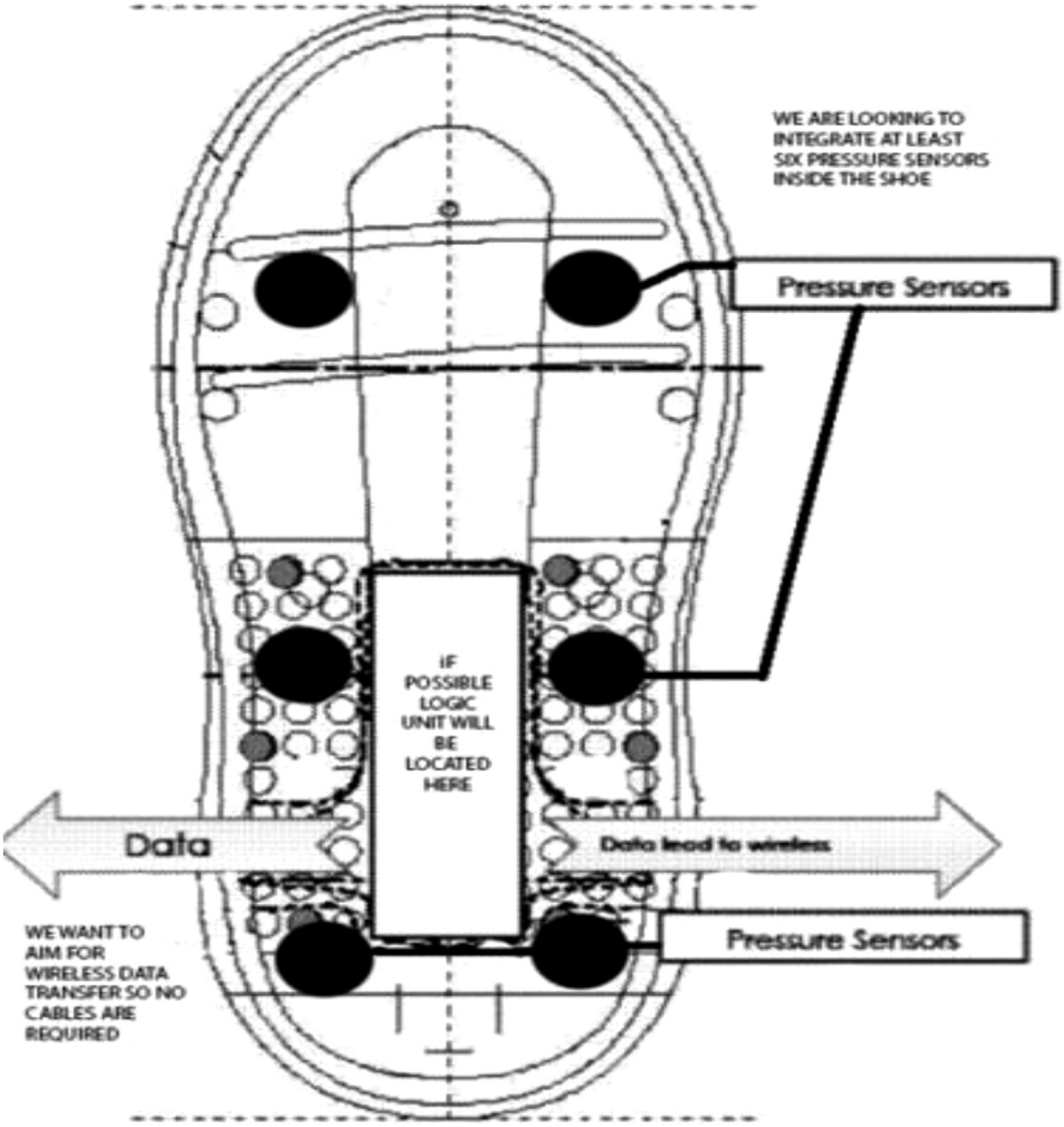

Fig. 2. Cross section view of therapeutic shoe showing points of pressure sensors [60].

Fig. 3. Area of the foot monitored [61].

Fig. 4. Custom-made functional insole [50].

Fig. 5. Diabetes footwear with velcro.

include puncture wounds, blunt injury, and injury resulting from walking or day to day activities often lead to callus formation under the metatarsal head. Footwear-related trauma has been identified as a frequent precursor to foot ulcerations. Injuries from small foreign bodies in footwear and pressure from ill-fitting footwear can cause puncture wound to develop unnoticed to patients that have loss of protective sensation [65]. Social factors like poor access to healthcare services, low social status, limited education and solidary life style is associated with foot ulcerations. Smoking any form of tobacco causes damage to the small blood vessels in the feet and legs. This damage can disrupt the healing process and is a major risk factor for infections and amputations [58,72,74].

6. Microbial characteristics of diabetic foot ulcer (DFU)

People suffering with diabetes are at risks higher of contacting microorganisms such as group *B. streptococci,* which may cause urinary tract infections, catheter-associated bacteraemia, cellulitis, skin and/or soft-tissue infections and chronic osteomyelitis [76]. *Streptococcus sp.* and *Staphylococcus sp.* are the most significant microorganisms instigating infection [77]. Athlete's foot, a fungal

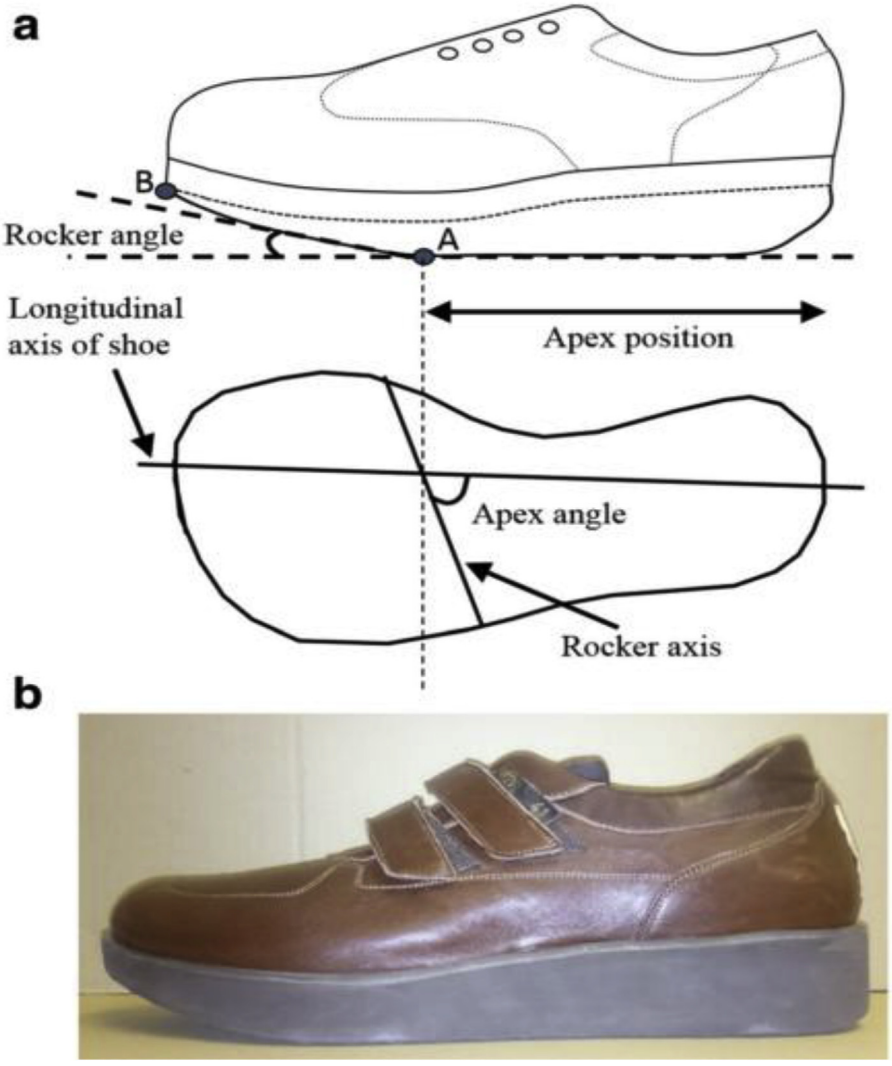

Fig. 6. (A) Illustration of rocker angle (RA), apex position and apex angle. (B). Example of rocker shoe with RA = 20° [53].

infection of the skin, can lead to more serious bacterial infections. Diabetic foot infections are usually considered polymicrobial. Pathogens implicated in chronic osteomyelitis in patients with diabetes include group A and group B *streptococci,* aerobic gram-negative bacilli, *Bacteroides fragilis, Escherichia coli, Proteus mirabilis, and Klebsiella pneumonia* [77].

7. Human neuropathic foot in its anatomy and biomechanics

Changes in foot biomechanics lead to increased mechanical stress on the plantar surface of the foot, and area strong contributor to these ulcers [68,78]. Knowledge of the anatomy of the foot, tendons, joints and skin of the foot is significant in footwear design. This helps to circumvent the consequences of nerve damage and delayed wound healing [79]. The understanding is imperative and requires taking the measurement of the feet because footwear manufacture is established on anatomical fixed points. Ling et al. [80] revealed that the foot is a multifaceted and biomechanical structure with 33 joints, 26 bones and 100 muscles, ligaments and tendons. It comprises of multifarious setup of nerves and blood vessels. Of the 208 to 214 bones in the skeleton, the ones to be found in the most mobile parts of the body, the hands and feet are among the smallest. The foot is divided into three parts: hind foot that comprises of the calcaneus's (heel bone) and talus (ankle bone); the midfoot with five short bones, and phalanges (toes) [75] (Fig. 9). The peripheral framework of the foot comprises of lateral side and dorsum of the foot, medial side and sole of the foot. Structurally the foot comprises of three sections which include the tarsus, metatarsus, and phalanges [76–84].

The phalanges or toes have fourteen toe bones, the big toe (hallux) has two phalanges and the other four smaller toes have three phalanges each. During an individual's usual walking, the foot goes through a gait cycle used by investigators and physicians to explain an individual pattern of walking. Gait analysis comprises of two stages, the stance and swing phase. The period at which the foot is in interaction with the ground during walking or running is called the stance phase and is divided into loading, response and midstance while the swing phase described the stage in which the foot is raised in the mid-air and not in contact with the ground [85]. The stance phase accounts for 60% and swing phase for about 40% of a particular gait phase [86].

A gait abnormality is common among individuals suffering with neuropathy due to DM. Through every stage of the gait sequence, the foot experiences a changeable degree of burden. This clarifies

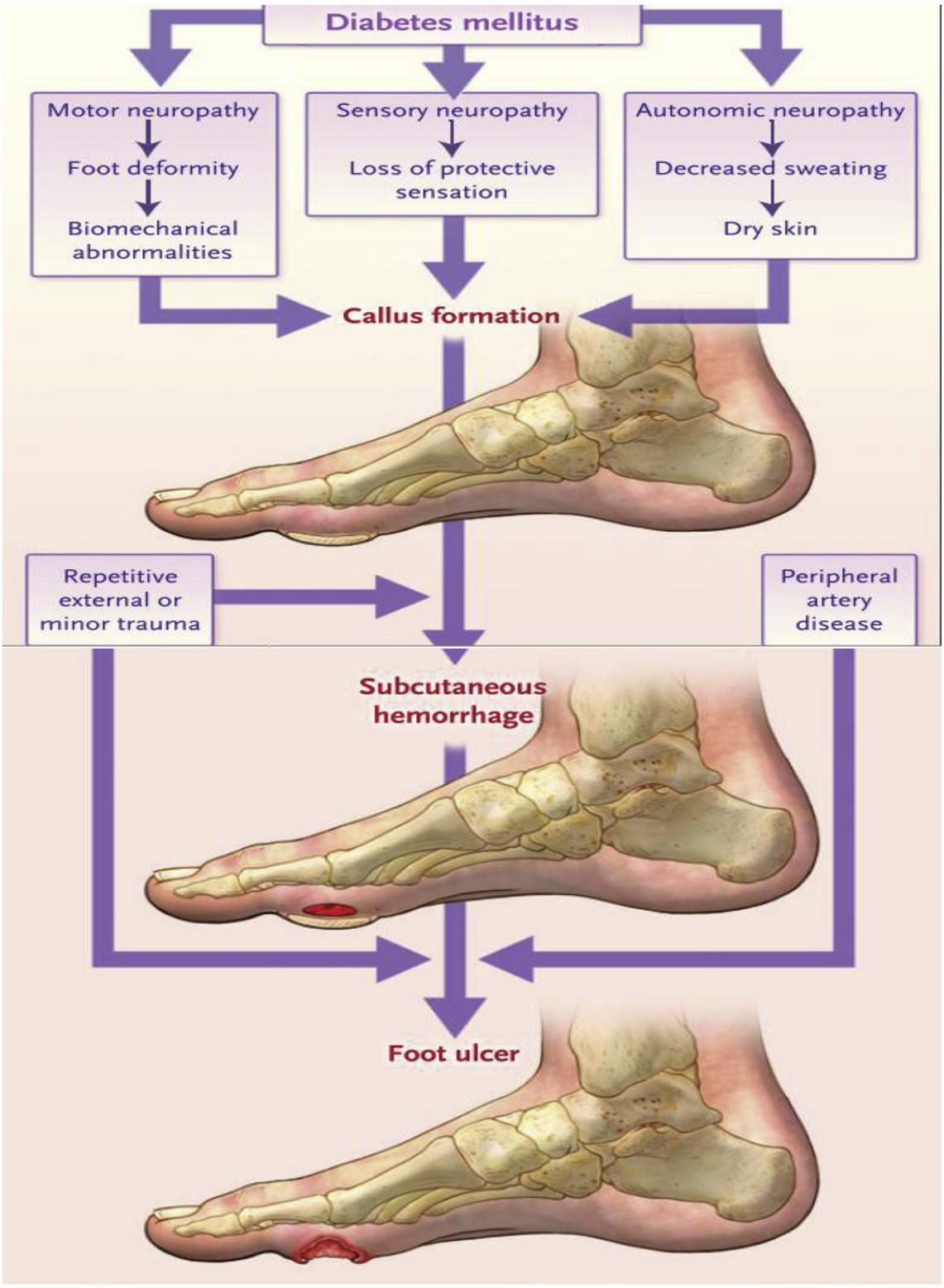

Fig. 7. Common pathway of diabetic foot ulcer occurrence and recurrence [72].

why ulcers of the foot take place at the heels and ball of the feet instead of the midfoot [83,85,87,88]. Foot measurements are of two types, the static and dynamic. This requires measuring the length, width, height and circumference of the feet in two different positions [89].

8. Limitation of the study

Limitation of this study was that barefoot or shear plantar pressure was not measured [90–92]. Such measurements would improve precision in calculating the cumulative plantar tissue

Fig. 8. Neuroischemic ulcer.

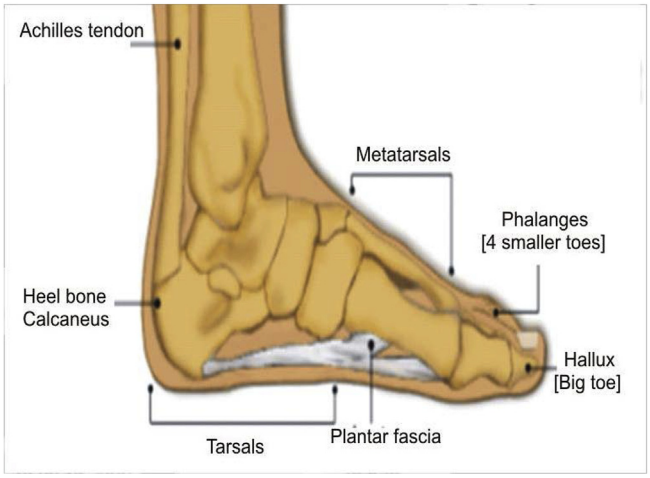

Fig. 9. Anatomy of the foot [81].

stress on the foot [93]. However, the strength of the study was the use of validated and objective methods for pressure and activity measurement that are also feasible to apply in daily clinical practice to help implementation of the findings [62,94–97].

9. Future perspective

This integrative review was limited to footwear intervention, to enable optimal comparison between the methodology qualities and to provide an overview of the evidence in this field of neuropathic diabetic foot care due to DM. The evidence base to support some methodology quality is quite better based on some high-quality RCTs. However more high-quality controlled studies are required for footwear intervention. Re-emergence of foot ulcer remains a major problem in individuals with diabetes [27,98–100].

Therapeutic footwear needs to be assessed prior to usage, and is expected to improve in order to meet the technical requirements in the future. This will enhance the assessment of pressure and activity over an extended period in a real-life setting. The cumulative plantar tissue stress should be improved. This may further advance the understanding of the load on the foot, in ulcer healing. Hence, more effort should be made in the design, measurement of the foot and choice of materials in the manufacturing of therapeutic footwear.

10. Conclusions

Therapeutic footwear as an intervention technique in the amelioration of ulcer and redistribution of plantar pressure in neuropathic diabetic foot requires the inclusion of technical features that should not be compromised from the design to the production of the footwear. It was observed in this finding that most studies did not measure barefoot or shear plantar pressure which would have improve the precision in calculating the cumulative plantar tissue stress on the foot. However, more high-quality controlled studies are needed to confirm the promising effects of footwear and offloading interventions designed to improve ulcers healing, or reduce plantar pressure.

The assessment of the literature shows that, therapeutic footwear with prefabricated insoles and rocker sole is more effective to improve the healing of foot ulcer and reduce relapse rate in comparison with conventional footwear. It is recommended in this studies that more high-quality controlled studies in the design of therapeutic footwear for diabetes patients be established.

Conflicts of interest

The authors declare no conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.dsx.2018.12.011.

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