

# Dressing plantar wounds with foam dressings, is it too much pressure?

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Diabetes and its associated complications have become a major concern locally, nationally and internationally. One such complication is lower extremity amputation, commonly preceded by chronic ulceration. The cause of this tissue breakdown is multi-faceted, but includes an increase in pressure, particularly plantar pressure. As such, the choice of dressing to be applied to a plantar wound should ideally not increase this pressure further. A commonly used and possibly more bulky dressing is the foam dressing. This pilot study investigates the plantar pressures associated with three common foam dressings (Allevyn<sup>®</sup>, Lyofoam<sup>®</sup> and Mepilex<sup>®</sup>) compared with a control dressing (Melolin<sup>®</sup>). Twelve healthy males and 19 females [SD] age 36.6 [10.4] were measured using the F-scan plantar pressure measurement system. Substantial variations in individual pressure changes occurred across the foot. No significant differences were identified, once a Bonferroni correction was applied. In healthy adults, it could be concluded that foam dressings do not have any effect on the plantar pressures of the foot. However, the need remains for a robust trial on a *pathological* population.

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Diabetes mellitus has become of growing concern locally, nationally and internationally particularly in Western Society. Approximately 1.9 million Americans over the age of 20 were diagnosed in 2010 (1). Almost 27% of the population over the age of 65 years of age are now living with diabetes mellitus (1). The lower limb complications associated with diabetes have been well described in the literature. Lower limb amputation is 15 times more likely in people suffering from diabetes (2) accounting for 50–75% of all non-traumatic lower limb amputations (2, 3). Furthermore, it has been shown that there is a 50% 5-year mortality rate associated with a lower limb amputation (4). Research shows that 85% of lower limb amputations were preceded by ulceration (5). Thus, it should follow that more appropriate ulcer management should lead to a reduction in amputation.

The aetiology of tissue breakdown leading to neuropathic and neuro-ischemic ulceration is multi-faceted, often involving a combination of an insufficient blood supply, increased pressure, structural deformity, fat pad atrophy and other physiological tissue changes, biomechanical changes and trauma (5–12). Nerves supplying the foot are responsible for motor, sensory and autonomic control with deterioration of nerve function precipitating

changes in loading and ability to sense pressure on the foot. A breakdown of the sensory system impairs a person's ability to detect forces applied to the foot. These forces may present as a high energy force in a singular incident (traumatic injury) or as a moderate force over a longer period, as may occur with plantar pressures in standing and walking (6, 7, 13). These plantar pressures may be broken down into vertical and shear components, both of which may play a role in tissue breakdown (14, 15).

The method by which mild to moderate energy (pressure) causes tissue damage is not as well understood. There are two seemingly opposing and separate theories. Firstly, it is suggested that moderate but long lasting pressures on the foot can lead to localised ischemia (7, 13, 16–19). Blood is forced from the tissues leading to necrosis (7, 13, 16, 17). For this to occur, the pressures need to reach levels greater than the pressure filling the tissues (17). Kosiak was instrumental in the development of this theory with a classic experiment of exposing dogs to closely controlled pressures for extended periods (7). Alternatively, it is thought that inflammation may occur in some of the tissues as a result of repetitive moderate pressures resulting in callus formation and further pressure increases. This was shown in a series of studies by Brand on rat footpads many years previously (6).

Subsequent tissue damage due to inflammatory autolysis will then occur (6, 16–19). Ensuing fluid buildup will become trapped and put further pressure on the deeper tissues resulting in a deeper ulcerative lesion. It appears most likely that a combination of these pathological mechanisms contributes to plantar ulcer formation in the neuropathic patient.

Management of neuropathic ulcers is multi-faceted, addressing all the factors that may affect or impede healing. This includes ensuring adequate blood supply, management and prevention of infections and bacterial burden, control of blood glucose levels and nutritional status, wound debridement, careful selection of appropriate dressings to achieve the appropriate wound environment and a decrease in or elimination of excessive plantar pressures (7–12, 19–32).

Due to the role played by pressure and deformity, an appropriate dressing choice is vital. Seaman (33) stated that an ideal wound dressing maintains a moist wound environment, absorbs excess exudate, eliminates dead space, does not harm the wound and provides thermal insulation and a bacterial barrier. It would also seem important that a dressing should not exacerbate wound breakdown by increasing plantar pressure or decreasing the vascular supply. The choice of dressing type may, therefore, be an important consideration in wound management. One group commonly chosen for use on the plantar surface of the wound is foams. Foam dressings are used for moderate to high exudative wounds to manage excessive moisture levels.

As outlined by Wolfe et al. 1991 in Foley (34), the quantity of pressure acting on a specific area of the foot is directly dependent upon the force applied to the foot and inversely dependent on the area to which the force is applied. If you apply a dressing particularly of a smaller size, it would seem reasonable that this will act like a focus point, much like a prominent joint, decreasing the area over which the force is applied. Therefore, the addition of this material on the bottom of the foot, specifically on the site of pathology, may have the effect of increasing plantar pressures leading to further wound breakdown via inflammatory autolytic or localised ischaemic processes or simply result in a delay of healing (Fig. 1).

Conversely, many professionals believe that the foam dressing is able to ‘cushion’ the wound. Therefore, it is important that the relationship between the application of a dressing and corresponding pressure change on the plantar surface of the foot be established.

A literature search was undertaken but only three articles were found which might relate to the likely effects of foam dressings on plantar pressures within the foot. Of the three identified articles, the first, by Ashford and colleagues (35), reported an *in vitro* evaluation of the characteristics of four different foams readily available in the marketplace. This article was an overview of dressing

material characteristics and durability that will prove useful for describing effects observed in *in vivo* studies of foam dressings during dynamic testing. Four foam dressings (Allevyn<sup>®</sup>, Biatain<sup>®</sup>, Lyfoam<sup>®</sup> and Tielle<sup>®</sup>) were put through a series of tests (35). This included a dry compression test, wet compression test, shear test and cyclical test procedure. The results varied across the gamut of tests, with different dressings performing differently under different conditions. The authors concluded that no one dressing was superior in all the tests and there were no significant differences between the dressings, but felt that Allevyn<sup>®</sup> was the best all-round ‘pressure-relieving’ dressing. However, in saying that, the authors inferred that the ability of a dressing to retain thickness and shape was a pressure-relieving characteristic but did not substantiate this in any way. They felt that the ability of the Allevyn<sup>®</sup> and Biatain<sup>®</sup> to retain their thickness in wet conditions with 10% lower strain when wet than when dry provided possible evidence of greater cushioning when wet. However, as an *in vitro* study, it is difficult to extrapolate findings to the effect foams have on the wound during gait. An outline of statistical analysis was not provided; however, it was mentioned that none of the results were significant.

The second study by Chockalingham et al. (36) investigated kinematic changes associated with the application of the same array of foam dressings described in the previous study to the feet of a normal subject sample. A strain gauge force plate system was utilised to test the same dressings as above on six healthy subjects with ‘normal’ gait patterns. The 5 cm × 5 cm dressings were applied to cover the plantar surface of the metatarsal heads. Subjects walked over the force plate, and data were assessed for anterior–posterior, medial–lateral and vertical components of the ground reaction force and their moments. Findings showed that the ground reaction forces measured with the Allevyn<sup>®</sup> were closest to barefoot in peak push-off, whereas others were noticeably raised. It was not reported if this finding was significant or not. Of direct relevance to the current study, they also found that Allevyn<sup>®</sup> resulted in a small reduction in the vertical component of the ground reaction force in five out of six subjects. Again, it was felt that Allevyn<sup>®</sup>, with its increased shock absorption capability and braking, could be considered to provide better pressure-relieving properties than other dressings (36). As with the earlier study, no details of statistical analysis were provided. It was not reported if any of the findings were significant. They concluded that further study was necessary. Whilst kinematic measures are important, this is not necessarily as clinically applicable as measuring direct plantar pressures over specific areas of the foot.

The third study of note also published by Chockalingham et al. (37) used a force plate to investigate the effects of pressure on foam dressings. In this study the same



Fig. 1. Wound that had been dressed with foam dressing (note the indentation).

foam dressings (Allevyn<sup>®</sup>, Biatain<sup>®</sup>, Lyofoam<sup>®</sup> and Tielle<sup>®</sup>) of 5 cm × 5 cm were applied to the plantar heel of only four ‘normal’ subjects and tested using the same strain gauge force plate as the previously described study. A similar outcome to previous studies was reported, with suggestions that Allevyn<sup>®</sup> performed closest to barefoot. However, in this study, Lyofoam<sup>®</sup> showed a decrease in reaction force, but it was commented that whilst this shows shock absorbing properties, this asymmetry of loading is an important indicator of gait dysfunction (37). It was not reported if any of these findings were significant. This study investigated the effect of the foam on the heel only which is not a common site for plantar ulceration as a result of dynamic biomechanics (5, 38). Rather, this occurs more commonly as a result of constant static pressures when a patient spends excessive time bed-bound or in a supine position with pressure localised to the heel, thereby restricting local blood flow. Thus, it appears that significant gaps still exist in our knowledge of the interaction of foam dressings and dynamic plantar pressures, particularly in the forefoot. It is important that this gap is addressed to better inform dressing choices in the management of plantar ulcerations. Thus, the aim of this study was to measure changes in plantar pressure variables as a direct result of the application of foam dressings. To avoid ethical concerns regarding the application of plantar dressings that may or may not increase pressures on a diabetic wound, it was decided that a pilot study on a healthy population should precede any further research on high-risk participants.

### Materials and methods

In summary, studies to date have not addressed the clinical application of foam dressings either through *in vivo* methods, addressing prevalent site of ulceration from dynamic causes or utilised clinically applicable measures. Therefore, to try and improve this situation, we elected to undertake a study comparing peak plantar pressures (Ppp) and pressure–time integrals (Pti) for three foam dressings with a control in healthy subjects during

dynamic gait. Ptis recognise the duration over which the plantar pressures are applied to a particular region. A double-blinded within-subject, experimental design was used on a sample of convenience. Ethics approval was obtained from the University of South Australia, Human Research Ethics Committee. Thirty-one subjects were recruited and consent obtained. Subjects were excluded if they had neuropathy, a poor vascular status, a current or previous ulceration, poor skin integrity, oedema, unsuitable footwear, an allergy to dressings or adhesive tapes or a medical history suggesting the presence of any risk associated with participating in the study. If subjects had callus present, this was debrided to reduce the likelihood of recording falsely high pressures and to reflect current wound management practice.

The F-Scan v6.3 (Tekscan Inc., Boston, MA, USA) in-shoe computerised pressure measurement device was used to collect data. Subjects were allowed to wear their own appropriate footwear without alteration to hosiery, insoles or similar, provided the conditions were kept consistent between sampling. A sampling rate of 50 Hz was used, the minimum recommended for walking measurements (39). Before calibration and measurement, a 5–10 min conditioning period was undertaken to meet the 2 min requirements for ‘bedding in’ as outlined by Pitei et al. (32) and the 5–10 min period suggested by Mueller and Strube (40) to decrease sensor variation and enable the subjects to familiarise themselves with the in-shoe sensors. F-scan calibration was undertaken using the method outlined in the F-scan v.6.3x user manual (41). Subsequent to calibration, measures were taken barefoot to allow the subject to get used to the recording procedure. Following this acclimatisation, measurements were taken with each of the three separate foam dressings (Allevyn, Lyofoam and Mepilex) chosen to represent those used regularly in local hospital clinics and a standard plain dressing (Melolin) to act as the control; all were applied directly to the foot. Melolin was selected to act as the control due to its low profile and ease of application whilst maintaining the need for a ‘sham’

dressing. Barefoot measures were taken, but these comprised part of the acclimatisation period, were not randomised and obviously not able to be blinded to participants and consequently were not included in statistical analysis. Dressings were applied in a random order by a third party with blinding applied to both the subject and examiner. Dressings were of standard size 5 cm × 5 cm. Any dressing larger than this was cut to the appropriate size. Dressings were applied to the first metatarsophalangeal joint (MPJ) of the right or left foot of every subject and fixed in place using *hypafix* tape dressing, chosen due to its frequent use in the clinical setting. The first MPJ was chosen as it is a common place for ulceration (5, 38, 42), is an easy site for dressing application and corresponds with a specific area of masking. Subjects walked along a 10-m long walkway and readings were recorded. All measurements were undertaken in a single session as it provides greater reliability if a force platform is not used for calibration (40). Subjects were allowed to walk at a self-selected pace.

The process of ‘masking’ involves the separation of the foot into discrete areas to allow for pressure comparisons within each of the areas, rather than across the foot as a whole. This provides more meaningful data by enabling more specific comparisons of these particular areas and also enables investigators to examine any transferring of the pressures. There appears to be no consistently recognised method of masking the foot. The most recent version of the F-scan (v.6.3x) Versatek™ software has a semi-automatic masking method whereby masking templates can be automatically applied to the foot and then manually altered to match the required profile, if the software unsuccessfully or inaccurately identifies the required landmarks. This software automatically divides the foot into the following regions: the medial heel, lateral heel, midfoot area, metatarsal 1, metatarsal 2, metatarsal 3, metatarsal 4 and metatarsal 5, toe 1, toe 2, toe 3 and toes 4/5 (Fig. 2).

When comparing Ppp and Pti data, the average from an aggregate of at least three steps is commonly used to avoid the variation that may exist between individual steps. This process also allows the elimination of the first

and last steps to reduce the effects of acceleration and deceleration. Data comparing each of the conditions were compared with control to analyse for change. Initially, descriptive statistics were investigated, determining the means and standard deviations for the quantity of change at each of the masked sites under each condition, to provide an understanding of the mean and distribution of the data. Data analysis was undertaken using ANOVA followed by individual *t*-tests with *post-hoc* Bonferroni correction to investigate for significant change.

## Results

Twelve males and 19 females mean [SD] age 36.6 [10.4] years participated in the study. Table 1 summarises the mean (standard deviation) for Ppp changes across the total foot, and each of the mask regions, for each foam dressing. Substantial variations in individual pressure changes occurred across the foot. Statistical analysis was undertaken to specifically assess for significance or lack thereof. ANOVA's were calculated for each of the conditions to assess for any change (Table 2) but showed no significance across any of the conditions within any of the regions. Two tailed *t*-tests were undertaken comparing the means across the whole foot and each of the 12 regions to assess for individual change with the conditions (Tables 3–5). The only significant change was identified when Mepilex was compared to control, with a *p*-value of 0.046 for the Ppp and a *p*-value of 0.034 (Table 5) for the Pti. However, this is no longer the case when a Bonferroni correction is applied to account for the multiple comparisons ( $\alpha$  value of 0.016).

## Discussion

The Ppp changes recorded at each of the mask regions were quite varied with no uniform response. Pti, whilst slightly less variable than Ppp, were still inconsistent. No statistical significance was found between any of the conditions on the foot overall or any of the regions. This does not seem to fit with our current understanding of pressure principles. Given that previous authors have successfully measured increased pressure changes to the plantar surface of the foot resulting from the presence of

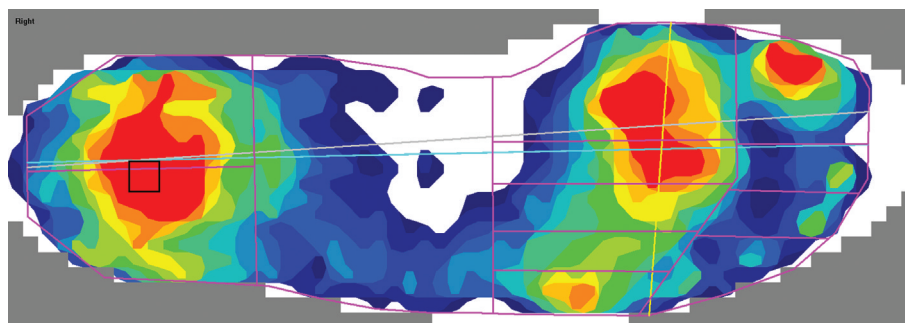


Fig. 2. Sample image of recorded stance with masking template applied.



**Table 1.** Peak plantar pressures—mean changes.

	Control vs. Allevyn	Control vs. Lyfoam	Control vs. Mepilex
Overall	0.18 (5.21)	0.38 (5.25)	0.61 (5.84)
Hallux	−0.43 (6.16)	−1.02 (9.80)	−1.79 (8.88)
Second digit	0.28 (5.70)	−0.89 (5.84)	−0.49 (5.38)
Third digit	−0.13 (4.43)	−1.07 (5.09)	−0.18 (4.32)
Fourth/fifth digit	−0.31 (4.59)	−0.61 (4.21)	−0.83 (5.79)
First MPJ	0.38 (7.81)	−0.08 (5.59)	−1.06 (8.11)
Second MPJ	−0.32 (3.64)	−0.60 (3.32)	−1.34 (8.57)
Third MPJ	−0.32 (4.43)	−0.80 (4.32)	−0.38 (5.20)
Fourth MPJ	0.86 (4.01)	0.83 (5.44)	−0.55 (4.62)
Fifth MPJ	0.64 (3.33)	0.15 (3.77)	0.03 (5.45)
Arch	0.09 (4.72)	0.97 (6.11)	−0.29 (3.15)
Medial Heel	−0.35 (2.86)	−0.86 (2.96)	−0.92 (3.82)
Lateral Heel	1.76 (8.27)	−0.53 (3.35)	0.52 (4.10)

similarly small volumes, these findings are unexpected (43). At a statistical level, the lack of significance can be explained by the large variation in the means and standard deviations of the change between each of the conditions. There may be a couple of reasons for these findings. It may be that there are simply no significant differences between the foam dressings and a control dressing, or between the foam dressings themselves. This would fit with the earlier reported papers where there was a lack of significance (35–37). This may also provide useful information to practitioners involved in wound management as it means that dressing choice may not detrimentally affect plantar pressures and subsequent wound healing. However, one must keep in mind that the converse of this is that there is no evidence that the dressing is able to significantly decrease the plantar pressures on the foot by a simple method of ‘cushioning’

**Table 2.** ANOVA of plantar regions.

ANOVA	P-value peak plantar pressure	P-value Pressure– time integral
Hallux	0.965277	0.984663
Second digit	0.94332	0.765596
Third digit	0.91441	0.973133
Fourth/fifth digit	0.708602	0.956613
First MPJ	0.97369	0.998888
Second MPJ	0.987374	0.996001
Third MPJ	0.995552	0.965631
Fourth MPJ	0.893907	0.945277
Fifth MPJ	0.980164	0.901253
Arch	0.910872	0.997631
Medial heel	0.972203	0.963101
Lateral heel	0.73985	0.869682

**Table 3.** T-test comparison Allevyn.

Allevyn vs. control	Ppp	P-ti
Overall	0.506	0.957
Hallux	0.703	0.991
Two digit	0.787	0.377
Three digit	0.873	0.228
Four/five digit	0.711	0.926
First MPJ	0.787	0.640
Second MPJ	0.626	0.333
Third MPJ	0.687	0.464
Fourth MPJ	0.239	0.366
Fifth MPJ	0.294	0.074
Arch	0.916	0.625
Medial heel	0.500	0.474
Lateral heel	0.244	0.411

the wound. An alternative explanation is that despite recruiting subject numbers to sufficiently meet the crude power analysis, the lack of findings may be due to a type II error brought about due to methodological issues or limitations. In the past, issues have been raised with the validity and reliability of the F-scan device (40, 44–46), with the calibration process and possible creep of the insoles (46, 47). Additionally, there have been issues raised with the use of the F-scan on varying surface hardness (47). Variability may have been introduced by allowing subjects to wear their own footwear, rather than standardising footwear and insole hardness.

Consequently, we must acknowledge that we have inadvertently introduced confounders by our choice to use this tool and the protocol employed. Also, using this tool, we are only able to measure the dressing–shoe interface at the location where the foam was applied and is therefore only a pseudo measure of the foot–dressing interface. This may not represent the true forces acting on

**Table 4.** T-test comparison Lyfoam.

Lyfoam vs. control	Ppp	P-ti
Overall	0.169	0.062
Hallux	0.566	0.524
Two digit	0.401	0.109
Three digit	0.250	0.232
Four/five digit	0.429	0.473
First MPJ	0.939	0.915
Second MPJ	0.322	0.919
Third MPJ	0.312	0.441
Fourth MPJ	0.400	0.716
Fifth MPJ	0.822	0.4
Arch	0.386	0.651
Medial heel	0.117	0.063
Lateral eel	0.386	0.61

**Table 5.** T-test comparison Mepilex.

Mepilex vs. control	Ppp	P-ti
Overall	0.046	0.034
Hallux	0.271	0.398
Two digit	0.619	0.065
Three digit	0.815	0.352
Four/five digit	0.433	0.89
First MPJ	0.471	0.859
Second MPJ	0.389	0.512
Third MPJ	0.688	0.083
Fourth MPJ	0.510	0.34
Fifth MPJ	0.978	0.655
Arch	0.615	0.837
Medial heel	0.190	0.530
Lateral heel	0.487	0.796

the wound. Additional ‘give’ in the shoe or deeper tissues may have led to false readings at this interface.

However, the single biggest issue is that, similarly with those studies reviewed above, this study was undertaken on a normal healthy population. It is quite possible that a person with normal sensation may feel slight variations in pressure caused by the dressing on the foot and compensate for this at a subconscious level during stance and gait. It has been shown that a person with inadequate sensation shows less variation in his or her centre of pressure during gait, than a sensate person (48). This is believed to occur due to the lack of nociceptive feedback. In a sensate person, there is subconscious variation to prevent an accumulative increase in pressure in a particular area over numerous steps. Therefore, the result of applying a dressing to an insensate foot may have vastly different outcomes due to the lack of feedback that has likely occurred in this sample.

## Conclusion

In this sample of young healthy adults, application of different foam dressings did not significantly alter Ppp or Pti. Superficially, we could conclude from this study and those reviewed that the effect of wound dressings, specifically foam dressings, on the plantar surface may not significantly impact the decision making an appropriate dressing choice. However, before final conclusions can be made, this article highlights, more than anything, the need for a robust repeated measures observational trial on a pathological population. Furthermore, future studies need to consider the availability of reliable best practice tools for plantar pressure measurement to ensure sufficient sensitivity required.

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