Fabrication and Characterization of Maltose Microneedles for Transdermal Drug Delivery

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**Purpose**
Maltose microneedles have strong mechanical properties and rapidly dissolve in skin. Therefore, they have been investigated to enhance transdermal delivery of various therapeutic compounds ranging from small molecules to macromolecules and micro/nano particles. This study describes fabrication technique and characterization of maltose microneedles for application in transdermal drug delivery.

**Methods**
Maltose microneedles were fabricated by melting technique (1500°C in vacuum oven, 30 min). Microneedle dimensions were measured by scanning electron microscopy. Mechanical properties of microneedles as well as array substrate were studied using a texture analyzer with axial force and transverse force. Mechanical uniformity of microneedles was also reported. Dissolution of the needles in dermatomed porcine ear skin after 1, 2, 3, 4, 5 minutes was studied using scanning electron microscopy. Skin microporation was observed in dye binding, histology and calcein imaging studies. Depth of microchannels created by maltose microneedles was measured by confocal laser microscopy. Dimension of microchannels were measured and calculated using scanning electron microscopy.

**Results**
Maltose microneedle dimensions were measured with needle length of 440.53 ± 14.59 μm (n=10), needle-to-needle distance of 513.86 ± 6.20 μm (n=10), needle base side of 163.98 ± 3.74 μm (n=10) and needle tip diameter of 13.14 ± 4.48 μm (n=10) (Figure 1). These dimensions facilitated microneedle microporation into skin. Microneedles were initially tested using a parafilm sandwich; 100 pores were created on second layer of parafilm by 100 maltose microneedles on an array. On the first parafilm layer, microchannels had square shape with side length of 34.87 ± 1.54 μm (n=10) which followed the cross section of microneedles. Also, an indented area of 5283.20 ± 557.67 sq. μm (n=10) was observed on this layer. After 1, 2, 3, 4 minutes in porcine ear skin, microneedle length decreased accordingly and disappeared at 5 minutes. Successful microporation was demonstrated by dye binding studies. Histology studies revealed that microneedles passed skin stratum corneum, viable epidermis and reached the superficial layer of skin dermis. Microneedle insertion resulted in uniform microchannels in skin (Pore Permeability Index: 5.7 ± 3.28, n=100, n rezo=1) (Figure 2). In confocal laser microscopy studies, depth of microchannels created by maltose microneedles was found to be 120 ± 7.45 μm (n=10). The area of ten randomly selected channels was measured using scanning electron microscopic images with ImageJ software. Area of pores created by maltose microneedles in porcine ear skin was 1883.92 ± 422.82 sq. μm (n=10).

**Conclusion**
Maltose microneedles were successfully fabricated by a melting technique and characterized for their dimensions. Their ability to microporate skin was demonstrated.