Point of care diagnosis for Kaposi’s sarcoma using portable confocal microscopy

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The problem – Please define the dermatologic clinical problem worth solving, the current solutions, and the strengths and weaknesses of the current solutions.

Kaposi’s sarcoma (KS) is the most common HIV-associated malignancy in sub-Saharan Africa. Despite the increasing availability of antiretroviral therapy (ART) in sub-Saharan Africa, the incidence of KS is still staggeringly high - higher than prostate cancer in the U.S. Survival is poor. A diagnosis of KS means patient should be promptly started on antiretroviral therapy (ART). For severe KS (pulmonary or gastrointestinal), which requires chemotherapy in addition to ART, we can’t start chemotherapy without a confirmed diagnosis. Currently, a confirmed diagnosis means a completed skin biopsy, which often takes 4-6 weeks given challenges of the environment. For these patients, a delay in chemotherapy often means death. Other conditions, such as bacillary angiomatosis, can clinically mimic KS. Starting these patients who have suspected but unconfirmed KS on chemotherapy is dangerous and potentially fatal. Therefore, a new point of care diagnostic test is needed for KS that circumvents the need for expensive and resource-intensive dermatopathology. Ideally, the test would be usable in the field, not more invasive than a skin biopsy, and provide accurate and rapid results.

Your solution – Describe how your solution is it different and why is it valuable.

We propose a new diagnostic approach that uses a low-cost smartphone confocal microscope to provide real-time diagnosis of KS. In this method, KS-suspected skin lesions can be imaged in vivo with a smartphone confocal microscope in a short procedural time (expected imaging time < 10 minutes). The smartphone confocal microscope can utilize natural contrast of the tissue to visualize key cellular features.
associated with KS. Confocal images can be immediately sent to an expert confocal image reader over the cellular network for image reading, or an automated image analysis application implemented in the smartphone can be used to render a diagnosis. With this approach, the diagnosis is delivered to the patient in a timely manner and the treatment is initiated while the patient is still at the local clinic.

Clinical hypothesis Summarize the scientific or technical basis of the drug/device/diagnostic/other technology you are developing, and briefly provide evidence that support its approach as useful and feasible.

For KS, (non-portable) confocal microscopy has been successfully utilized as an imaging technique (see Grazziotin et al, "Preliminary evaluation of in vivo reflectance confocal microscopy features of Kaposi’s sarcoma," Dermatology 2010). The smartphone confocal microscope will be realized by our unique imaging approach, termed spectrally-encoded confocal microscopy (SECM). SECM is a reflectance confocal microscopy technique that can acquire cellular images along a line without using any beam scanning device. We have already demonstrated in vivo cellular imaging of esophagus using a small SECM endoscopic device.

Product profile and development plan- Describe the product (i.e. some information of what it is) and what stage it is in (e.g. concept, preclinical, prototyped, closed beta, etc. as applicable). Also please include the next major milestone (and costs to that milestone) in the product’s development.

The low-cost smartphone confocal microscope will be realized by our unique imaging approach, SECM. As mentioned above, SECM is a reflectance confocal microscopy technique that can acquire cellular images along a line without using any beam scanning device. In this research, we will extend the technology for two-dimensional scan-less confocal imaging in conjunction with a smartphone. A small optics module, which contains an SECM imaging optics and a cheap light emitting diode (LED) powered by AA batteries, will be mounted on a smartphone. The SECM optics module, which will be in contact with the tissue, will generate confocal images on the imaging sensor of the smartphone. The confocal images will be saved and displayed in the smartphone real time. The portable device is currently in prototype phase.

Value of your solution – What is your rough estimate of the yearly market revenue potential (and what are some for the basic assumptions underlying that estimate, e.g. this product could be used by X individuals per year, etc.).

In East Africa alone, there are approximately 400,000 new Kaposi’s sarcoma cases a year (based on a population of 150 million, with an incidence of 270 cases per 100,000 population). The target population for this low-cost device is therefore substantial. In addition, there are development opportunities domestically as related to other skin cancers and vascular skin lesions, where immediate, bedside diagnosis would be useful.