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Characterizing Region-Specific Gastrointestinal and Oral Microbiomes in Sjögren's Disease Using Novel Ingestible Mini-Pill Sampling Technology

Abstract: This study will generate the first region-specific gastrointestinal microbiome profile in Sjögren's disease using a validated ingestible mini-pill, establishing whether small intestinal dysbiosis — inaccessible by stool sampling — and oral-to-gut microbial translocation contribute to the systemic immune dysregulation characteristic of SjD. Every published GI microbiome study in SjD relies on stool, which captures only the distal colonic microbiota and misses the small intestine — the primary site of gut-associated lymphoid tissue, Peyer's patches, and mucosal immune priming. We address this critical gap using a novel, passive, 3D-printed ingestible mini-pill (Del-Rio-Ruiz et al., Device, 2024) with pH-sensitive enteric coatings that dissolve at target GI regions and hydrogel beads that autonomously collect and seal luminal content. The device carries IRB non-significant risk designation and is undergoing first-in-human validation in an active NIH R33 dietary intervention trial (R33DK132314). Thirty SjD (ACR/EULAR) patients will each swallow 6 mini-pills — three targeting the upper GI tract and three the proximal colon — while simultaneously providing stimulated and unstimulated saliva, subgingival plaque, and stool. Three aims will be pursued: 1) characterize region-specific GI and oral microbiota in SjD versus 30 matched healthy R33 controls using 16S amplicon and shotgun metagenomic sequencing; 2) quantify oral-to-GI microbial translocation via SourceTracker2 to evaluate the oral-gut axis; and 3) correlate region-specific microbial features with ESSDAI disease activity, salivary flow rate, FACIT scores, and joint assessments. The concurrent enrollment of controls under identical protocols eliminates inter-study batch effects, yielding uniquely rigorous comparative data. Findings will establish the small intestinal microbiome as a tractable research target in SjD and provide the foundation for future R01/P30 applications focused on the microbiome-autoimmune axis.

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