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Effects of foot posture and heel padding devices on soft tissue deformations under the heel in supine position in males: MRI studies

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Abstract—Heel ulcers (HUs) are the second most common pressure ulcers (PUs). Despite the significant morbidity and economic cost associated with HUs, there remains a lack of understanding of the basic pathophysiology of PUs because of limited basic research. There are only sparse data regarding the efficacy of prevention aids such as heel padding devices, and these data are based mainly on epidemiological research rather than biomechanical models and deformation measurements. This study was designed to explore the effects of foot posture and support stiffness properties on soft tissue deformations using magnetic resonance imaging (MRI). Subjects were scanned with and without weight bearing, in neutral external rotation position and in 90 degrees to supporting surface and with different heel padding devices. Tissue strains were calculated for skin, subcutaneous tissue, and effective (total) soft tissue. We found skin strains with the foot in external rotation to be significantly greater than when the foot was upright. Heel padding devices have a statistically significant effect on reducing the extent of deformations in both skin and subcutaneous tissues. Furthermore, the design features of heel padding devices have substantial influence on tissue deformations. This study demonstrates how MRI provides convenient, accurate, and quantitative comparison of biomechanical performances of heel padding devices.

Key words: foot posture, heel ulcers, MRI, padding devices, pressure ulcers, skin strain, soft tissue deformation, support stiffness, support surfaces, weight bearing.

INTRODUCTION

Heel ulcers (HUs) are the second most common pressure ulcers (PUs) after sacral ulcers [1–6]. The prevalence of HU in hospitalized patients ranges between 10 and 18 percent, and the predominant age group of patients is 71 to 80 yr [7]. According to European data, between one in four and one in five patients within an acute hospital setting (i.e., neurology, intensive care units, chronic and acute care units) will have a PU, so the malady, at large, is widespread [8]. Various conditions have been identified as risk factors of PU development. Age, malnutrition, sensory deficit, multiple morbidities, circulatory abnormalities, spinal cord injury, stroke, surgery, anemia, diabetes mellitus, peripheral vascular disease, and hip fracture in the elderly are some of the major risk factors suggested in the literature [3]. Morbidity that is specifically associated with HU consists mainly of

Abbreviations: ANOVA = analysis of variance, FWB = full weight bearing, HU = heel ulcer, MRI = magnetic resonance imaging, NWB = non-weight bearing, PU = pressure ulcer.

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pain and reduced mobility, but it can also manifest as local and systemic infection, renal failure, multiorgan failure, limb loss, and even demise of patients [3,6,9–10].

Despite the significant morbidity and economic cost, there remains a lack of understanding of the basic pathophysiology of PU because of limited basic research. The most common staging system for PU is based on the ulcers' anatomical depth. This system may imply that PUs gradually develop from the superficial skin layer into the deep soft tissues [10]. However, an alternative etiology theory with solid empirical evidence to support it exists, in which the ulcer forms first in the deep soft tissues, usually over a bony prominence, and then continues to spread throughout the more superficial soft tissues toward the skin. This process has recently been referred to in the literature as the "inverted cone" model [10–11].

HU prevention aids can be categorized into two main groups according to their action mechanism. The first consists of heel padding devices that create a pressure-relieving support under the heel, so the limb weight is dispersed over a larger area and against a softer supporting surface. The second group consists of heel offloading devices aimed at elevating the heel from the supporting surface, thereby preventing the formation of a PU. In the medical literature, there is sparse information regarding the efficacy of these prevention devices, and the data are based mainly on epidemiological and observational research rather than biomechanical models and deformation measurements [3,12–14].

HUs develop when sustained mechanical loading is applied to the soft tissues of the posterior aspect of the heel while lying in a supine position. Recent published data demonstrated that there are threshold values for tissue deformation and exposure time to deformation levels that determine the tissue tolerance to PU [15–17]. Using a computational model, Sopher et al. recently demonstrated how soft tissue deformations in the supported heel are influenced by the stiffness of the overlying support surface [6]. Furthermore, the relationship between heel rotation and soft tissue deformations was characterized computationally. However, this model considered the soft tissues as a homogenous material without distinguishing between skin and subcutaneous tissues, despite that in a real-world scenario, they hold different mechanical properties [6]. Computational models, physical (phantom) models, or even human dissection models can only partially simulate the realistic mechanical properties, and so the actual levels of tissue deformations, that exist in a living human heel organ. The aim of the present study was to explore the effects of foot posture and support stiffness properties on soft tissue deformations under the heel in vivo, in a magnetic resonance imaging (MRI) setting. To the best of our knowledge, this is the first study to investigate these soft tissue deformations in interactions with foot posture and supports as related to the etiology of HU.

METHODS

Study Cohort

In order to establish a normative baseline for heel tissue deformations, 10 healthy male volunteers were recruited. Subjects were aged 32.8 ± 3.79 yr (values are shown as mean and standard deviation throughout the article unless otherwise stated). Their height and weight were 178 ± 6 cm and 80.5 ± 11.78 kg, respectively, giving a body mass index of 25.25 ± 3.18 kg/m^2. Exclusion criteria were absolute and relative contraindication for MRI, e.g., cardiac pacemakers (or other metallic implants) or metallic foreign bodies, as well as claustrophobia, psychiatric disorders, and limitations on lying still for prolonged time periods. We further excluded subjects with known underlying diseases that impair mobility and those with a history of leg, ankle, or foot injury; pelvic fractures; or surgery.

Magnetic Resonance Imaging Protocol

Subjects were scanned on a 1.5 T magnetic resonance system (OPTIMA, GE Medical Systems; Milwaukee, Wisconsin). Images were obtained using axial T1-weighted images (time of repetition/time of echo = 760/7.9, field of view = 200 mm, slice thickness = 3 mm), which provide the best anatomic contrast: fat shows a high-intensity signal whereas skin and bone show low signals. Each subject was scanned with and without weight bearing in a neutral position ("neutral" external rotation) and in 90°, where the degree of foot rotation was measured between the bisector line of the heel and the supporting surface. Later, each subject was scanned using three different heel padding devices with the heel in 90° and in neutral external rotation (that is, a total of 10 scans per subject). Neutral external rotation was measured as the angle of external rotation, in the neutral supine position. A non-weight bearing (NWB) scan was acquired by positioning an inflatable cushion under the calf so there was no heel-support contact. A corresponding

full weight bearing (FWB) scan was obtained by allowing the heel to be supported.

Heel Padding Devices

Three commercially available heel padding devices were selected for this study: two foam sock-like padding devices placed around the foot and ankle (devices 1 and 2) and a foam suspension boot placed around the foot, ankle and calf (device 3) (**Figure 1**). The padding material in all three devices was soft, compressible polyurethane medical-grade foam.

The stress-strain curves of each heel padding material were measured in unconfined compression, using an electromechanical uniaxial testing system (INSTRON 5544; High Wycombe, United Kingdom). The loading rate was 20 mm/min. Tests were repeated three times each. Corresponding elastic moduli were calculated by linear approximation of the stress-strain curves for the 20 to 60 percent strain domain, representing normal use in a clinical setting (as shown in the present MRI studies). The tests yielded that the elastic moduli of devices 1, 2, and 3 were 5.7 ± 1.8, 4.9 ± 0.6, and 7.7 ± 0.8 kPa, respectively.

Data Analysis

Mean soft tissue deformations were calculated directly from the MRI scans. Two different measurements were obtained for the skin and subcutaneous tissues (fat) in each subject. The anatomical landmark for these measurements was the area of minimal tissue thickness under the calcaneus (in the NWB posture), where HUs are most likely to occur. Tissue deformations were calculated as follows: for the skin, we first recorded the thickness from the NWB scan by measuring the distance from the exterior apex of the heel vertically to the skin-subcutaneous boundary, SK_{NWB} (**Figures 2–3**). Then, we obtained the same measurement using the same technique from the FWB scan, SK_{mod}. The average skin strain was therefore calculated as **Equation (1)**:

$$\%SK = (SK_{NWB} - SK_{mod})/SK_{NWB} \quad . \qquad \textbf{(1)}$$

Similarly, for subcutaneous tissue, we measured the distance from the skin-subcutaneous boundary directly to the calcaneus in the NWB (SUB_{NWB}) and weight bearing/padding (SUB_{mod}) MRI scans, and calculated the average subcutaneous tissue strain as **Equation (2)**:

$$\%SUB = (SUB_{NWB} - SUB_{mod})/SUB_{NWB} \quad . \qquad \textbf{(2)}$$

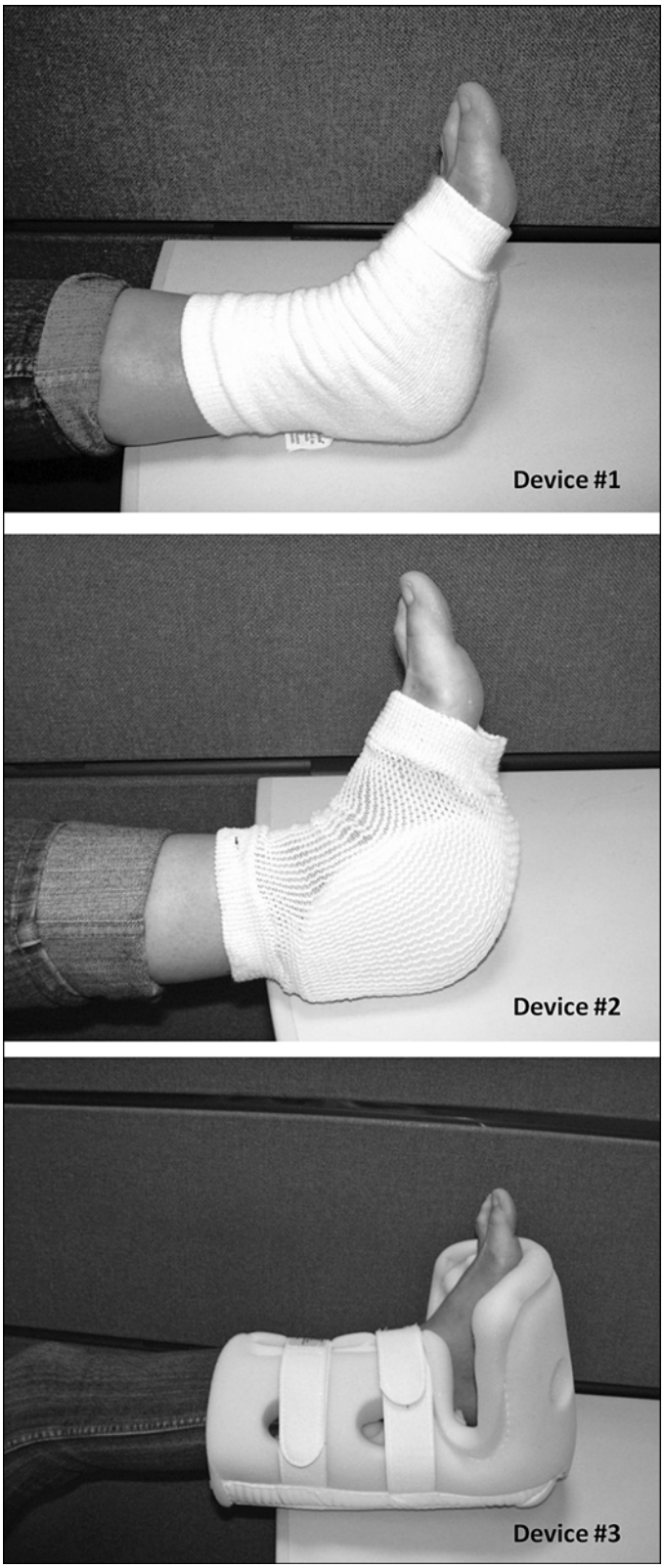

Figure 1.
Heel padding devices 1, 2, and 3 used in present study.

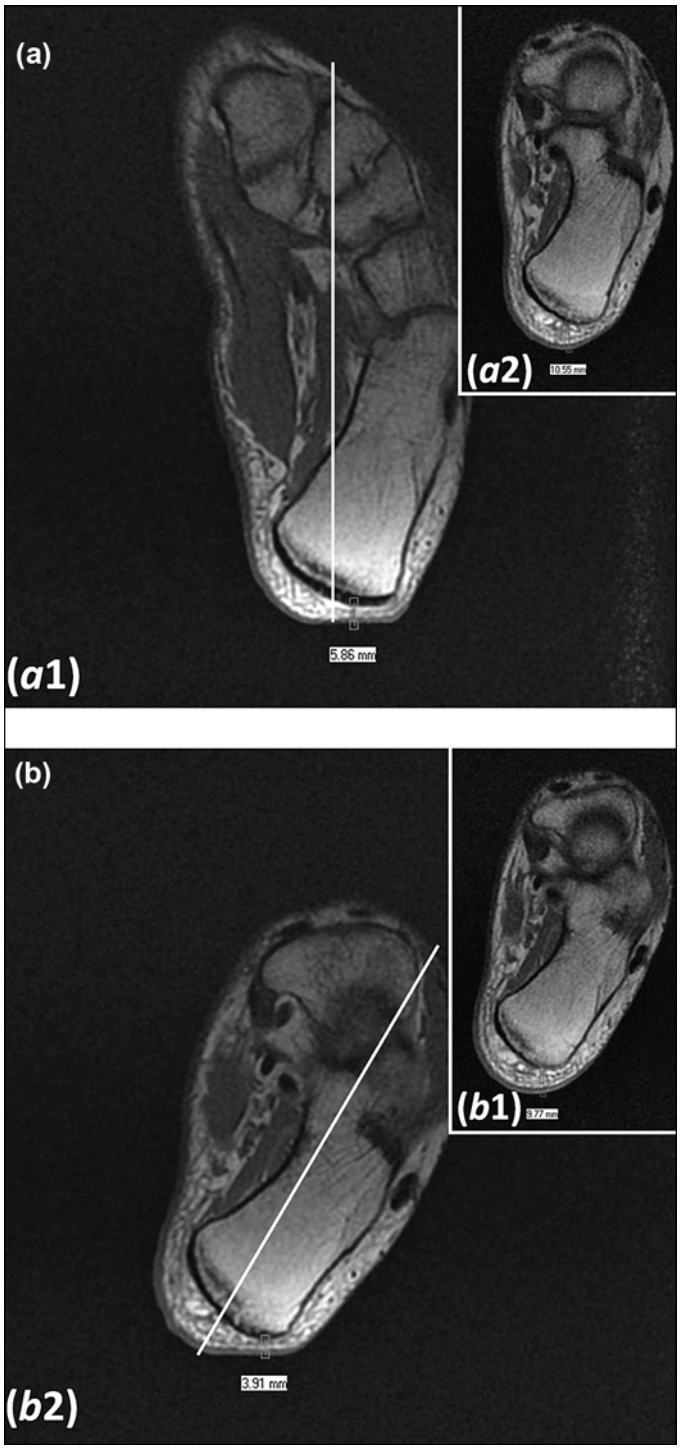

Figure 2.
Effective soft tissue strain measurements in left heel during **(a1)** full weight bearing (FWB) and **(a2)** non-weight bearing (NWB) at upright (90°) position, compared with **(b1)** FWB and **(b2)** NWB at neutral external rotation of foot.

For effective soft tissue strain (skin and subcutaneous tissue taken together as one tissue material), we calculated the total soft tissue deformation of both skin and subcutaneous tissue for NWB ($TOTAL_{NWB} = SK_{NWB} + SUB_{NWB}$) and weight bearing/padding device ($TOTAL_{mod} = SK_{mod} + SUB_{mod}$). We then calculated the effective strain as **Equation (3)**:

$$\%TOTAL = (TOTAL_{NWB} - TOTAL_{mod})/TOTAL_{NWB} \quad \textbf{(3)}$$

Statistical Analysis

We obtained descriptive statistics for tissue thickness under the calcaneus and average strains %SK, %SUB, and %TOTAL in each subject.

We conducted two-way analysis of variance (ANOVA) for the factors of foot posture and heel padding device type (including a hard surface as baseline) to determine whether internal tissue strains differed because of any of these factors. For each analysis, a corresponding post hoc Tukey-Kramer multipairwise comparison followed for determining specific differences between variables. All the *p*-values reported herein are two-sided. A p-value < 0.05 was considered statistically significant.

RESULTS

The means (±1 standard deviation) and 95 percent confidence intervals of strains in skin, subcutaneous tissue, and effective soft tissue in different foot postures and using different heel padding devices are listed in the **Table**. Skin strains with the foot in external rotation were significantly greater than when the foot was upright ($p = 0.01$). Foot padding devices significantly reduced skin strains ($p = 0.002$). Strains in the subcutaneous tissues, however, were not significantly different between the rotated and upright foot posture conditions ($p = 0.37$). There was a significant reduction in subcutaneous tissue strains when using heel padding devices ($p < 0.001$). Effective soft tissue strains did not significantly differ between foot postures ($p = 0.50$), but again, the heel padding devices were able to significantly lower the effective tissue strains ($p < 0.001$). The ANOVA did not demonstrate an interaction between the foot posture and device type factors.

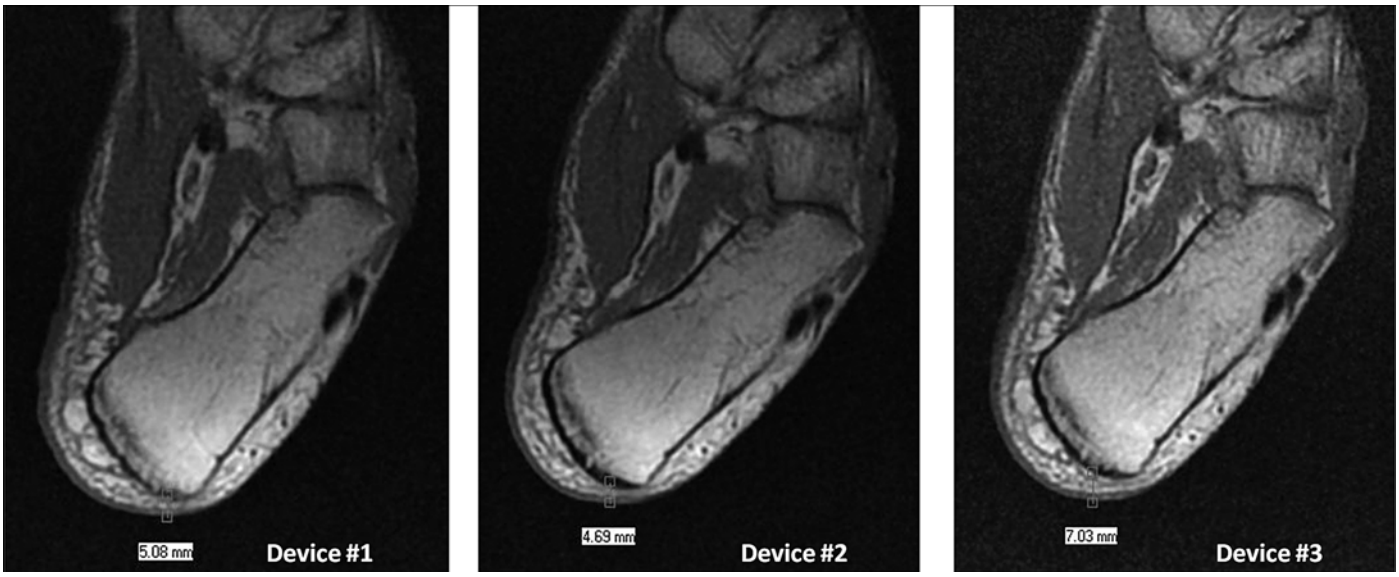

Figure 3.
Effective soft tissue strain measurements in left heel while using heel padding devices 1–3 at neutral external rotation of foot.

DISCUSSION

This study is the first attempt to investigate how foot posture and heel padding devices affect internal soft tissue deformations and strains in the posterior heel in lying humans. The work is highly relevant for understanding the etiology of HU given that the "inverted cone" theory [10–11] becomes increasingly accepted and also for development and evaluation of protective means. We demonstrate here that weight-bearing MRI is a highly effective research methodology for this purpose.

The soft tissue surrounding the heel is prone to PU because of unique anatomical characteristics. While the plantar aspect of the heel is capable of withstanding the pressure and shear loads exerted when standing and during ambulation, the posterior aspect of the heel appears to have a lower tolerance to mechanical loads, probably because of a thinner layer of skin and subcutaneous tissues with tenuous blood supply. Our present data indicate that deformations in skin are greater when the foot is positioned in neutral external rotation compared with a 90° upright posture, but subcutaneous tissue deformations were not significantly affected by posture (which also caused the effective tissue deformations to appear as noninfluential). This is in partial agreement with previous computational modeling work in our group that did identify an effect of foot posture on tissue deformation levels but could not point to the tissue types contributing to this effect given the modeling assumptions [6].

Our present data suggest that heel padding devices have a statistically significant effect on reducing the extent of deformations in both skin and the subcutaneous tissues of the posterior heel, which was a very consistent finding here (**Table**). This result agrees with previous computational work in our laboratory [6] and highlights the importance of using heel support devices to protect the feet of immobilized and insensitive patients from HU.

In particular, we investigated soft tissue deformations at the posterior heel while using simple heel protector designs (devices 1 and 2) and a more complicated design of an offloading heel support (device 3) (**Figure 1**). While all devices performed similarly in reducing skin deformations, the latter device was superior in reducing subcutaneous tissue strains (**Table**). Hence, the design features of heel supporters can substantially influence heel tissue deformations and therefore the HU risk of the individual, as indeed has been observed in terms of clinical outcomes when analyzing patient data [13]. MRI studies provide the means for convenient, clinically relevant, accurate, and quantitative comparisons of the biomechanical performances of such heel protectors and should also be highly useful in the design phase of these medical devices. It should be emphasized in this regard that it is the overall design of the device, not just its material stiffness properties, that will determine biomechanical

Table.
Tissue strains measured by means of magnetic resonance imaging. Data are provided as mean ± standard deviation, and lower and upper limits of corresponding 95% confidence intervals are shown in parentheses.

Tissue Measure	FWB	Heel Padding Device 1	Heal Padding Device 2	Heel Padding Device 3
Skin–ER	36.75 ± 10.50 (30.24–43.26)	31.87 ± 11.04 (25.03–38.71)	29.59 ± 10.60 (23.02–36.16)	24.98 ± 11.37 (17.93–32.03)
Subcutaneous–ER	64.25 ± 11.67 (57.02–71.48)	56.29 ± 8.69 (50.90–61.68)	55.24 ± 9.58 (49.3–61.18)	29.11 ± 12.63 (21.28–36.94)
Total Soft Tissue–ER	59.40 ± 9.35 (53.60–65.20)	51.60 ± 7.70 (46.83–56.37)	50.77 ± 8.08 (45.76–55.78)	26.30 ± 11.46 (19.20–33.40)
Skin–90°	32.21 ± 8.04 (27.23–37.19)	23.53 ± 8.09 (18.52–28.54)	22.33 ± 8.80 (16.88–27.78)	21.09 ± 7.66 (16.34–25.84)
Subcutaneous–90°	62.76 ± 8.08 (57.75–67.77)	59.42 ± 9.80 (53.35–65.49	56.25 ± 9.20 (50.55–61.95)	34.97 ± 13.75 (26.45–43.49)
Total Soft Tissue–90°	50.11 ± 6.70 (53.96–62.26)	53.87 ± 8.83 (48.40–59.34)	51.02 ± 8.31 (45.87–56.17)	30.67 ± 13.22 (22.48–38.86)

ER = external rotation, FWB = full weight bearing.

efficacy, since, for example, device 3—which gave the best performances (**Table**)—also had the stiffest material characteristics. The effectiveness of an offloading device was demonstrated clinically in the Donnelly et al. study [14]. In a group of 240 patients hospitalized because of a proximal femur fracture, the authors demonstrated a five-fold reduction in HU occurrence when an offloading heel padding device was used [14].

We acknowledge several shortcomings of our work. First, we investigated a relatively small and homogenous cohort in terms of age and body mass index, but given that subjects were young and healthy adults, the soft tissue strains provided in the **Table** can at least be considered as a normative baseline, which still shows very large deformations of the heel tissues during weight bearing. In older, frail individuals, with thinner heel soft tissue structures, deformations are possibly larger and, if conditions that stiffen tissues are also involved, such as diabetes or edema in the heel, mechanical stresses will also be influenced and would increase [9]. Hence, it should be borne in mind that the soft tissue deformations were recorded in healthy young individuals that do not necessarily hold the same biomechanical or physiological properties as the soft tissues of elderly or diabetic individuals who are known to be prone to HU [9]. Second, we measured tissue deformations and strains, but tissue deformations cannot directly predict internal tissue damage. Actual damage would depend on the individual's tissue tolerance, which in turn depends on factors such as age, chronic and acute diseases, and history of HU. We therefore believe that further research is warranted, especially with respect to studying subjects with diabetes, obesity, peripheral vascular diseases, or other known or potential risk factors for HU.

The analyses made herein regarding tissue deformations in the supported heel only refer to tissue thickness changes between the calcaneal bone edge and supporting surfaces, which, from an engineering point of view, only represents one component of the strain tensor (that is, compression strain), and does not account for tension and shear strains. Moreover, the analyses provide the mean compression strain, rather than the localized strains in soft tissues near the bone or the strain distributions in the weight-bearing tissues. The aforementioned engineering measures of internal tissue loads, particularly the complete strain tensor, can be determined in full using three-dimensional finite element analyses of the heel, based on the MRI scans acquired in the present study, and this will be our next goal in pushing this research work forward. Nevertheless, the present study already provides valuable quantitative information regarding the absolute values of the (mean) tissue strains occurring with and without heel padding devices. Given that HUs are a very poorly researched subject (which is a paradox considering the fact that they are the second most prevalent PUs [1–6]), with no quantitative studies of their biomechanics-related factors so far, it is essential that some hard data are reported as a basis for future work.

CONCLUSIONS

To conclude, this study provides an MRI-based evidence for the ability of heel padding devices to reduce internal soft tissue deformations, with the extent of reduction in deformations being dependent on the design characteristics of the specific device. We believe that this study should be extended to larger groups, including patient groups susceptible to HU and where the MRI data can also be correlated with clinical outcomes of HU prevention and/or healing.

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Acquisition of data: S. Tenenbaum, A. Levy, N. Shabshin.
Analysis and interpretation of data: S. Tenenbaum, A. Levy, N. Shabshin, A. Herman, A. Gefen.
Drafting of manuscript: S. Tenenbaum, A. Levy, N. Shabshin, A. Gefen.
Critical revision of manuscript for important intellectual content: N. Shabshin, A. Gefen.
Statistical analysis: S. Tenenbaum, A. Levy, A. Herman.
Study supervision: N. Shabshin, A. Gefen.
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REFERENCES

1. Amlung SR, Miller WL, Bosley LM. The 1999 National Pressure Ulcer Prevalence Survey: A benchmarking approach. Adv Skin Wound Care. 2001;14(6):297–301. [PMID:11794440] http://dx.doi.org/10.1097/00129334-200111000-00012
2. Cheneworth CC, Hagglund KH, Valmassoi B, Brannon C. Portrait of practice: Healing heel ulcers. Adv Wound Care. 1994;7(2):44–48. [PMID:7812583]
3. Fowler E, Scott-Williams S, McGuire JB. Practice recommendations for preventing heel pressure ulcers. Ostomy Wound Manage. 2008;54(10):42–48, 50–52, 54–57. [PMID:18927483]
4. Salcido R. What is the “purple heel”? Adv Skin Wound Care. 2006;19(1):11. [PMID:16477153] http://dx.doi.org/10.1097/00129334-200601000-00002
5. VanGilder C, MacFarlane GD, Harrison P, Lachenbruch C, Meyer S. The demographics of suspected deep tissue injury in the United States: An analysis of the International Pressure Ulcer Prevalence Survey 2006–2009. Adv Skin Wound Care. 2010;23(6):254–61. [PMID:20489387] http://dx.doi.org/10.1097/01.ASW.0000363550.82058.7f
6. Sopher R, Nixon J, McGinnis E, Gefen A. The influence of foot posture, support stiffness, heel pad loading and tissue mechanical properties on biomechanical factors associated with a risk of heel ulceration. J Mech Behav Biomed Mater. 2011;4(4):572–82. [PMID:21396606] http://dx.doi.org/10.1016/j.jmbbm.2011.01.004
7. Pressure ulcers in America: prevalence, incidence, and implications for the future. An executive summary of the National Pressure Ulcer Advisory Panel monograph. Adv Skin Wound Care. 2001;14(4):208–15. [PMID:11902346]
8. Vanderwee K, Clark M, Dealey C, Gunningberg L, Defloor T. Pressure ulcer prevalence in Europe: A pilot study. J Eval Clin Pract. 2007;13(2):227–35. [PMID:17378869] http://dx.doi.org/10.1111/j.1365-2753.2006.00684.x
9. Gefen A. The biomechanics of heel ulcers. J Tissue Viability. 2010;19(4):124–31. [PMID:20584612] http://dx.doi.org/10.1016/j.jtv.2010.06.003
10. Cichowitz A, Pan WR, Ashton M. The heel: anatomy, blood supply, and the pathophysiology of pressure ulcers. Ann Plast Surg. 2009;62(4):423–29. [PMID:19325351] http://dx.doi.org/10.1097/SAP.0b013e3181851b55
11. Le KM, Madsen BL, Barth PW, Ksander GA, Angell JB, Vistnes LM. An in-depth look at pressure sores using monolithic silicon pressure sensors. Plast Reconstr Surg. 1984;74(6):745–56. [PMID:6505095] http://dx.doi.org/10.1097/00006534-198412000-00001
12. McInnes E, Bell-Syer SE, Dumville JC, Legood R, Cullum NA. Support surfaces for pressure ulcer prevention. Cochrane Database Syst Rev. 2008;(4):CD001735. [PMID:18843621]
13. Junkin J, Gray M. Are pressure redistribution surfaces or heel protection devices effective for preventing heel pressure ulcers? J Wound Ostomy Continence Nurs. 2009;36(6):602–8. [PMID:19920740] http://dx.doi.org/10.1097/WON.0b013e3181be282f
14. Donnelly J, Winder J, Kernohan WG, Stevenson M. An RCT to determine the effect of a heel elevation device in pressure ulcer prevention post-hip fracture. J Wound Care. 2011;20(7):309–12, 314–18. [PMID:21841719]
15. Gefen A. The Compression Intensity Index: A practical anatomical estimate of the biomechanical risk for a deep tissue injury. Technol Health Care. 2008;16(2):141–49. [PMID:18487860]

16. Linder-Ganz E, Engelberg S, Scheinowitz M, Gefen A. Pressure-time cell death threshold for albino rat skeletal muscles as related to pressure sore biomechanics. J Biomech. 2006;39(14):2725–32. [PMID:16199045] http://dx.doi.org/10.1016/j.jbiomech.2005.08.010
17. Agam L, Gefen A. Pressure ulcers and deep tissue injury: A bioengineering perspective. J Wound Care. 2007;16(8): 336–42. [PMID:17927080]

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