Push-button Phlebotomy

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To pivot is to survive in high-technology startups. Android did not begin as software for mobile phones, but rather as an operating system for digital cameras. The original idea for Twitter was a directory of podcasts. And Seventh Sense Biosystems (7SBio) began around bioactive pigments that, when tattooed, were to change color to signal an alteration in body chemistry for health-monitoring applications. Along the way, the development got a little bloody, so to speak. The tattoo nanotechnology ended up hitting capillaries that bled and interfered with the color readout. So what did the company do? They threw out the diagnostic application and began to focus on a painless way to sample capillary blood.

Cofounder and MIT professor Robert Langer had started another company focused on making blood draws less painful. That company (Sontra Medical, now Echo Therapeutics) had shown him “what a really important area this is.” 7SBio’s Touch Activated Phlebotomy (TAP) is a sterile, single-use blood collection device designed for operation by a user with or without a health care professional.

How Does It Work?

A challenge with designing a painless blood stick is that the skin has a lot of elasticity. This saves us from bleeding each time we bump into something, but makes pressing microneedles into the skin a challenge. TAP has addressed this through a design that deploys a thin needle at an awesome acceleration to create micropunctures in the skin.

The device is like a computer mouse with a base designed for contact with the skin (Fig. 1). The base has a release liner that exposes hydrogel to generate a seal with the skin for the device’s integrated vacuum. A user places the device on his or her skin (anywhere, although the forearm or upper arm is most convenient) and presses a button. This fires a needle that punctures the skin above the dermis. The vacuum seeps capillary blood out of the micropunctures and through microfluidic channels into a collection chamber with prefilled lithium heparin or EDTA. To transfer the blood to an analyzer, a technician places a precision pipette into a blood access port at the bottom of the device (Fig. 2). TAP collects up to 100 μL of blood.

Chief Executive Officer of 7SBio, Howard Weisman, considers its ease of use, minimum need for training, and fast turnaround time as key benefits. A significant design innovation of TAP is the use of a snap dome spring, similar to that used as an automatic reset in buttons on iPhones or remote controls. The spring fires only once, at which time the 3.2 mJ of potential energy is quickly transferred into kinetic energy to pierce the skin with an acceleration of 100 000 m/s².

How Does the Snap Dome Do It?

A snap dome is essentially a bistable element, which means it is stable in either its convex or concave configuration. As a snap dome is pressed, it goes through a transition from convex to flat to concave. During the convex-to-flat transition, the outer annular section of the dome is stretched and stores energy. This energy is released (quite quickly) as the dome comes out on the other side in the flat-to-concave transition. As a dome is just a thin sheet of metal, this small energy can accelerate it to the exceptionally high speeds seen in TAP.

Where Can This Technology Fit in the Laboratory?

“The future is about capillary blood,” says Weisman. “Many instruments today work on capillary blood, but
are not used extensively because the only real collection source is a finger stick.”

Abbott and Abaxis both have point-of-care systems that use capillary whole blood and can be used with TAP. “Abbott markets iStat and Abaxis markets Piccolo,” says Weisman. “Each of these devices have multiple cartridges with preset menus of analysis. Alere markets several instruments that range from Hb A1c measures to cardiac markers.”

The central laboratory may not be too far away. “There are also a few central lab analyzers that have been recently introduced to the market that also use microsamples of whole blood,” says Weisman. “These central lab instruments are typically validated with venous whole blood, but we believe that capillary blood will work here too, considering that they require sample volumes below 100 microliters.”

“The obvious caveat is that more work is needed to better understand the impact of low- or microvolume capillary versus venous collection,” writes Shannon Haymond in an email to *Clinical Chemistry*. Haymond is the Director of Clinical Chemistry and Mass Spectrometry at the Ann & Robert H. Lurie Children’s Hospital of Chicago, and she is currently talking with 7Sbio to set up a pediatrics-focused study. Haymond says she is excited about TAP.

“It is designed to collect minimal volumes with minimal pain,” she writes. Besides topical pain therapies and methods of distraction, in pediatrics, she says, “we don’t currently have an elegant solution for these problems.”

Moreover, Haymond sees another potential benefit for the young patient: because it is meant to be user operated, “this device has the potential to decentralize phlebotomy and empower patients and their families to actively participate in the lab testing process,” she writes. “The decentralization piece may be underappreciated, as not all laboratory blood draw sites staff phlebotomists specially trained in pediatric collections.”

A challenge for the company, she writes, might be infiltrating today’s clinical lab operations. In the nonpediatric setting, she says, “highly automated laboratories are forced to use larger collection tubes that are compatible with robotic components of laboratory automation systems.” In the pediatric lab, she explains, the small tubes they use normally are already not compatible with the traditional larger robotic systems, lowering the barrier of entry for a device like TAP—but the barrier will be higher elsewhere.

“If the goal is to develop a device that will integrate with clinical lab operations, then an ideal solution would be a device that collects low volume with minimal pain and is compatible with current laboratory automation and workflows—like a tube version of TAP,” says Haymond, who also believes a natural next phase for this device is integrating it into a diagnostic.

If capillary collection is truly to be the future, as Weisman hopes, Haymond believes “a revolution in the lab testing industry is needed to enable use
of smaller volume samples on a large, automated scale.”

Author Contributions: All authors confirmed they have contributed to the intellectual content of this paper and have met the following 3 requirements: (a) significant contributions to the conception and design, acquisition of data, or analysis and interpretation of data; (b) drafting or revising the article for intellectual content; and (c) final approval of the published article.

Authors’ Disclosures or Potential Conflicts of Interest: No authors declared any potential conflicts of interest.