Microneedle Device to Detect Early Lyme Disease

VANDERBILT UNIVERSITY
CTTC Center for Technology Transfer & Commercialization

Addressed Need

The *Borrelia burgdorferi* sensu lato family of spirochetes causes Lyme disease (LD) in animals and humans. As the geographic territory of host ticks expands across the globe, surveillance measures are needed to measure transmission rates and provide early risk testing of suspected bites. Early detection remains a challenge because the current standard uses an indirect 2-step serological assay to measure host antibody response, which develops several weeks after infection.

After being deposited into skin, *B. burgdorferi* multiplies locally at the bite site before migrating through tissues. *B. burgdorferi* genotypes can be detected by PCR in the skin of patients who develop lesions, but this approach is challenged by the pain of obtaining a skin biopsy suitably large and the reduced assay performance of PCR caused by inhibiting substances commonly used in tissue fixatives. Additionally, a skin biopsy requires a trained nurse or doctor and the use of an anesthetic to numb the skin.

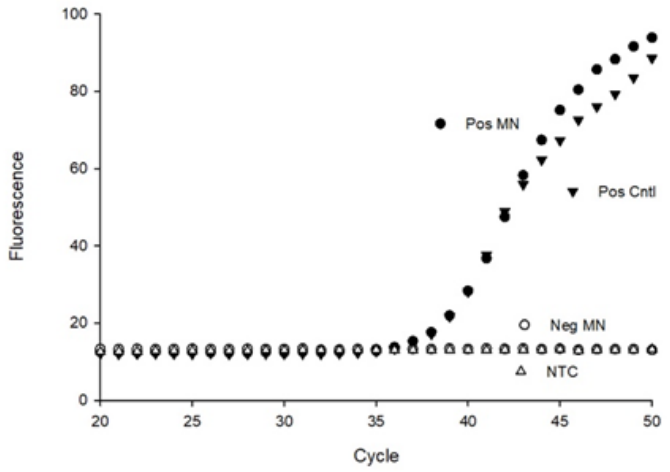

Figure 2: After injecting porcine ear skin with inactivated spirochetes, MN patches were applied to collect bacteria. PCR amplification of bacterial DNA from the patches shows that in just 10 minutes of application, the experimental MN patches (Pos MN) absorbed approximately the same amount of bacteria as the positive control (Pos Cntl).

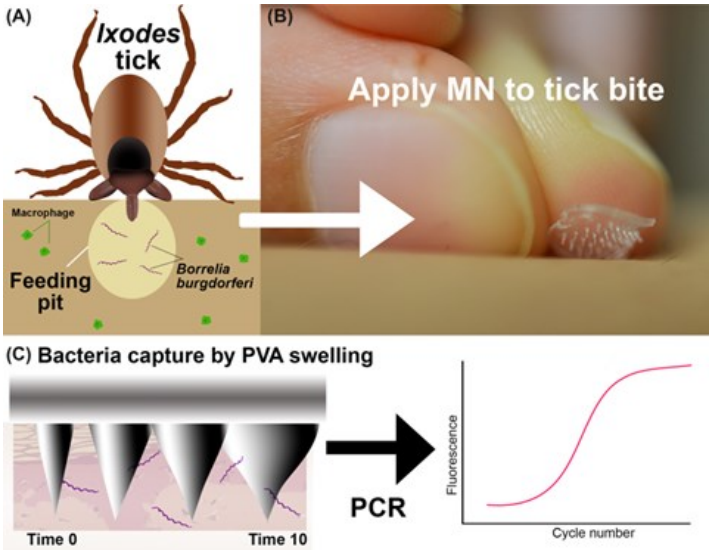

Figure 1: Overview of the bacteria detection method. **(A)** Graphic showing Ixodes tick feeding and inserting *B. burgdorferi* bacteria into skin. **(B)** A MN patch is manually placed onto the skin. **(C)** Swellable PVA MN patch captures bacteria in skin, allowing for direct detection by PCR.

Technology Description

An inexpensive and simple means to collect the bacteria at the site where they are most concentrated may allow for early detection by PCR. We have developed a microneedle (MN) device to sample interstitial fluid and capture bacteria directly from skin— quickly, affordably, safely, and painlessly. After sampling, the MN patch is easily dissolved in water or buffer, and bacterial DNA is detected by PCR. Performance was tested by spiking porcine ear skin with inactivated *B. burgdorferi*, with an approximate 80% recovery of bacteria. With further development, this simple, direct PCR method could be a transformative approach for early detection of the causative agent of Lyme disease and enable rapid treatment for patients while infection is early and numbers of systemic bacteria are still low.

Intellectual Property Status

Patent application has been filed.

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