

A New Understanding of the Application of Tissue Strain by Negative Pressure Wound Interfaces through 3-Dimensional Finite Element Analysis

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ABSTRACT

Within the wound care arena, the understanding of the effects of Negative Pressure Wound Therapy (NPWT) upon tissue and the processes of healing are still being developed. Optimisation of the level of strain applied to the tissue to affect the healing process, without causing undue stress on the tissue and pain to the patient, remains a key clinical objective.

To provide additional understanding of the tissue strain and forces applied by different NPWT tissue interface materials, physical assessments of open cell reticulated foam (OCRF)⁺ and a polyester dressing with void spaces on contact surface (PDVS)^{**} were performed to confirm their 3-dimensional structures and material behaviour. This material structure information was then used to produce three-dimensional finite element analysis (FEA) models. These FEA models were then used to assess the predicted levels of strain applied to the tissue by these dressing materials under different levels of applied negative pressure.

The findings of this study have been compared with those of Wilkes *et al*¹. Key differences in the findings from this new study are that the tissue strain distribution predicted for the OCRF dressing is highly non-uniform with localized high strains. Compared to this, the tissue strain distribution predicted for the PDVS is highly uniform with only small differences between the average and maximum values. Another important difference between the two systems is that the strain distribution across the tissue surface for the OCRF dressing will be random because of the random nature of the foam struts, whereas the tissue surface strain distribution produced with the PDVS system is more uniform because of its stable and uniform structure under applied negative pressure.

These differences in the homogeneity of the tissue response and in the degree of stress applied to areas of tissue to which NPWT is applied are important factors for clinicians to consider in wound management. Within the recognised limitations of current viscoelastic material models of tissue and skin, the predicted tissue strains as a function of time for one of the interface materials assessed in this study compare favourably with previous clinical findings².

INTRODUCTION

Three dimensional FEA models of two different NPWT systems PDVS and OCRF dressings have been developed in this work and analysis have been carried out under different applied negative pressures. Model development and analyses have been performed using the Abaqus version 6.9-1.

Previous two dimensional finite element analyses have shown that the PDVS provides broader contours of predicted tissue surface strain than the OCRF³. Additional three dimensional FEA studies were required to provide a fuller analysis of the predicted tissue surface strain affected by these two different dressings.

In the clinical application of negative pressure wound therapy devices, constant negative pressure can be applied to the patient's tissue for periods ranging from a few hours to days. This prolonged NPWT application will result in creep of the tissue layer contacting the dressing surface, with the resulting tissue surface strains increasing with increased time of NPWT application. A time-dependent analysis was carried-out to simulate the creep behaviour of the surface tissue layer as a function of time under constant applied negative pressure.

MODEL DEVELOPMENT

The structure of the two systems considered in this work is quite complex and therefore the first task was to create numerical geometric data of the two systems.

To obtain the geometric structure of the OCRF dressing, Computed Tomography scans of samples of were performed in a microCT scan machine (Metris X-tec 320kV custom bay). From these scans, three dimensional shapes of the structures were generated. These images were then imported in the *Dicom* image format and filtered using *ScanIP* software to reduce noise. The dressing structures were then segmented from the image data and converted in to finite element meshes using *ScanFE* software, with the mesh size controlled by the image resolution.

As the CT-scans of the PDVS did not capture the variation in contours of the wound contact surface, probably due to the resolution of the microCT scanner being too high to resolve this geometry, finite element models of the PDVS were produced using a combination of digital imaging and conversion of the resulting computer-aided design geometry into a finite element model.

The resulting finite element meshes were exported in the Abaqus input file format and then imported into Abaqus CAE to develop FEA models of the two dressing systems and the underlying 1.5mm thick surface tissue layer. Wound tissue was modelled as a non-linear hyperelastic type material.

RESULTS

The FEA results obtained for the OCRF dressing were compared with those obtained previously by Wilkes *et al*¹, as shown in Figure 1. The predicted tissue surface strains at 125mm Hg negative pressure from this analysis were very similar in trends and in predicted levels of strain to those reported by Wilkes *et al*, validating the FEA methods applied in this study.

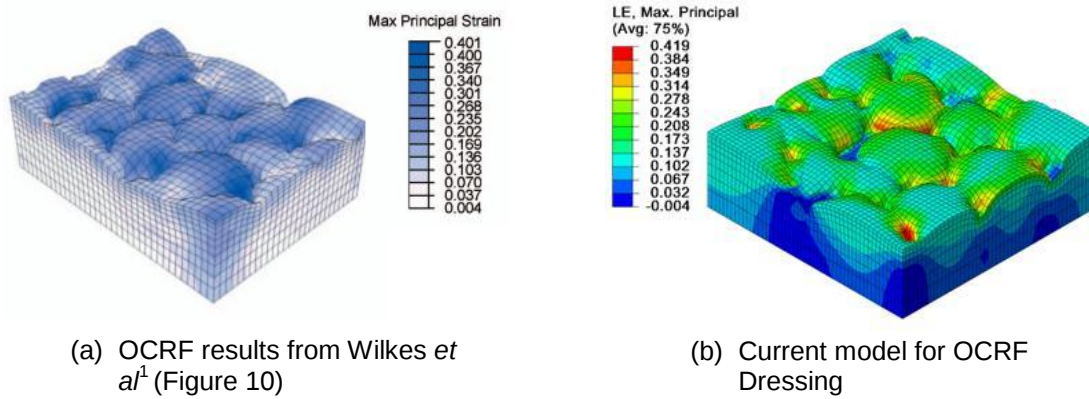


Figure 1. Comparison of Wilkes et.al and current predicted tissue strains at 125mmHg negative pressure for the OCRF dressing.

The predicted tissue surface strain distribution from the PDVS at 75mm Hg negative pressure is shown in Figure 2. Analysis of the wound contact surface deformation produced for the PDVS system showed it to have elliptically-shaped Bio-Dome™ structures of mean dimensions: 0.96mm major radius, 0.77mm minor radius, with an eccentricity of 0.56.

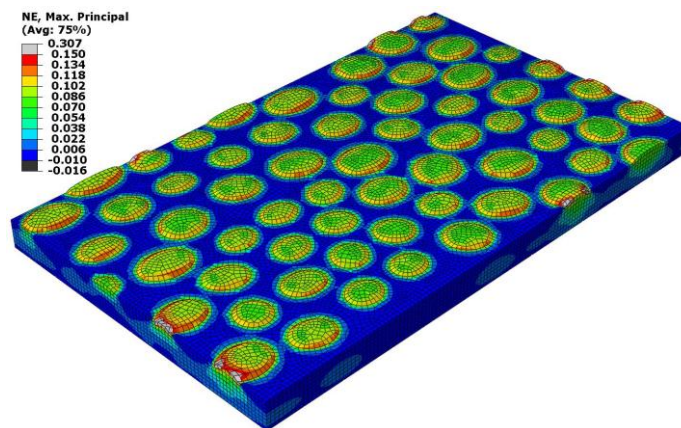


Figure 2. Predicted strain distribution on tissue surface layer from PDVS at 75mmHg applied negative pressure.

Comparisons of the predicted tissue surface strain between the PDVS and the OCRF dressing were then performed at 125mm Hg negative pressure to show the difference in applied strain and the homogeneity of that applied strain (see Figure 3).

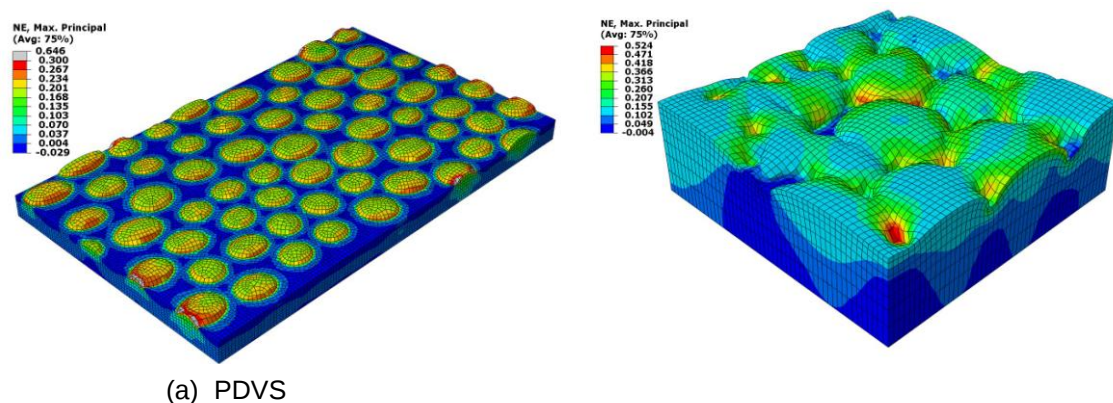


Figure 3. Comparison of tissue surface strains for PDVS and OCRF dressings, at 125mmHg applied negative pressure.

Time-dependent analysis was then performed to assess the viscoelastic creep response of skin tissue under prolonged (24 hour) application of constant negative pressure at 75mm Hg with the PDVS. The results for this are shown in Figure 4 using both 0.5% creep per decade and 1% creep per decade material models for the response of skin tissue.

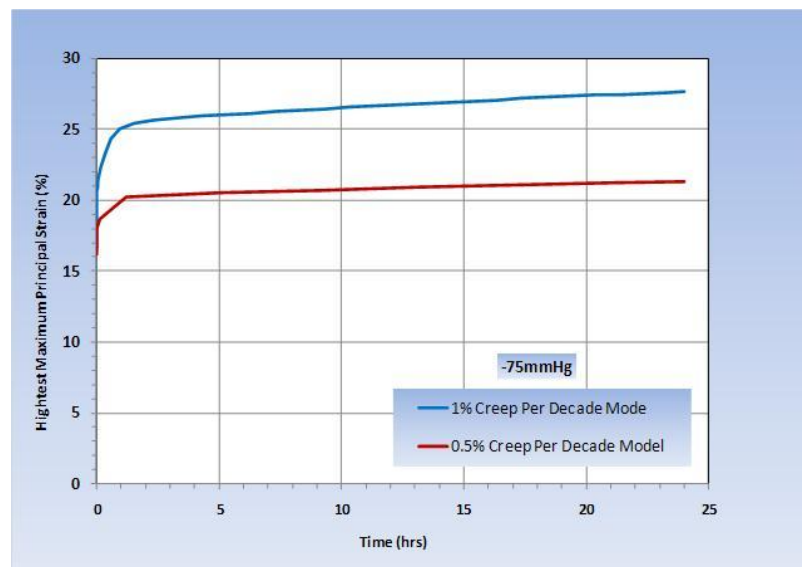


Figure 4. Predicted tissue creep strain over 24 hours at 75mm Hg negative pressure application under the PDVS using the 0.5% and 1% per decade creep rate models.



Figure 5. Close-up of granulation tissue response to tissue strain applied by PDVS (Courtesy of Amy J Walker, St. Joseph Medical Centre)

This analysis showed that maximum applied tissue surface strains can increase by up to 45-65% in 24 hours, assuming a 1% per decade viscoelastic creep model for the response of skin tissue. The analysis showed that the tissue strain increases significantly over the first 2 hours of NPWT, followed by a phase of low linear strain increase.

CONCLUSION

The FEA model and results developed within this study for OCRF were found to compare favourably with the model and results published in 2009 by Wilkes *et al*¹.

Comparison of the 125mm Hg applied negative pressure FEA results obtained for the PDVS and the OCRF dressing shows that whilst the average tissue surface strains produced are very similar, the maximum strains predicted for the OCRF dressing are higher but highly localised. However, the predicted tissue strain for the PDVS is fairly uniform across the surface of each Bio-Dome™ structure.

Another important difference between the two dressings arises from the differences in the structure that is in contact with the tissue surface. The tissue strain distributions produced by the OCRF dressing will be random because of the random structure of the struts in contact with the tissue surface. The PDVS consists of a uniform structure, which remains structurally stable under applied negative pressure, and therefore produces uniform tissue strains. The strain distribution produced by the PDVS can be directly related to the shape and size of the individual Bio-Dome™ structures on the wound contact surface.

A time-dependent analysis was performed to predict the strain increase due to creep of the viscoelastic tissue surface layer when subjected to constant negative pressure over a period of time. This analysis, using an assumed tissue creep rate of 1% per decade showed that strains can increase by up to 65% under an applied negative pressure of 75mm Hg over a 24 hour period if constant applied negative pressure is maintained. This analysis shows that time-dependent tissue creep behaviour is an important aspect of NPWT devices, which can be used clinically for prolonged periods on wound tissues which are highly nonlinear and viscoelastic in their rheological behaviour.

A qualitative comparison of the predicted tissue strain under the PDVS with clinical findings from a wound managed using this dressing within the Engenex® NPWT system showed that this FEA data supports clinical observations².

Key differences in the findings from this new study are that the tissue strain distribution predicted for the OCRF dressing is highly non-uniform with localised maximum strains. Compared to this, the tissue strain distribution predicted for the PDVS is highly uniform with only small differences between the average and maximum values. Another important difference between the two systems is that the strain distribution across the tissue surface for the OCRF dressing will be random because of the random nature of the foam struts, whereas the tissue surface strain distribution produced with the PDVS system will be more uniform because of its stable and uniform structure under applied negative pressure. These differences in the homogeneity of the tissue response and in the degree of stress applied to areas of tissue to which NPWT is applied between the OCRF dressing and the PDVS are important factors for clinicians to consider in wound management. Within the recognised limitations of current viscoelastic material models of tissue and skin, the predicted tissue strains as a function of time for one of the interface materials assessed in this study compare favourably with previous clinical findings².

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⁺GranufoamTM dressing

⁺⁺Bio-DomeTM is a trademark of Boehringer Technologies, L.P.

Engenex is a registered trademark of Boehringer Technologies, L.P.