InnovationU

A Startup Case Study: SageSpectra

April 16, 2024

Texas A&M Memorial Student Center | Webinar

АМ

TEXAS A&M

Texas A&M Innovation | The Texas A&M University System 175 Century Square Drive, Suite 200, College Station, TX 77840 Innovation.tamus.edu | 979.246.0500 | @TamInnovation

Welcome



Pete ONeill Chief Innovation Officer Texas A&M Innovation



TEXAS A&M

Panelists



John Hanks Founder and Inventor SageSpectra



<u>Madi Heck</u> Co-founder and CEO SageSpectra



TEXAS A&M



Arterial Disease screening

1



Mission: Redefine healthcare through the fusion of multispectral technology, patient information, and AI, enabling proactive detection, personalized care, and revolutionary monitoring solutions for improved patient outcomes.

Initial Application: Early Screening for Peripheral Arterial Disease to prevent complications and avoid long-term acute care costs.





Peripheral Artery Disease (PAD)

Narrowing or blocking of the arteries that carry blood from the heart to the legs and arms.

Without intervention the outlook is bleak



21% PAD patients have 21% increased risk of heart attack, stroke, hospitalization, or death

Advanced PAD called Critical Limb Ischemia leads the 5year all-cause mortality rates



4



Early Diagnosis

With early diagnosis, treatment is low-cost, simple and effective

Early-Stage Interventions



Results

Reduced mortality risk ranging from **20 to 54%** over 8-year period



Our Solution

SageSpectra is a low-cost, portable device that accurately screens any patient at risk of PAD in <3 minutes.





How it Works





Multiple wavelengths of light projected into tissue measure tissue optical absorption and toe ppg.



Four total measurements on each leg. Each measurement takes ~15s.



Tissue absorption, toe ppg, and patient demographic data are used as inputs to predict PAD.







Validation Trial Results

Table 1: SageSpectra Preliminary Data Set

	n (limbs)
PAD: Monophasic or Biphasic in either Dorsalis Pedis or Posterior Tibial arteries	25
Without PAD: Triphasic in both Dorsalis Pedis & Posterior Tibial arteries	24
Total	49

	n (limbs)
Low ABI≤0.9	13
Normal 0.9 <abi≤1.4< td=""><td>22</td></abi≤1.4<>	22
Non-compressive or ABI>1.4	14
Total	49



Validation Trial Results

Table 2: Proprietary Algorithm Results for Predicting Obstruction¹

	Accuracy
SageSpectra PAD Algorithm (n=49 limbs)	86.5%
Ankle Brachial Index (n=35 limbs)	62.8%

Table 3: Competitor Digital PAD Algorithm Results for Predicting Obstruction

	Accuracy
Competitor Digital PAD Algorithm (n=360 limbs) ²	83.6%
Ankle Brachial Index (n=360 limbs)	75.6%

- 1. Accuracy reported using same k-fold cross validation method
- 2. Non-invasive Detection of Vascular Disease of the Lower Extremity; Clinical Evaluation of QuantaFlo[™] Compared to Doppler and Definitive Imaging, Schaefer, M. et al

Future Potential Use Cases



Tissue Health



Exclusive Licensing Agreement with Texas A&M University

Established partnership with The S.A.V.E. Clinic. Commitment from Espada Vascular, Hospitals of Providence, and Vascular Institute of Phoenix for future clinical trials.

First Feasibility Trial Completed. Next study underway January – April 2024.

Internal funding through licensing and contracting agreements for alternative applications expected to generate \$120k in NRE revenue and additional contracting fees of \$15k-\$30k.

Working Gen 2 Prototype

Two patents:

US 11/847,294 Granted (Jan 2. 2024)

US 18/487,268 Pending



Where Are We Now?

Board



Madi Heck CEO MBA, MEng



Dr. Michel Saint-Cyr CMO MBA, MD Plastic Surgeon



John Hanks Director of Business Dev. 30+ years industry experience



Dr. Amir Zavareh CTO Ph.D. Electrical Engineering





Dr. Lyssa Ochoa
 Official Advisor
 Vascular Surgeon
 Founder – The S.A.V.E. Clinic

Advisors listed have committed their clinics to serve as clinical sites for upcoming SageSpectra clinical trials



Dr. Jeffrey Martinez Unofficial Advisor Vascular Surgeon Founder – Espada Vascular



Dr. Sandeep Rao Unofficial Advisor Interventional Radiologist Hospitals of Providence¹³





Thank You

20M Americans affected by PAD

It's time to help them!

To further the conversation, contact Madi: Madi_Heck@sagespectra.com



Appendix



Competition





16

SageSpectra

Sage**Spectra**





Business Model: Solution as a Service

Targeting Home Healthcare Companies



Customers pay a \$220 subscription per month per device.

*Price is based on COGS and customers' price for services.

Second feasibility trial



Design device for manufacturing & manufacture 10 devices -Proposal & Quote Received from Paragon Innovations



Begin *preparation* for multisite clinical trials (n=300) -Commitment from four clinics to acts as clinical sites

Conduct multisite clinical trials (n=300)

'25

Work towards 510k approval

For Year 2024 activities, SageSpectra is pursuing \$1.25M in funds

510k approval

26 Sta

Start making revenue



References

[1] Yost, Mary L. "The True Prevalence of PAD and the Economics of Major Amputation." Endovascular Today. Bryn Mawr Communications, May 19, 2021. https://evtoday.com/articles/2021-may/the-true-prevalence-of-pad-and-theeconomics-of-major-amputation.

[2] Allison, Matthew A., Elena Ho, Julie O. Denenberg, Robert D. Langer, Anne B. Newman, Richard R. Fabsitz, and Michael H. Criqui. "Ethnic-Specific Prevalence of Peripheral Arterial Disease in the United States." American Journal of Preventive Medicine 32, no. 4 (2007): 328–33. <u>https://doi.org/10.1016/j.amepre.2006.12.010</u>.

[3] Shu, Jun, and Gaetano Santulli. "Update on Peripheral Artery Disease: Epidemiology and Evidence-Based Facts." Atherosclerosis 275 (2018): 379–81. <u>https://doi.org/10.1016/j.atherosclerosis.2018.05.033</u>.

[4] Smolderen K, Heath K, et al. Clinical Research Study Screening for Peripheral Artery Disease: Journal of Vascular Surgery, 06/01/2022: Vol 75, Issue 6, P2054-2064. https://www.jvascsurg.org/article/S0741 5214(22)00340-8/fulltext

[5] Sillesen H, Falk E: Peripheral artery disease (PAD) screening in the asymptomatic population: why, how, and who? Curr Atheroscler Rep, 13(5):390-395. and Hirsch: Peripheral Arterial Disease Detection, Awareness, and Treatment in Primary Care JAMA, 2001: Vol 286: 1317-1324

[6] McRae B, Brown CD. Summary of Safety and Effectiveness for QuantaFlowTM Medical Device. [510(k) number: K1430094]. U.S. Food and Drug Administration. 2022. Available from: <u>https://www.accessdata.fda.gov/cdrh_docs/pdf14/K143094.pdf</u>



References

[7] Schaefer E, Long J, Pollick C. "Non-Invasive Detection of Vascular Disease in the Arteries of the Lower Extremity; Clinical Evaluation of QuantaFloTM Compared to Doppler and Definitive Imaging." Supplement to the Cath Lab Digest. March 2016.

[8] Feringa, Harm H.H., Virginie H. van Waning, Jeroen J. Bax, Abdou Elhendy, Eric Boersma, Olaf Schouten, Wael Galal, Radosav V. Vidakovic, Marco J. Tangelder, and Don Poldermans. "Cardioprotective Medication Is Associated with Improved Survival in Patients with Peripheral Arterial Disease." Journal of the American College of Cardiology 47, no. 6 (2006): 1182–87. <u>https://doi.org/10.1016/j.jacc.2005.09.074</u>.

[9] Jansen-Chaparro, Sergio, María D. López-Carmona, Lidia Cobos-Palacios, Jaime Sanz-Cánovas, M. Rosa Bernal-López, and Ricardo Gómez-Huelgas. "Statins and Peripheral Arterial Disease: A Narrative Review." Frontiers in Cardiovascular Medicine 8 (2021). <u>https://doi.org/10.3389/fcvm.2021.777016</u>.

[10] Pad intervention. CardioVascular Coalition. (2017, April 21). <u>https://cardiovascularcoalition.com/cardiovascular-care/pad-intervention-2/</u>

[11] Jones WS;Patel MR;Dai D;Vemulapalli S;Subherwal S;Stafford J;Peterson ED; (2013, February 5). High mortality risks after major lower extremity amputation in Medicare patients with peripheral artery disease. American heart journal. https://pubmed.ncbi.nlm.nih.gov/23622919/

Questions & Answers



Texas A&M Innovation Future Events

- 10th Annual Texas A&M New Ventures Competition, May 21-22, 2024
- Innovation Connect, Summer 2024
- Innovation Forward "IF" Conference, November 11-12, 2024, Hall of Champions at Texas A&M University



Thank you!

Website: https://innovation.tamus.edu Email: innovation@tamus.edu Social media: @TAMInnovation Office: 175 Century Square Drive, Suite 200, College Station, 77840





INNOVATION