Study of Transdermal Vaccines for COVID-19 Using Microneedle Drug Delivery System

Takaaki Terahara／Hisamitsu Pharmaceutical Co., Inc.

A microneedle (MN) is an array-based substrate on which tiny needles are placed; medical applications of MN-based technologies have been developed in recent years. MN-based vaccine administration has been shown to deliver antigens into the skin, in which immune cells, such as dendritic cells, are abundant, and have demonstrated dose-sparing effects that cannot be obtained with existing injectable vaccines. Hisamitsu's microneedle technology, the HalDisc® Technology, has several advantages, such as high immunogenicity, rapid rise in antibody titer, short administration time, and improved heat stability; therefore, it is valuable during pandemics.

During the COVID-19 pandemic, while the spread of infection was suppressed by mRNA-based vaccines, there were some concerns about systemic adverse reactions, such as fever and malaise, and the countermeasures needed against new variants. Further, the duration of efficacy was reported to be shorter in the elderly than in younger subjects. Therefore, it is necessary to develop safer and more effective vaccines that can induce sufficient immunity even in immunocompromised patients. In addition, given the requirement for vaccines that are suitable for booster immunity and routine vaccination against COVID-19, developing protein-based vaccines which are proven to demonstrate high efficacy and can be conveniently administered is an urgent need.

In the present study, we are arranging an animal study using a COVID-19 protein antigen to evaluate the immunogenicity-enhancing effects of the MN formulation and analyze the mechanisms underlying these effects. To prove the high immunogenicity of MNs, two different formulation, one coated with COVID-19 antigen and the other with a combination of antigen and adjuvant, are prepared and used for various studies. Immunogenicity studies are performed using adult and aged animals to compare the MN-based administration group with the intramuscular administration group of various adjuvant-containing protein antigens. Cytokine assays and gene expression analyses are performed to assess the mechanisms underlying these immunogenicity-enhancing effects.

If the above studies show the expected efficacy, MN-based vaccines may not only serve as a promising response to the spread of unknown infectious diseases but may also represent an effective option for administering booster doses of vaccines during normal times for immunocompromised subjects, such as those with underlying diseases and the elderly.