Influence of tip diameter on the insertion force of single solid microneedles

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Introduction

The outermost layer of the skin acts as a barrier protecting the body against influences from the environment, while the deeper skin layers are rich in immune-responsive cells. Consequently, the skin provides an ideal target to administer vaccines, although this is complicated by the dense structure of its outermost layer. The use of microneedles is a promising method to deliver these vaccines intradermally and directly target the immune-responsive cells. However, to effectively and reproducibly apply microneedles to the skin, it is essential to understand the process of skin penetration by these microneedles. Therefore, it is crucial to obtain insights in the force required to reproducibly penetrate the skin with microneedles. This insertion force was previously measured for relatively blunt microneedles (60-160 μm tip diameters) and found to be linearly dependent on tip frontal area [1]. In the current study, the insertion force of smaller tip diameters was measured to represent the current research focus on sharper microneedles. In addition, the findings of the experiments were compared with those predicted by a finite element model.

Experimental & computational methods

Individual solid microneedles with tip diameters ranging from 5 to 37 μm were inserted in a pre-stretched human skin sample placed on a polydimethylsiloxaan substrate. Microneedles were inserted with a controlled velocity of 0.05 mm/s and the force was measured using a micro-indentation device. A sudden decrease in the force indicated the moment of insertion. Axisymmetric finite element (FE) analyses mimicking the experiments were performed in Abaqus. In the model, insertion into the skin was assumed to occur at a failure stress (von Mises) of 30 MPa in the skin [2].

Results & discussion

The insertion force linearly increased with tip diameter with means ranging from 20 to 167 mN (Fig. 1A). This linear increase in insertion force was also predicted with the preliminary results of the FE analyses. Pooling data from the present study with those from a previous study [1], reveals the relationship illustrated in Fig. 1B. It is apparent that the insertion force is linearly related to the radius for sharp microneedles, while for tip diameters larger than approximately 80 μm the force is proportional to the square of the radius.

Conclusion

Both experimental and preliminary finite element analyses revealed a linear increase of penetration force with increasing tip diameter for sharp microneedles.

References

1. Davis et al., J Biomech, 37, 1155-1163 (2004)
2. Wildnauer et al., J Invest Dermatol. 56:72-80 (1971)

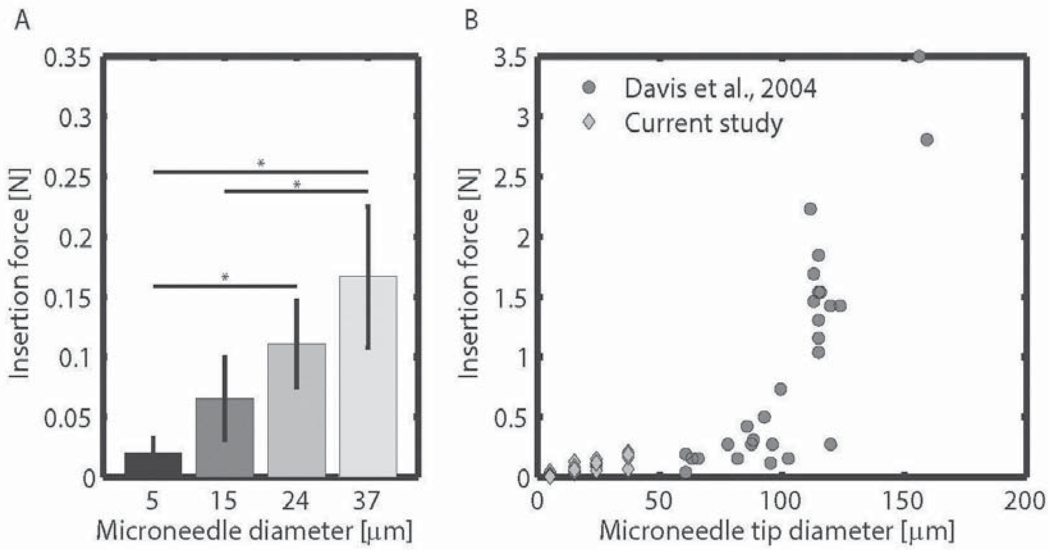

Fig. 1. The influence of microneedle tip diameter on the insertion force. A) Mean and standard deviation of the force at insertion per tip diameter. B) Pooled data of the study by Davis et al., (2004) and the current study.