

Could dissolvable microneedles replace injected vaccines?

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The microneedle patch can dissolve in the skin, delivering the flu vaccine painlessly. Credit: Prof. Shinsaku Nakagawa

Flu vaccines delivered using microneedles that dissolve in the skin can protect people against infection even better than the standard needle-delivered vaccine, according to new research published in *Biomaterials*. The authors of the study, from Osaka University in Japan, say their dissolvable patch - the only vaccination system of its kind - could make vaccination easier, safer and less painful.

According to the World Health Organization, immunization prevents an estimated 2-3 million deaths every year. The continued threat of pandemics such as H1N1 swine flu and emerging infectious diseases such as Ebola makes <u>vaccine development</u> and <u>mass vaccination</u> a priority for global healthcare. Most vaccines are injected under the skin or into the muscle using needles. While this is an effective delivery



method, it requires medical personnel with technical skills and brings the risk of needle-related diseases and injuries.

The new microneedle patch is made of dissolvable material, eliminating needle-related risks. It is also easy to use without the need for trained medical personnel, making it ideal for use in developing countries, where healthcare resources are limited.

"Our novel transcutaneous vaccination using a dissolving microneedle patch is the only application vaccination system that is readily adaptable for widespread practical use," said Professor Shinsaku Nakagawa, one of the authors of the study from Osaka University. "Because the new patch is so easy to use, we believe it will be particularly effective in supporting vaccination in developing countries."

The new microneedle patch - MicroHyala - is dissolvable in water. The tiny needles are made of hyaluronic acid, a naturally occurring substance that cushions the joints. When the patch is applied like a plaster, the needles pierce the top layer of skin and dissolve into the body, taking the vaccine with them.

The researchers compared the new system to traditional needle delivery by vaccinating two groups of people against three strains of influenza: A/H1N1, A/H3N2 and B. None of the subjects had a bad reaction to the vaccine, showing that it is safe to use in humans. The patch was also effective: people given the vaccine using the microneedles had an immune reaction that was equal to or stronger than those given the vaccine by injection.

"We were excited to see that our new microneedle patch is just as effective as the needle-delivered flu vaccines, and in some cases even more effective," said Professor Nakagawa.



Previous research has evaluated the use of microneedles made of silicon or metal, but they were not shown to be safe. Microneedles made from these materials also run the risk of breaking off in the skin, leaving tiny fragments behind. The new dissolvable patch eliminates this risk, as the microneedles are designed to dissolve in the skin.

"We have shown that the <u>patch</u> is safe and that it works well. Since it is also painless and very easy for non-trained people to use, we think it could bring about a major change in the way we administer vaccines globally," said Professor Nakagawa.

More information: "Clinical study and stability assessment of a novel transcutaneous influenza vaccination using a dissolving microneedle patch" by Sachiko Hirobe, Hiroaki Azukizawa, Takaaki Hanafusa, Kazuhiko Matsuo, Ying-Shu Quan, Fumio Kamiyama, Ichiro Katayama, Naoki Okada, Shinsaku Nakagawa (DOI: 10.1016/j.biomaterials.2015.04.007). The article appears in *Biomaterials*, Volume 57 (July 2015)

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