GS04-1 Efficient transdermal delivery of human parathyroid hormone (1-34), an osteoporosis drug, by using self-dissolving microneedle arrays

○ Chihiro NAITO[1], Hidemasa KATSUMI[1], Tomoko SUZUKI[1], Ying-shu QUAN[2], Fumio KAMIYAMA[2], Masaski MORISHITA[1], Toshiyasu SAKANE[1,3], Akira YAMAMOTO[1]

[1]Kyoto Pharmaceutical University, [2]CosMED Pharmaceutical Co., Ltd, [3]Kobe Pharmaceutical University

Human recombinant parathyroid hormone (1-34) ($hPTH_{1-34}$) is a peptide that consists of 34 amino acids. It is widely used for the treatment of osteoporosis. The route of delivery of $hPTH_{1-34}$ has been limited to a once-daily or once-weekly subcutaneous injection because of the low absorption characteristics of peptides and proteins such as $hPTH_{1-34}$ from the gastrointestinal tract. However, frequent injections are both inconvenient and painful for patients and reduce quality of life. Transdermal drug delivery is painless and allows ease of application. Therefore, this route is considered to be an attractive method for the delivery of peptides and proteins. However, the stratum corneum, the outermost layer of the skin, restricts the permeation of macromolecular drugs through the skin.

Recently, we successfully developed a transdermal delivery system for peptide and protein drugs by using dissolving microneedle arrays (MNs), composed of hyaluronic acid (HA). In the present study, we designed and developed dissolving MNs composed of HA as the base material for the efficient transdermal delivery of $hPTH_{1-34}$. We demonstrated that transdermal delivery of $hPTH_{1-34}$ after the application of our MNs was almost equivalent to that after subcutaneous injection in rats. In addition, $hPTH_{1-34}$-loaded MNs were found to effectively suppress decreases in bone density in a rat model of osteoporosis. These findings indicate that our dissolving MNs have a potential use in formulations for the transdermal delivery of $hPTH_{1-34}$ and for the treatment of osteoporosis.

These findings indicate that our MNs are promising formulations for delivering $hPTH_{1-34}$ to the skin.