The value of finite element analysis (FEA) in screening novel microneedle geometries for drug delivery to reduce manufacturing and development costs and time

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Background: Finite element analysis (FEA) is a powerful computational tool used to understand how structures respond when external forces and factors are applied and adjusted. Employing FEA is hypothesized to reduce the costs and time associated during product development processes by identifying incompatible structures prior to manufacture. Microneedles (MNs) are standalone structures, which may be combined into an array. MNs can be considered as a physical permeation enhancer, improving drug delivery, commonly across the skin. The geometry of a MN has a marked effect on the insertion profile, including the insertion depth. With the advent of additive manufacturing, more complex and novel MN geometries can be readily explored. This work explores whether FEA can be used to computationally predict whether novel MN geometries will be able to withstand insertion into skin without buckling/fracturing.

Methods: CAD designs for a range of MNs with heights between 500 - 1400 μm were designed in SolidWorks® 2022. An FEA model was developed in Abaqus® 2017. Increasing loads (N) were applied to the surface of the MN intended to pierce the skin. The fracture force was obtained when the Von Mises stress was equivalent to the yield strength of the material, indicating the MN will likely buckle/fracture. Single MNs were manufactured using a microArch® S130, whilst arrays of MNs were printed using an Elegoo Mars 4 Ultra. A TA-XT Plus texture analyser was used to physically quantify the fracture force and validate the FEA model. Low-vacuum mode SEM was used to visualize the fractured MNs (FEI Quanta650).

Results: First, the FEA model was used to calculate the fracture force of individual MNs with and without barbs. Low variability in the fracture force between geometries was observed, likely due to the barbs not being present at the tip of the MN where the load was applied. This gives confidence that the addition of barbs will not have any detrimental effect on MN insertion but may aid anchoring in the skin. However, the physical fracture force was determined to be considerably higher than the FEA calculated. To check the validity of the FEA model, MNs were examined using SEM to understand the fracturing pattern. SEM confirmed the MNs fractured as anticipated, laterally close to the tip of the structure. The inaccuracies may indicate properties for the material are significantly different to those used in the model. To further understand factors that may contribute to model inaccuracies, the effect of MN height and tip surface area were tested in the FEA. Interestingly, with a larger tip surface area, computational and experimental values were more accurate. These simulations showed that as MN height tip surface area increased the MNs were more likely to fracture when the same load was applied.

Conclusions: A FEA model was developed which facilitated the prediction of trends between MN geometries, reducing manufacturing requirements of MN prototypes. Differences between buckling forces observed in the computational model versus physical characterization may be attributed to the material properties, including the effect of UV post-curing. Future work will include material characterization of multiple resins to improve the accuracy of estimations produced by the FEA.