Improved Diagnostic Tools and Structural Vaccines for Lyme Disease

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Unmet Need
The microbial organism *Borrelia burgdorferi* causes the common infection termed Lyme disease. This infection is transferred to humans by deer ticks and is common in areas of North America and other countries where large deer populations are found. In the U.S., the CDC has estimated that up to 476,000 cases of Lyme disease were diagnosed in 2019, although less than 10% that number are reported to CDC. *Borrelia* infections, which are on the rise the last decade, are highly morbid if not diagnosed early. However, there are no vaccines as yet to protect against *Borrelia* infection, despite renewed recent interest followed market withdrawal of an initial vaccine generated by GSK in the 1990s. Furthermore, current blood tests to diagnose infections rely on few antigenic proteins encoded by the *Borrelia* genome, such that misdiagnosis occurs with some frequency.

Opportunity
Using genetic-based computational and structural approaches, LIMR researcher Sunil Thomas has defined antigenic peptide epitopes encoded by the *Borrelia* genome that offer superior utility for applications to diagnose and prevent infections. Specifically, these epitopes offer accurate and sensitive tools for diagnostic blood tests. Further, they define the basis for a multivalent structural vaccine that can effectively generate the potent immunity desired to prevent or clear *Borrelia* infections. These peptides are not derived from the *Borrelia* gene encoding the outer membrane protein OspA, which has been controversial as a vaccine target. As such, they offer novel agents to create an effective vaccine.

Unique Attributes
The chief unique attribute offer by this technology is the specific *Borrelia* peptide sequences that have been identified, and their antigenic character as immune-recognized epitopes in human. A multivalent structural vaccine composed of these antigenic peptides may offer lower risk compared to other approaches that have taken to date, because it lacks features that have been challenged by other approaches. First, there is no infective agent in the vaccine. Second, there are no antibodies against *Borrelia* encoded proteins in the vaccine. Lastly, there are no sequences from the OspA protein in the vaccine.

Clinical Applications
As noted above, the *Borrelia* peptide sequences that been identified offer two core applications. First, they offer use to potentially improve the accuracy and sensitivity of blood tests to diagnose Lyme disease, based on their antigenic character as targets for the natural antibodies that arise in patients with the disease. Second, they offer use to form the basis for a multivalent structural vaccine that can stimulate protective immunity against *Borrelia* infection.

Stage of Development

On the basis of a small retrospective study of blood specimens from human individuals diagnosed with Lyme disease, these peptides were shown to be recognized specifically by natural antibodies that arise specifically in these patients, as compared to non-infected individuals.

For use in diagnostic applications, the technology is at a pre-501(K) development stage. For use in vaccine applications, the technology is at a pre-IND development stage.

Intellectual Property

US 20220160856 A1. Published May, 2022. "Methods and Compositions for the Diagnosis, Prophylaxis and Treatment of Lyme Disease."

References and Publications

Thomas S. Structure-Based Design of Diagnostics and Vaccines for Lyme Disease. Methods Mol Biol. 2022;2410:411-422.

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