

# Material Analysis for Therapeutic Insoles

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## Methodology

**Keywords:** Diabetes, Leprosy, Therapeutic footwear, customized insoles, offloading.

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# Abstract

**Background:** Customized footwear with appropriate insole material for offloading is widely used for preventing ulceration in diabetic and leprosy affected patients.

**Methods:** Finite element analysis was carried out on a 3 dimensionally modelled insole. The insole was tested with the boundary condition of constant geometry, constant loading and varied material properties to identify the biomechanical behaviour of material.

**Results:** The study demonstrates that Ethylene Vinyl Acetate and Micro Cellular Rubber reduce the elevated plantar pressure significantly in comparison to the other materials commonly used in fabricating foot orthosis.

**Conclusion:** The comparison of the insole materials provides the health worker the required knowledge for selection of appropriate material for therapeutic insoles. The mechanical analysis of materials through the computer aided analysis would help therapeutic footwear designer to design, fabricate and use appropriate insoles.

## Background

About 0.5-3% of the world's population, having diabetes, are affected by foot ulceration. Peak plantar pressures are identified as one of most common risk factors for ulceration [1–3]. In approximately 20% of patients with diabetic foot ulcers, the underlying infection leads to the amputation [4]. Peak plantar pressures are common in anaesthetic foot of patients with peripheral vascular diseases and leprosy. Change in the foot structure due to repeated plantar ulceration or amputations can lead to irregular distribution of plantar pressures [5]. It has also been established that the use of orthoses like medial arch support, metatarsal bar and other customized insoles relieve the pressure of the foot and prevent ulcers [6]. Studies have also established that the reoccurrence of the ulceration could be prevented if the plantar pressure is maintained below 200 Kilopascals [7]. Foot ulcers, caused by peak plantar pressures can be significantly reduced through appropriate footwear and customized insoles [8]. Though various materials are suitable to fabricate orthoses and footwear, the limitations have been the cost and durability. The health staff and patients lack scientific evidence to identify and use ideal material in fabricating orthotic insoles. Scientifically validated evidence on the changes and deformation in the material to the varied external forces would help the clinicians and patients select appropriate material for fabricating orthosis. Identifying appropriate materials that would be durable and cost effective while effectively dissipating the peak plantar pressures of the foot, is the need of the hour. Footwear with ideal insoles which dissipate the pressure are essential for people who have deformed, ulcerated and anaesthetic feet [9]. Materials like the Micro Cellular Rubber (MCR), Ethylene Vinyl Acetate (EVA), Polyurethane are commonly used insole materials in fabricating appropriate footwear for various foot related problems [9–11]. The materials are also preferred and are commonly used in designing footwear for leprosy as well as diabetic patients.

The aim of this study is to compare different materials and determine an effective and ideal insole that can be used in preventing foot ulcers and effectively dissipating peak plantar pressure, in diabetic and leprosy affected patients. This simulation study would enable the clinicians identify the durability and the limitations of the various orthotic material to external forces. Finite element analysis has been established as an effective method of studying materials used in orthotic fabrication [12]. Simulation software for finite element analysis was used to establish mechanical properties of material ideal for fabricating orthoses and footwear. An insole was designed and simulated with different material properties, without altering its geometry, to determine a suitable material for effective offloading. The material properties of Butyl Rubber, Ethylene Vinyl Acetate (EVA), Isoprene, Natural Rubber, Neoprene, Polyurethane and Micro Cellular Rubber (MCR) were compared and tested through the designed insole. The response of the materials to the simulation study and their effect in dissipating peak plantar pressures have been analysed in this study.

## Methods

The insole and realistic model of a foot was designed using Computer Aided Designing (CAD) software. Finite Element Analysis (FEA) was used to study the interaction between the foot and insole and to evaluate the biomechanical behaviour of the identified materials. SOLIDWORKS 2018 software was used for designing the insole and ANSYS 2019 R1 was used to carry out finite element analysis and to evaluate the mechanical property of the designed insole and bio-mechanical response of foot with the insole. The mechanical properties like elasticity, stress, strain and deformation of each material was analysed on the designed insole.

An insole of 10 mm thickness was designed using computer aided designing software (SOLIDWORKS). The designed insole model was then exported to the computer aided analysis software (ANSYS) to carry out simulation. Simultaneously, Computed Tomography (CT) images of the foot in the subtalar neutral position to create a realistic foot model ideal for providing a foot insole [13]. Then foot-insole assembly was created on CAD and exported to ANSYS for simulation. On the imported assembly, static structural analysis was carried out on the insole by altering the material properties like Young's modulus and Poisson's ratio. Analysis of the different insole materials like isoprene, butyl rubber, polyurethane, neoprene, microcellular rubber, ethylene vinyl acetate and natural rubber were carried out through constant loading geometric and meshing properties.

(Insert figure 1) shows the assembly of model for static structural analysis of insole with the properties of neoprene material.

The deformation of the insole materials were simulated and tested by applying a force of 686.7N (70Kg) through the foot model on the insole as shown in Fig. 1. Mechanical behaviour, occurrence of total deformation, equivalent elastic stress and strain distribution on the insole was analyzed.

Relationships between stress and strain were independent of time and loading properties. The elasticity of the material denotes the complete and immediate recovery of the material to its original shape on

removal of load. Among the materials, the one with the lowest elastic modulus has the highest elastic property [14–16].

## Results

(Insertfigure2) shows deformation assembly of a model and simulation result of deformation of neoprene insole due to loading condition.

The deformation results of the insole materials were analysed. The result showed that Micro Cellular Rubber exhibited maximum deformation when compared with other materials. The materials exhibited elastic deformability, linear stress and strain until the yield point. Greater deformation exhibited a greater displacement in the insole [17].

(Insertfigure3) shows graphical representation of the deformation on insole for various materials. Mechanical properties like stress, strain and deformation represent the strength, resistance to failure, hardness, elasticity and shock absorption property of the materials.

Each material was analysed for the stress by measuring the intensity of a reaction to the externally applied load. Its internal force acting perpendicular to a unit of area within the material was also analysed for stress [18].

(Insertfigure4) shows graphical representation of stress formation on various materials. The analysis revealed that Ethylene Vinyl Acetate (EVA) material had the lowest stress concentration when compared to other materials. Hence it provides greater elasticity when compared with other materials.

## Discussion

A total of seven materials were simulated and analysed in the study. The analysis establishes that of all the materials tested, EVA and MCR are ideal in effectively dissipating the peak plantar pressures without compromising on the aesthetic value. EVA demonstrated a low stress value and MCR had high deformation values. These materials when used as insoles would significantly offload the foot with peak plantar pressures.

The simulation study indicates the effectiveness of EVA in undergoing maximum deformation. The insoles made of EVA and polyurethane would be effective in lowering peak plantar pressure. Results of earlier studies have shown similar results as that of the present study in demonstrating that EVA has good shock absorption property and is highly durable [19–20]. Studies have established that a three layered footwear with MCR as midsole, polyurethane foam as insole, and EVA as the outer sole may lower the plantar pressure effectively [5]. Footwear consumption across the world has reached 24.2 billion in 2018 causing dumping of synthetic polymers, increasing the environmental pollution. In order to overcome this problem, bio-degradable material like Polyurethane (PU) could eventually replace the

existing materials [21]. Deproteinised natural rubber latex (DPNR) could also be used as a therapeutic insole with an excellent pressure reduction and shock absorption property [22].

Micro-cellular Rubber (MCR) insoles are widely used and are recommended for leprosy affected patients with anaesthetic feet [23]. Studies have established that lack of design and colours could decrease the acceptability of footwear among patients [24–25]. MCR insoles if made in different colours without compromising on the properties established in the study could increase the acceptance among the leprosy affected patients. Above compared materials are used as insoles for therapeutic footwear fabricated for anaesthetic feet. This study has established that materials properties of EVA and Polyurethane are ideal in dissipating pressures. These materials could be used to increase the acceptance of footwear among patients. Use of technology and technology based interventions has been established to be useful in improving compliance and adherence to treatments [26]. So, further studies on simulating the interactions between the foot and insoles would help in improving treatment outcomes and compliance to wearing footwear. Using internet of things and sensor technology would help in understanding the wear and tear of the insoles. It would also help in improving the quality of life of those affected by debilitating diseases like Leprosy and Diabetes.

## Conclusions

The study establishes the significance of each material and its offloading properties in an anaesthetic foot. The accessibility and the easy availability of MCR and EVA make them more suitable in offloading an anaesthetic foot.

## Declarations

### **Ethics approval and consent to participate:**

Ethics review board review and approval was required for this study. All study procedures were approved by the Schieffelin Institute of Health-Research and Leprosy Centre, ethics review board, approval number: 14:05:04.2

### **Availability of data and materials:**

All data generated or analysed during this study are included in this published article.

### **Competing interest:**

Authors don't have any competing interest.

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## Authors contributions:

Dr.Sathish Kumar Paul (Corresponding author) contributes on Conceptualization, Data curation, Investigation, Supervision and validation.

Mr.David Prakash Kumar (Co-author1) contributes on Funding acquisition and Project Administration.

Mr.B.Siva (Co-author2) contributes on Formal analysis, Methodology, Software, Visualization and writing draft.

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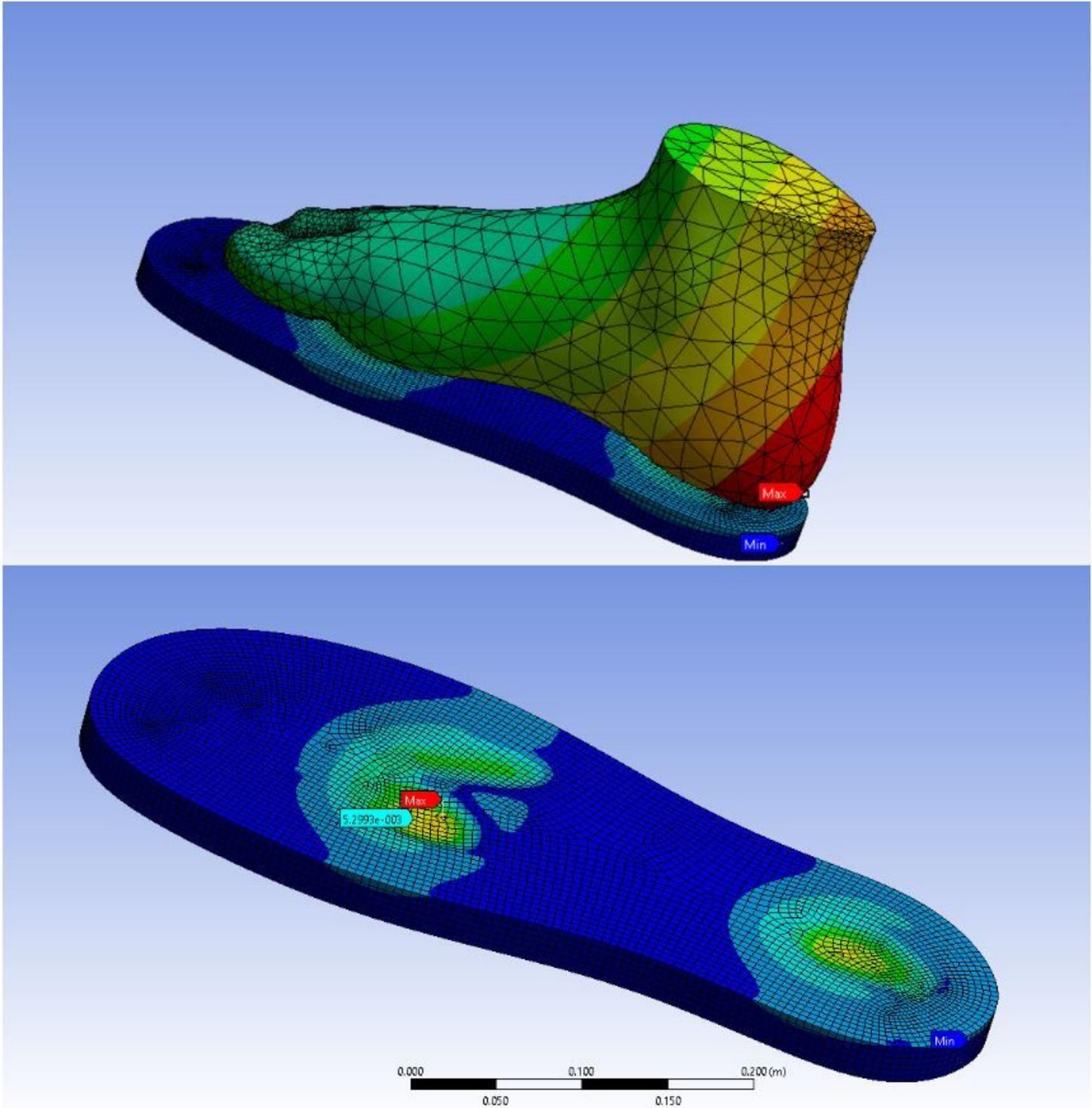
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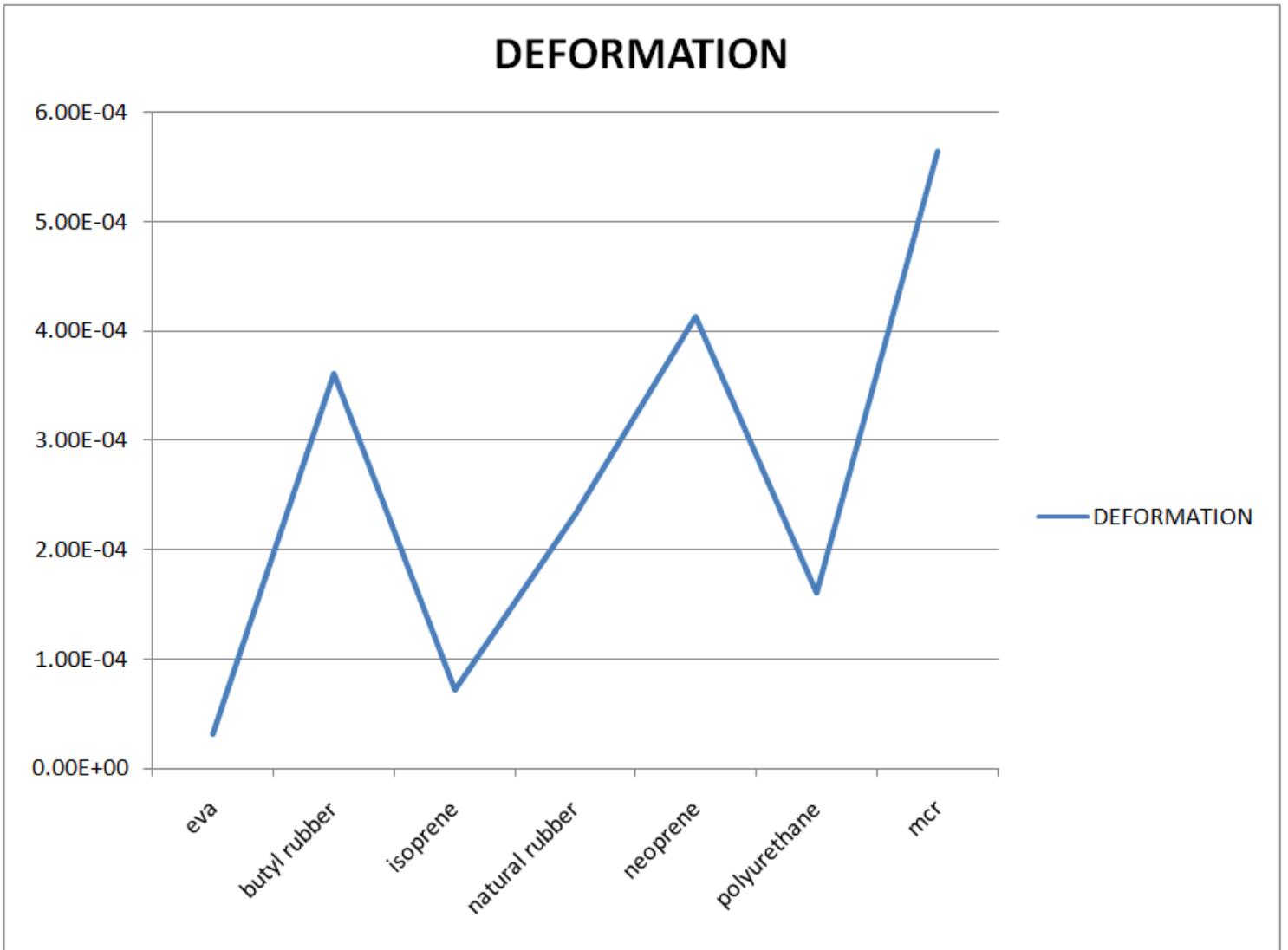
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## Figures



**Figure 1**

shows the assembly of model for static structural analysis of insole with the properties of neoprene material.



**Figure 2**

shows deformation assembly of a model and simulation result of deformation of neoprene insole due to loading condition.

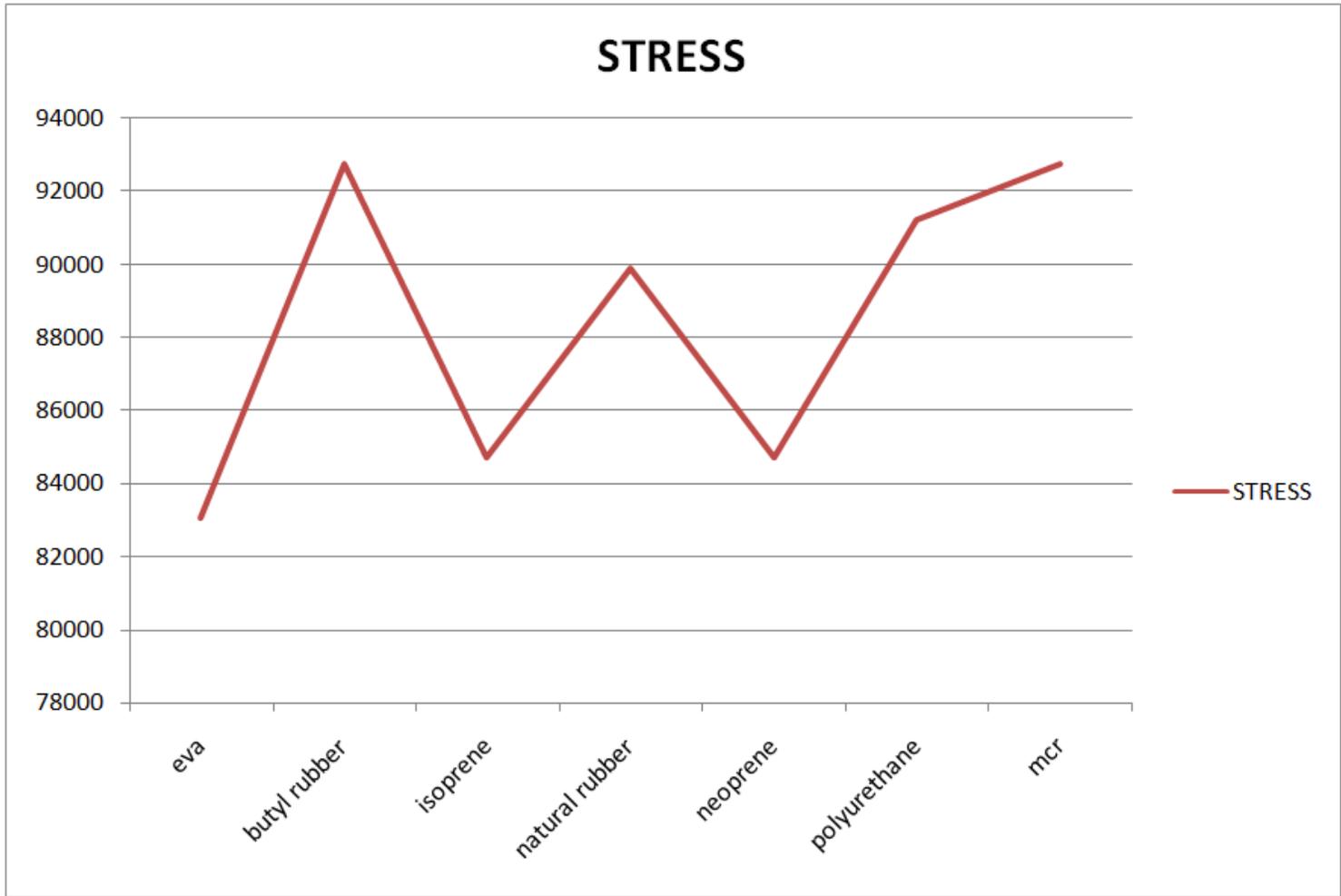
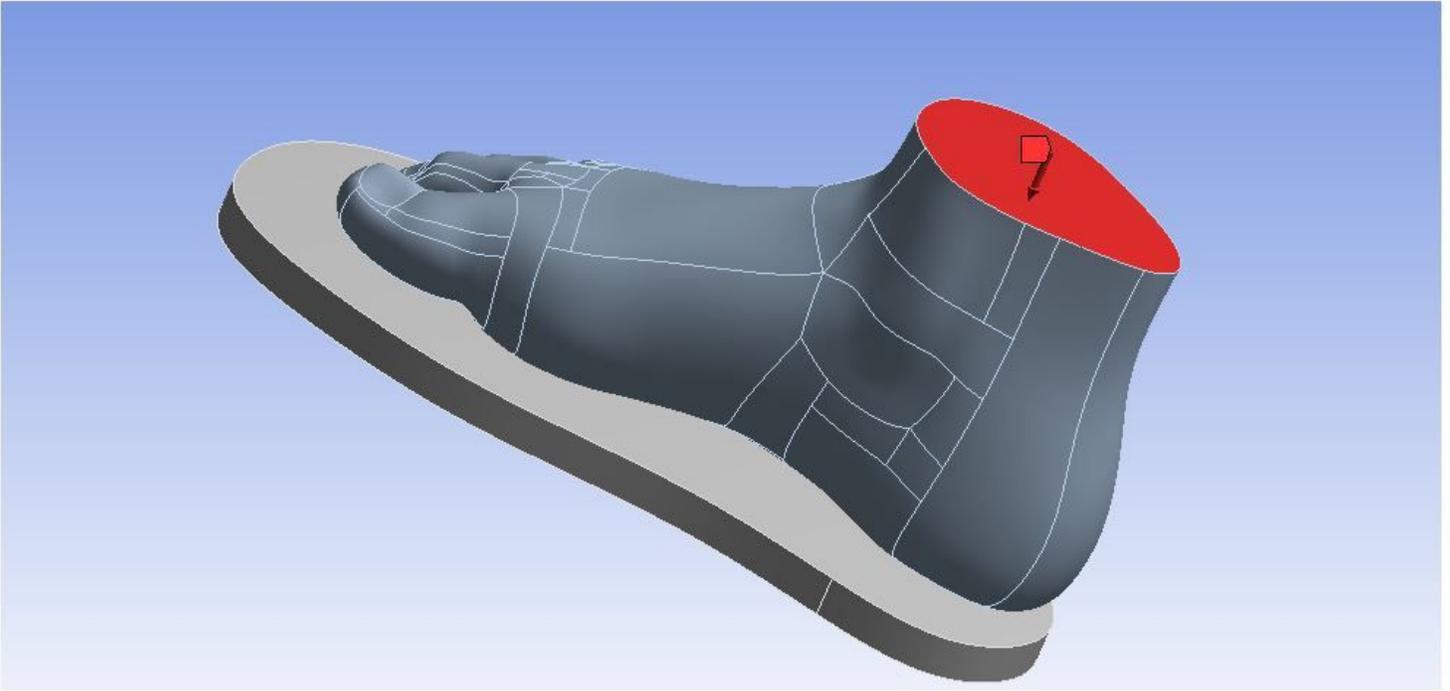


Figure 3

shows graphical representation of the deformation on insole for various materials. Mechanical properties like stress, strain and deformation represent the strength, resistance to failure, hardness, elasticity and shock absorption property of the materials.



**Figure 4**

shows graphical representation of stress formation on various materials. The analysis revealed that Ethylene Vinyl Acetate (EVA) material had the lowest stress concentration when compared to other materials. Hence it provides greater elasticity when compared with other materials.