Measurement of Flow in a Cerebral Fluid Shunt
New ICD-10-PCS Code Request - 03/09/2021

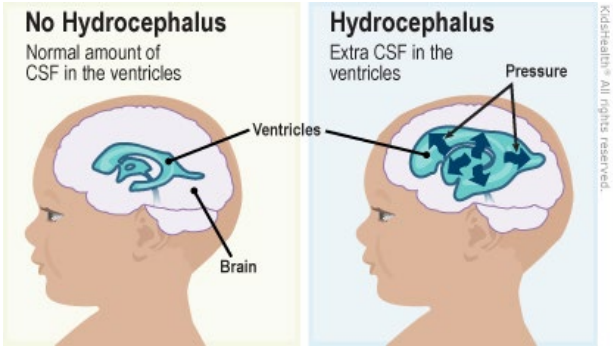
Presenters: Dr. Matthew Potts, MD
Dr. Adam Zysk, PhD

On Behalf of Rhaeos Inc.

Background: Hydrocephalus and CSF Shunt Surgery

Condition

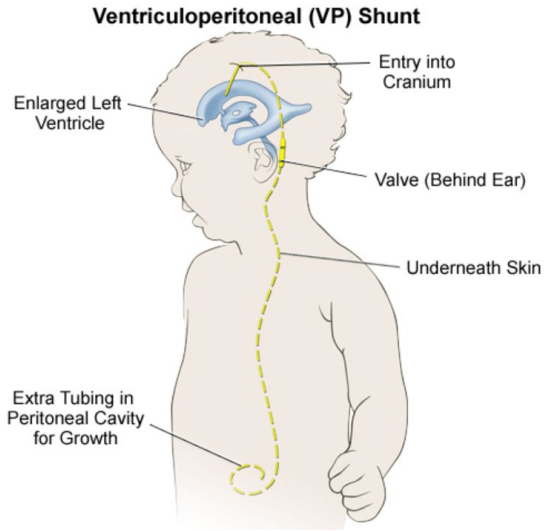
- Hydrocephalus is a condition of excess fluid buildup in the cavities (ventricles) of the brain.
- Hydrocephalus affects over 1 million people in the United States.



Source: https://kidshealth.org/en/parents/hydrocephalus.html

Primary Treatment

- Cerebrospinal (CSF) Shunt Surgery is a surgical procedure to implant a shunt to drain the fluid out of the brain to another site.
- Shunts fail regularly – Imaging (CT Scan/MRI and Shunt Series) currently used to determine shunt functionality.



Source: http://bamb.onmason.com/the-project/

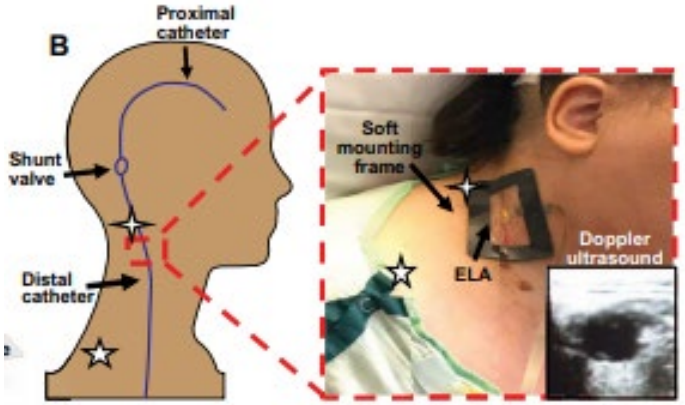
New Procedure Description

- The new procedure assesses flow of CSF through an existing implanted CSF shunt non-invasively using a new device.
- Existing ICD-10-PCS codes do not describe the application of the new sensor, the acquisition of flow data, the wireless transmission of the data, or interpretation of the results.
- The procedure gives important spot check information on the presence of flow in the CSF shunt to a physician in order to assist in the determination of shunt function or malfunction.

Source: Hurley Dan. Skin-Worn Sensor Shows Promise for Noninvasive Detection of Shunt Malfunction in Patients with Hydrocephalus. Neurology Today 2018, 18(24): 13.

Procedural Steps

1. The CSF shunt tube is localized in a skin region where the tube is superficial (typically on or near the clavicle) via visual inspection and palpation by a physician.
2. The wireless electronic device, about the size of an adhesive bandage, is adhered to the skin overlying the shunt tubing.
3. The device is paired wirelessly to a receiver (e.g., a mobile phone or tablet via Bluetooth communication).
4. Measurement is initiated in minutes.
5. Results of flow data are displayed on the receiver.
6. Physician reviews and interprets the result to aid with clinical decision making.



Source: Krishnan SR, Ray TR, Ayer AB, et al. Epidermal electronics for noninvasive, wireless, quantitative assessment of ventricular shunt function in patients with hydrocephalus. Science Translational Medicine 2018, 10(465): eaat8437.

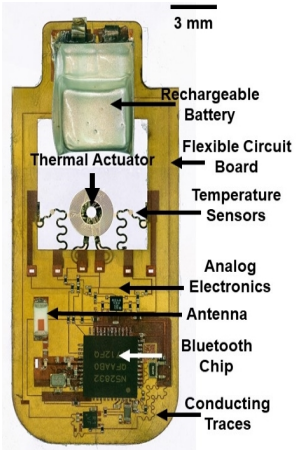
Care Settings

- Post-Operative after shunt placement surgery (to confirm functionality of newly-implanted shunt).
- Pre-Operative for patients undergoing CSF shunt revision surgery (to validate shunt malfunction).
- Emergency Department for patients showing symptoms of shunt malfunction.

New Device Overview

- Adhesive bandage with soft, flexible skin-like electronics.
- Noninvasive wireless wearable composed of thermal actuators and sensors to detect flow.
- Disposable/single-use device.
- Determines flow in shunts in minutes.

Source: Courtesy of the John Rogers Laboratory, Northwestern University



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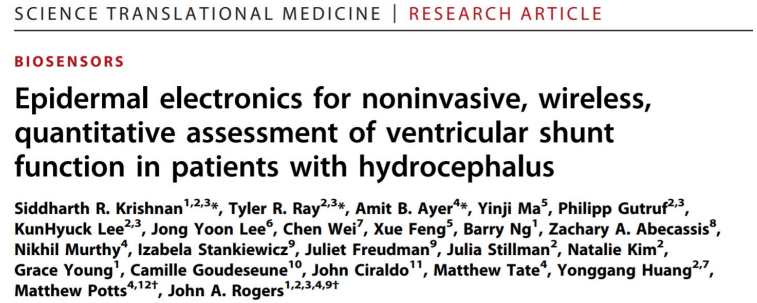
Clinical Data

- New procedure and technology published in Science Translational Medicine and Nature Digital Medicine journals.
- Used on 20+ patients to date.
- Expected to be used in 100+ patients by the end of 2021.
- Potential skin irritation from device adhesive may occur. No complications or adverse events reported to date.

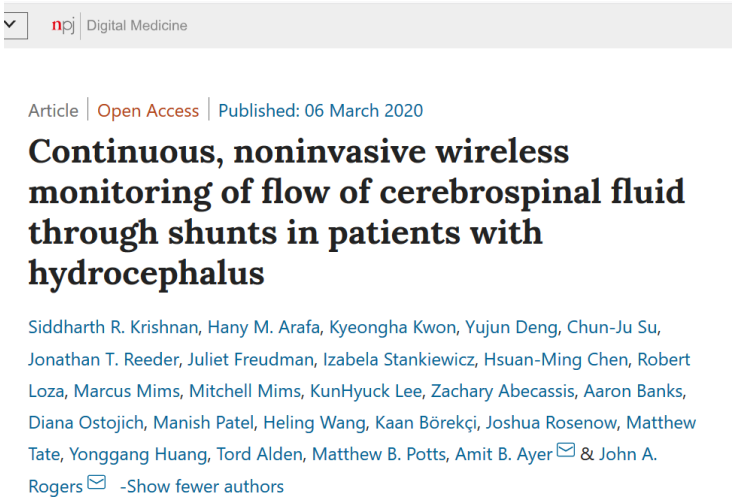


SCIENCE TRANSLATIONAL MEDICINE | RESEARCH ARTICLE

BIOSENSORS

Epidermal electronics for noninvasive, wireless, quantitative assessment of ventricular shunt function in patients with hydrocephalus

Siddharth R. Krishnan[1,2,3]*, Tyler R. Ray[2,3]*, Amit B. Ayer[4]*, Yinji Ma[5], Philipp Gutruf[2,3], KunHyuck Lee[2,3], Jong Yoon Lee[6], Chen Wei[7], Xue Feng[5], Barry Ng[1], Zachary A. Abecassis[8], Nikhil Murthy[4], Izabela Stankiewicz[9], Juliet Freudman[9], Julia Stillman[2], Natalie Kim[2], Grace Young[1], Camille Goudeseune[10], John Ciraldo[11], Matthew Tate[4], Yonggang Huang[2,7], Matthew Potts[4,12†], John A. Rogers[1,2,3,4,9†]



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Continuous, noninvasive wireless monitoring of flow of cerebrospinal fluid through shunts in patients with hydrocephalus

Siddharth R. Krishnan, Hany M. Arafa, Kyeongha Kwon, Yujun Deng, Chun-Ju Su, Jonathan T. Reeder, Juliet Freudman, Izabela Stankiewicz, Hsuan-Ming Chen, Robert Loza, Marcus Mims, Mitchell Mims, KunHyuck Lee, Zachary Abecassis, Aaron Banks, Diana Ostojich, Manish Patel, Heling Wang, Kaan Börekçi, Joshua Rosenow, Matthew Tate, Yonggang Huang, Tord Alden, Matthew B. Potts, Amit B. Ayer & John A. Rogers -Show fewer authors

Procedure Details

- The new procedure is used for the detection of flow in implanted cerebrospinal fluid (CSF) shunts by a qualified physician on patients with hydrocephalus.
- The procedure can be performed multiple times per inpatient admission.
- A description of the procedure performed will be recorded in the physician's notes and is part of the patient's medical record.
- Existing ICD-10-PCS codes do not describe the application of the new sensor, the acquisition of flow data, the wireless transmission of the data, or interpretation of the results.

THANK YOU