Background: Ovarian cancer, the most deadly female reproductive malignancy, has a high mortality rate because there are very few symptoms in the early stages of disease development that allow for early and/or accurate diagnosis. Most cases are diagnosed at stages when the disease has metastasized, making it much more difficult to treat or cure. Although many advances have recently been made in chemotherapy, surgery and the understanding of the genetics of ovarian cancers, little has changed with respect to mortality. In fact, 70% of women who develop ovarian cancer die from it. Therefore, there is a clear clinical need for a viable screening technique for early detection of ovarian cancer.

Invention: The present invention provides for minimally invasive, inexpensive, and highly effective diagnostic screening for ovarian cancer in women without requiring general anesthesia or surgery. The invention, a miniature optical imaging device called a falloposcope, combines Multispectral Fluorescence Imaging (MFI) and Optical Coherence Tomography (OCT) to generate high-quality images of ovarian tissue that can be used to help determine if the tissue is cancerous. The present invention offers an ideal method for ovarian cancer screening because it is exquisitely sensitive to early neoplastic changes. This technology is minimally invasive, is inexpensive, has been shown in multiple diseases to have high sensitivity and specificity, and provides localization of the cancerous tissue.

Application: This diagnostic technology could either be adopted as a primary screening method in women at risk for developing ovarian cancer, or as a confirmatory method following a positive test result from another type of cancer screening. Ideally, the relatively simple imaging technique, which could be performed under local anesthesia and sedation, is a more acceptable follow-up test. This technology was developed with inexpensive optical components, works in concert with contrast agents for molecular imaging, and can inherently determine the location of the disease.

Advantages: Presently available ovarian cancer screening tools are either high invasive or cannot provide the level of tissue specificity needed to accurately diagnosis ovarian cancer at an early stage. By accessing the ovaries through the fallopian tubes, no incisions are required and the fallopian tube as well as the ovary can be examined. Therefore, this optical imaging device provides the potential for inexpensive and minimally invasive detection of ovarian cancer through a natural orifice – which reduces invasiveness as well as providing full visualization of potential origin sites of ovarian cancer. This instrument could
enable, for the first time, screening for ovarian cancer that would be similar in procedure and invasiveness to a colonoscopy. Therefore, this technology is highly relevant with a tremendous current impact, and remains both critical and high impact for early detection of ovarian cancer under many different future scenarios.

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