

INTESTINAL BIOMARKER PREDICTS RESPONSE TO TREATMENT FOR INFLAMMATORY BOWEL DISEASE

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Technology Description

Researchers in the Stappenbeck lab have discovered an objective histologic biomarker on intestinal cells that can predict a patient's response to ustekinumab treatment for Crohn's disease or ulcerative colitis. Specifically, the length of microvilli (MV) could provide a companion diagnostic to personalize patient care or could be used to stratify patients in clinical trials.

Although the number of treatment options for inflammatory bowel disease (IBD) is expanding, there is no objective criteria for selecting therapy for an individual patient. Currently, the appropriate medication for IBD (Crohn's disease and ulcerative colitis) is determined through an iterative process of trying a drug and monitoring patient response. MV length in the intestinal mucosa is an empirical biomarker of malabsorption within the digestive tract and therefore offers a potential solution to this problem. A baseline MV length can be determined from a pre-treatment ileal biopsy. Then this value can help predict clinical and endoscopic response to biologic therapy, with normal MV length indicating the therapy is more likely to be effective. This method of selecting IBD treatment could be used to stratify patients in clinical trials for new IBD drugs or to help clinicians manage patients to optimize drug treatment.

Stage of Research - The inventors validated this histological biomarker by retrospectively analyzing biopsy samples from 95 patients who participated a clinical trial of ustekinumab for Crohn's disease. Patients with microvilli at least 1.7 microns long had a significantly greater clinical response to treatment than those with shorter microvilli.

Publications - Van Dussen, K., Li, K., Simpson, K., Claggett, B., Friedman, J., Perrigoue, J., Stappenbeck, T. (2019). [Microvilli length predicts clinical response to ustekinumab in Crohn's patients from the UNITI-2 trial](#), 7(10), 1411-1425.

Applications

- **Companion diagnostic** to determine personalized therapy plan for inflammatory bowel disease (Crohn's disease and ulcerative colitis)
- **Clinical trials stratification**

Key Advantages

- **Objective prediction criteria:**
 - five measurements from 10 villi on standard H + E stained slides reliably determine length of microvilli
 - could shorten time to find effective treatment option

Patents – Provisional Application Filed