Drug testing without syringes

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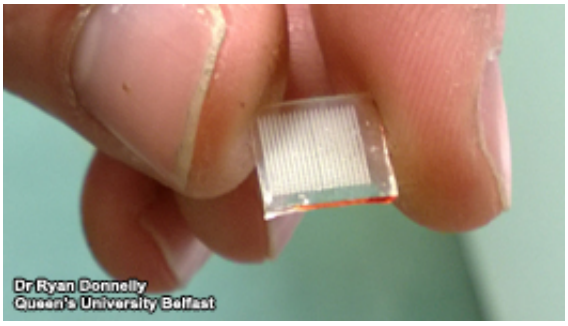


Microneedle patch that could be used for painless drug sampling

Microneedles on a sticking-plaster-like patch may be the painless and safe way doctors will test for drugs and some infections in the future, thanks to work supported by the Engineering and Physical Sciences Research Council (EPSRC).

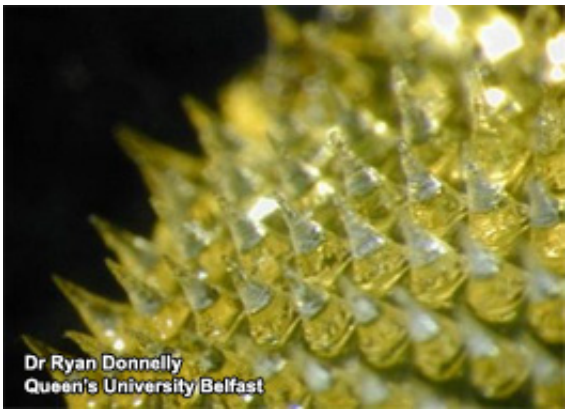
Samples of the rough, absorbent patches are being tested in the Queen's University Belfast laboratories of Dr Ryan Donnelly, an award-winning researcher in the School of Pharmacy. The experiments are showing that the forest of tiny polymer needles on the underside of the patch, when pressed into the skin, can absorb the fluid in the surface tissue, taking up at the same time the salts, fatty acids and other biological molecules found there as well.

"The important thing is that we typically find the same compounds in this interstitial fluid as you would find in the blood," Dr Donnelly

explains. "But, compared with drawing blood, our patches can get their samples in a minimally invasive way. And it's far safer than using a conventional needle. These microneedles, once they have been used, become softened, so that there's no danger of dirty needles transferring infection to another patient, or one of the healthcare workers. Two million healthcare workers are infected by needlestick injuries every year."

The microneedle sampling technique is a development of earlier and ongoing experiments using similar patches to deliver drugs and vaccines painlessly – the sensation when they are pressed onto the skin is a bit like the roughness of Velcro, Dr Donnelly reports.

The microneedles are made of polymer gel – similar to the material used in superabsorbent nappies. For their original, injecting function, they are pre-loaded with vaccine or drug compounds that will be released into the skin on contact with the interstitial fluid.



Close up of the fluid-swollen needles on a microneedle patch.

But the flow can go both ways. So that for the sampling variants, the

backing material can be made chemically attractive to target compounds, encouraging them to diffuse into the gel with interstitial fluid drawn out of the skin and locking them in place for later analysis.

Dr Aaron Brady, a clinical pharmacist in Dr Donnelly's group, is currently conducting the first clinical evaluation of the technology using caffeine as a model drug (though he admits that finding caffeine-free volunteers for the control group can be hard). Eyman Eltayib, a PhD student with the group, is also trialling the technique for blood-free glucose sampling at her home university in Khartoum, Sudan. Future targets for sampling could include, for example, therapeutic drugs where monitoring the correct dose can be important

"Theophylline, the asthma drug, is one compound doctors might want to track this way," says Dr Donnelly. "It has a very narrow therapeutic range – too much and you can harm the patient, too little and it won't do the job. During our EPSRC project, my PhD student Ester Caffarel-Salvador has shown theophylline in the blood of rats can be indirectly detected using our microneedles. In the future, patches could also be designed for medics treating TB, particularly in sub-Saharan Africa. Patients are very bad at completing their long courses of antibiotic treatment, the main cause of drug-resistant TB. A simple, cheap technique like this would let healthcare workers monitor compliance, even with a minimum of training."

Real-time monitoring could be a realistic option in the future and might involve combining the microneedle technology with simple laser-based detection ("SERS") of drug compounds inside the gel. The group already has proof-of-concept for this idea and are now looking to extend the range of drug concentrations that can be detected in this manner. Electrochemical detection is another attractive possibility that might allow patients to use the technology in their own homes. If connected wirelessly to their healthcare provider, they could then have their

medicines or doses changed based on the microneedle readings, both enhancing patient care and saving NHS resources.

Children's charity Action Medical Research, through a generous donation from The Henry Smith Charity, is now funding Dr Donnelly to develop the minimally-invasive microneedle sampling technology for monitoring therapeutic drug levels in babies.

"Premature babies have very limited blood volumes and are prone to bruising and scarring when blood samples are taken," Dr Caroline Johnston, Research Evaluation Manager at Action Medical Research for children explains. "There is a real need for a safe, reliable and painless way to monitor these babies' drug levels, and these microneedles are so far proving to have all the right characteristics."

The group is currently in discussions with a major medical manufacturer with a view to producing prototype commercial devices, the first stage ahead of full clinical trials.

Provided by Engineering and Physical Sciences Research Council