Development of polymeric microneedles for transdermal and intradermal drug delivery: Opportunities, challenges and solutions.

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Unique microneedle arrays prepared from crosslinked polymers, which contain no drug themselves, are described. They rapidly take up skin interstitial fluid upon skin insertion to form continuous, unblockable, hydrogel conduits from attached patch-type drug reservoirs to the dermal microcirculation. Importantly, such microneedles, which can be fabricated in a wide range of patch sizes and microneedle geometries, can be easily sterilized, resist hole closure while in place, and are removed completely intact from the skin. Delivery of macromolecules is no longer limited to what can be loaded into the microneedles themselves and transdermal and intradermal drug delivery is now controlled by the crosslink density of the hydrogel system rather than the *stratum corneum*, while electrically modulated delivery is also a unique feature. This technology has the potential to overcome the limitations of conventional microneedle designs and greatly increase the range of the type of drug that is deliverable transdermally and intradermally, with ensuing benefits for industry, healthcare providers and, ultimately, patients.

In this presentation, the utility of these hydrogel-forming microneedles for sustained delivery, for up to 14 days from a single patch application will be described, with applications in infectious diseases, schizophrenia, HIV treatment and cardiovascular disease all discussed in depth. Translational considerations, pertaining to industrial manufacture, patient use and regulatory approval will also be covered.