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# Design, conduct and challenges of a clinical trial utilizing elastic light scattering spectroscopy in the thyroid

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Thyroid cancer is the most common endocrine malignancy. The standard of care in the management of a patient with a thyroid nodule is fine-needle aspiration biopsy (FNA) with cytological evaluation. While 5-10% of nodules are malignant, 10-25% of FNAs are indeterminate. Consequently, about twice as many patients undergo surgery for a suspicious lesion that turns out to be benign as undergo surgery for a known malignant lesion. A more accurate molecular and ultrastructural based algorithm would be useful to improve diagnostic accuracy. Noninvasive optical tissue diagnosis mediated by fiber-optic probes can be used to perform non-invasive, or minimally-invasive, real-time assessment of tissue pathology in-situ. Elastic light-scattering spectroscopy (ESS) is a point spectroscopic measurement technique, which is sensitive to cellular and subcellular morphological features. Normal and abnormal tissues can generate different spectral signatures as a result of changes in nuclear size, density, and other sub-cellular features, the optical-spectroscopy equivalent of histopathological readings. ESS is optimal for use in the small-volume area as found in thyroid FNA. An important advantage of ESS is that it provides an objective and quantitative assessment of tissue pathology that may not require on-site special expertise and subjective image interpretation as in conventional histopathology. Here we will describe our experience in the clinical application of elastic scattering spectroscopy in the thyroid.

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