

April 17, 2024 | Colin Miller | Posted In: [Start-Ups](#)

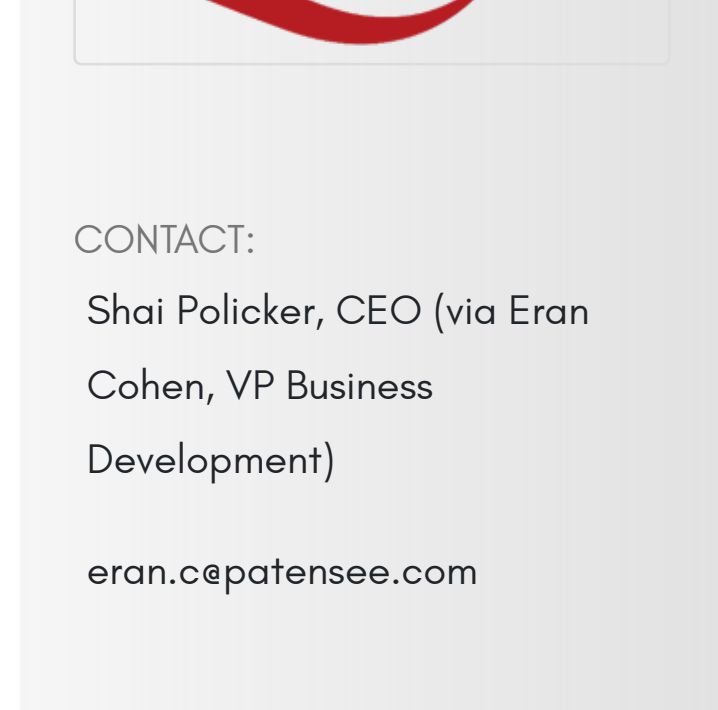
PatenSee Revamps Hemodialysis Monitoring

SHARE | LINKEDIN | TWEET | EMAIL | BOOKMARK



ARTICLE SUMMARY :

Proper monitoring during hemodialysis is crucial for catching complications early before they develop into more costly and health-threatening situations, yet most clinicians lack the time to implement it consistently. PatenSee’s contact-free solution aims to improve monitoring protocols without adding to the clinical workload.



CONTACT:
Shai Policker, CEO (via Eran Cohen, VP Business Development)

eran.cepatensee.com

Israel’s MEDX Xelerator is responsible for launching many of the country’s most innovative medtech start-ups over the last seven years. (See *“MEDX Xelerator’s Strategy for Seeding Device Companies: Intensive Collaboration,”* MedTech Strategist, September 15, 2022.) Led by Shai Policker, the early-stage incubator offers its portfolio companies clinical support from Sheba Medical Center as well as financial backing and other benefits. Policker, whose background is in electrical engineering and business, has been involved in the start-up space for more than two decades, focusing his

efforts on commercialization, clinical trial operations, and R&D, and he now serves as interim CEO of **PatenSee**. Originating from hemodialysis providers’ expressed need for improved monitoring of arteriovenous (AV) fistulas and detecting complications before they become emergencies, PatenSee’s founders were the winners of MEDX’s 2019 entrepreneurial challenge, which it ran in cooperation with its strategic partners. The win was an accolade that came with a million-dollar investment and full incubation package. The company’s prestigious scientific advisory board, which includes key opinion leaders like acclaimed nephrologist Charmaine Lok, MD, is now also a distinguishing factor.

Hemodialysis is a treatment for end-stage renal disease that involves creating a connection between a vein and an artery, known as a fistula, to serve as an access point to the bloodstream to remove waste products from the blood that in healthy patients would otherwise be managed by the kidneys. Policker explains that because veins are more passive return vessels compared to arteries, which are acclimated to high-pressure blood flow, fistulas are often subject to stenosis and residue buildup, leading to obstruction of the vessel or thrombus. In contrast with peritoneal dialysis, which utilizes the abdominal lining for continuous filtration, hemodialysis is generally more suited for patients in precarious condition who require a more active dialytic process.

Clinicians can diagnose stenosis using a “look, listen, and feel” approach, comprising a visual exam, palpation of the access site, and the use of a stethoscope to check for irregular blood flow. Another common diagnostic, known as the elevation test, entails having the patient raise their arm over the height of the heart and checking for delayed fistula drainage, which would indicate obstruction. In practice, however, operational demands in the clinic render these methods unrealistic to implement for large groups of patients. Plus, even secondary testing such as Doppler ultrasound may not detect partial obstructions. “In reality, less than 5% of patients are receiving proper monitoring,” says Policker. Stenosis is initially asymptomatic and relatively unpredictable, and he mentions that some patients develop a complete obstruction within two months, while others go years without an issue.

In the event of a partial obstruction, an interventional radiologist can use a balloon or stent to open the vein. Alternatively, in cases where a clot completely blocks blood flow, the patient would require a thrombectomy, which entails a surgical intervention with a significantly higher risk for the patient as well as much higher costs for the healthcare system. If either intervention is unsuccessful, the fistula could fail, forcing clinicians to create a new one at the extremities or use a central line instead, significantly increasing infection risk. The more attempts the care team must make to reestablish vascular access, the more costs augment and the more patient prognosis declines.

PatenSee’s hemodialysis monitoring solution uses a patented combination of imaging modalities that provide a complete set of monitoring guidelines to accurately triage fistula health, alleviating the operational burden on patients and potentially improving the management of vascular access in these patients (see *Figure 1*). Placed in the waiting room of the dialysis area of a hospital or community clinic, PatenSee’s technology is contact-free, guiding patients’ arm placement with a projected image and performing scans in under two minutes, a fraction of the time that manual monitoring may take. Once complete, data from the scan is stored offline, and the system will flag patients who require further attention, giving them time to schedule an appointment with an interventional radiologist for more thorough testing. Patients can use the device autonomously without the expertise of a clinician, a facet of the system that Policker believes will not only democratize the technology, but also homogenize care quality across clinics.



While the above scenario represents the primary use-case for the device and the majority of its users, the CEO is also keeping apprised of the small but growing home dialysis market and predicts that PatenSee’s monitoring capability will eventually be integrated into home dialyzers. Although CMS has pushed for more patients in the US to move to home dialysis, only 5% of the eligible population currently receives care this way. Several predicate devices exist in the monitoring market today, but Policker says none of them provides a robust enough solution, particularly without contact, compared with PatenSee’s. These devices are mainly wearable imaging or physiological data sensors that do not mimic the complete monitoring battery. In-line monitoring via the access catheter is also possible, but the sensitivity and specificity of this method are inadequate to provide the same degree of early screening as the PatenSee System.

The results of the start-up’s *first-in-human study of 60 patients*, in partnership with Israeli HMO Clalit, were presented at the World Congress of Nephrology in 2022. The next step for PatenSee is completing an international pilot study, followed by a \$10(k) FDA submission. A collaborative multicenter study between PatenSee and dialysis provider **Fresenius Medical Care** was also announced this February and is expected to commence this quarter.

As of February 2022, PatenSee has raised just over \$2 million between its seed round and an additional SAFE (Simple Agreements for Future Equity) instrument, supported by MEDX and its partners, including **Boston Scientific**, and nondilutive matching funds from the Israeli Innovation Authority. The company is currently seeking to raise an additional \$4 million to fund the pilot study, \$10(k) submission, and initial commercial launch. Policker notes that the dialysis space is not as consolidated as it once was now that several patient management companies such as **Strive**, **Interwell**, and **Somatus** have entered the market, and he recognizes the potential for strategic partnerships as the market moves toward a value-based payment structure.

Reimbursement was top-of-mind from the beginning of PatenSee’s journey. As Policker says, “Our goal is not to secure a new kind of payment, but simply to fit into the evolving value-based world of end-stage kidney care.” He recalls a time 5-10 years ago when complications would fall to payors to cover and dialysis providers were not exposed to the consequences of inadequate monitoring, creating a weak incentive, if any, to incorporate better monitoring into the dialysis workflow. In general, dialysis clinics receive a bundled payment from CMS based on the number of sessions a patient undergoes. If a patient has to miss a session due to having to deal with a thrombus or stenosis, it constitutes a loss for everyone except the provider. Now, within the patient management model that Strive and others have introduced, budgets are allocated per dialysis patient per year. Since a large portion of these budgets are devoted to resolving access site issues, preventative monitoring is strongly incentivized.

THE MOST INTIMATE MEDTECH PARTNERING CONFERENCE
APRIL 16-18 | Dublin, Ireland

More from [Start-Ups](#)

- PatenSee Revamps Hemodialysis Monitoring**

Genasence: Pioneering Gene Therapy for Joint Diseases

A Current Affair: MTI Start-Ups' Novel Solutions in Neurostimulation

Auxetics and the Physics of Venous Stenting

Articles from [Colin Miller](#):

- EMERGING MARKETS**

Longstanding No More: MTI Start-Ups Address Longstanding Needs in Women’s Health

November 27, 2023 | Colin Miller | MedTech Strategist

With the common goal of improving the standard of care in women’s health, MedTech Innovator cohort members May Health, Bloomlife, and Madorra have developed novel technologies with a human-centric approach.

[Read Article](#)

START-UPS

NeuroSignal: Democratizing Transcranial Doppler

March 18, 2024 | Colin Miller

BUSINESS STRATEGIES

Newcomers and Incumbents Push for Evolution of Organ Transplant Market

April 05, 2024 | Colin Miller
- START-UPS**

Insight Medbotics: Operating Robotically Inside the MRI

February 07, 2024 | Colin Miller

START-UPS

Happitech: Smartphone Cardiac Monitoring by Design

January 16, 2024 | Colin Miller