



Early results from clinical study presented at major U.S. burn conference

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Accuracies of 92% and 88% in detection of severe thermal burn injury in adults and children, respectively

Article published in Journal of Burn Care and Research on histological burn depth research

LONDON, U.K. AND DALLAS, TX, U.S. Spectral MD Holdings, Ltd. (AIM: SMD), a predictive analytics company that develops proprietary AI algorithms and optical technology for faster and more accurate treatment decisions in wound care, announces that it has presented early clinical results from the Expanded Proof of Concept multi-centre clinical study at three scientific presentations at Southern Region Burn Conference held from 4-7 November, 2021, in New Orleans, Louisiana.

The results of the first multi-center study using Spectral MD's burn imaging technology include 124 adult and pediatric participants. In adult participants, the performance with cross-validation from the AI model for identification of non-healing burn regions showed 92% accuracy, an improvement on the previously reported accuracy of 91% for the DeepView® Wound Imaging Solution in early healing assessment of adults. In pediatric patients, the AI performance showed 88% accuracy, underlining how the technology is responding with significant reliability to variability in the study population.

Compared to the precise and early healing assessment of Spectral's DeepView® Wound Imaging Solution for burn wounds, the current standard of care relies on physicians using a wait-and-see approach of up to 21 days to determine the need for surgery. This results in a higher probability of infections, additional costs, longer hospital stays and over-excision of viable skin.

The Southern Region Burn Conference is one of the largest scientific burn conferences held each year with hundreds in attendance. The titles of the presentations related to Spectral MD's work and the presenters were as follows:

- **“Initial Experience Using Artificial Intelligence for the Assessment of Pediatric Burn Depth.”** – Dr. James H. Holmes IV
- **“Iterative Refinement of a Histologic Algorithm for Burn Depth Categorization Based on 1142 Consecutive Burn Wound Biopsies.”** – Dr. Herbert Phelan
- **“Rise of the (Learning) Machines: Artificial Intelligence for the Assessment of Adult Thermal Burns.”** – Dr. Jeffrey Carter

The Company also announces that a study publication has been published in the Journal of Burn Care and Research, written by Dr. Herbert Phelan, titled “Use of 816 Consecutive Burn Wound Biopsies to Inform a Histologic Algorithm for Burn Depth Categorization”. The study was originally presented at the 2021 American Burn Association Conference and details the years of work performed by Spectral MD and clinical colleagues to characterise burn depth using histologic parameters. The histologic methods being developed through this research are applied to the development of DeepView®'s AI algorithm for burn detection.

Wensheng Fan, Chief Executive Officer of Spectral MD, said: *“The results not only demonstrate excellent AI performance metrics, they also show the technology is responding well to demographic and geographic variability in the study population. As such, we have already bolstered our infrastructure to facilitate expansion of the study to additional sites and have begun enrolling in a larger study to complete AI algorithm development.*

“This is an important milestone for Spectral MD and begins an exciting period where we look to initiate a publication process concerning the results from our clinical studies in both the burn and DFU indications. We look forward to providing further updates from our clinical studies which detail the substantial improvement to the standard of care that DeepView® can deliver for burn and DFU patients.”

Jeffrey Carter, MD, Medical Director of University Medical Center New Orleans Burn Center, said: *“This is an exciting time for Spectral MD and the burn community as we open new sites for the next study phase and begin to share the great results we have already established.”*

Jeffrey Thatcher, Ph.D, Chief Scientist of Spectral MD, said: *“This meeting marks the first time we present results from a multi-center study with the DeepView® burn assessment technology. This study, involving participants aged seven months and older, was critical toward our goal of understanding the use of this technology for both adults and children with burn injuries.*

“We are also pleased to publish research by Spectral MD in the Journal of Burn Care and Research. The publication, written by Dr. Phelan, details a substantial period of histological research by the Company and its clinical colleagues into burn depth. The Journal is the official publication of the American Burn Association, and we look forward to contributing further research in the future.”

The presentation of the early clinical results from the multi-centre clinical study is an important milestone and represents the start of the Company's publication process in relation to the results from its clinical studies in the burn and diabetic foot ulcer (“DFU”) indications. The funding and technical development of the DeepView burn assessment technology has been supported in whole by the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response under contract number 75A50119C00033.

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About Spectral MD:

Using its DeepView® Wound Imaging Solution, an internally developed AI technology and multispectral imaging solution that has received FDA Breakthrough Designation for the burn indication, Spectral MD is able to distinguish between non-healing and healing human tissue invisible to the naked eye. Spectral MD currently is able to provide 'Day One' healing assessments for burn wounds and diabetic foot ulcers with other applications being explored.

Spectral MD has to date received substantial support from the U.S. government with contracts from institutions such as Biomedical Advanced Research and Development Authority, National Science Foundation, National Institute of Health and Defense Health Agency in support of the burn application for its DeepView® solution, with total grant funding received to date from all of these organizations of over \$93 million, including \$40.5 million received in 2021. This grant funding is non-dilutive to our shareholders and the Company believes it validates the important nature of our mission and technology. The Company leverages this funding to support R&D efforts that are applicable to burn, DFU and potentially other indications where DeepView can play an important role in Day 1 wound healing assessment.

The Company has two principal trading subsidiaries, Spectral MD, Inc. and Spectral MD UK Limited.

DeepView®

DeepView® is a predictive analytics platform that integrates proprietary AI algorithms and advanced optical technology for wound healing predictions. It is non-invasive, non-radiation, non-laser and does not require the use of injectable dye. This integration can be characterised into four distinct components: DeepView® imaging, data extraction, AI model building and AI wound healing prediction.

- The DeepView® imaging technology consists of patented, proprietary, multi-spectral optics and sensors that can classify wound tissue physiology and capture the viability of various biomarkers within the skin. The imaging technology extracts appropriate clinical data, processes the image, and displays a comparison of the original image next to an image with a colour overlay of the non-healing portions of the wound. The image acquisition takes 0.2 seconds, and the output takes approximately 20 to 25 seconds.
- The DeepView® data extraction consists of proprietary optics that are able to collect millions of data points from each raw image. This information is then used to build and continually improve the AI model, which is trained and tested against a proprietary database of more than 66.7 billion pixels with an ever-growing input of clinically validated data points.
- The AI algorithm then produces a predictive wound healing assessment in the form of an objective, accurate, and immediate binary wound healing prediction. This prediction is graphically represented to the clinician through a coloured overlay of the original image that annotates the non-healing portion of the wound.

DeepView® is designed to allow clinicians to make a more accurate, timely and informed decision regarding the treatment of the patient's wound. In the case of DFUs, a non-healing assessment would provide the clinician with the appropriate justification to use an advanced wound care therapy on 'Day One' as opposed to waiting 30 days and potentially losing the patient to lack of patient follow-up or risking patient noncompliance with standard wound therapy. For burn wounds, the clinician can make an immediate and objective determination to identify appropriate candidates for surgery as well as determining what specific areas of the burn wound will require skin grafting. DeepView®'s current accuracy for determining the healing potential of burn wounds is 92 percent in adults and 88 percent in children, compared with current physician accuracy of 50 to 70 percent. The current clinical accuracy of DeepView® is 83 percent for DFUs. Both of these accuracy percentages are expected to increase with additional R&D efforts, including clinical studies.