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Noninvasive Wireless Epidermal Sensors for Evaluation of Ventricular Shunt Function

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Background

Ventricular shunts are critical in the clinical management of hydrocephalus, which affects an estimated 750,000 patients in the United States alone. Shunt assemblies typically involve two silicone catheters connected upstream and downstream of a regulated valve to drain excess CSF from the ventricular system to a distal absorptive site. While effective in CSF diversion and prevention of the clinical sequelae of hydrocephalus, including seizure, coma, and neurological injury, shunts are highly prone to failure due to fibrinous catheter ingrowth, kinking, discontinuity, infection, or distal malabsorption. Clinical diagnosis of shunt malfunction is challenging due to the non-specific symptomatology of patients, including headache, nausea, and somnolence. Though failure rates for shunts approach 100% in 10-year follow-up, diagnostic tests are limited in their efficacy. MRI is costly and interferes with shunt valve settings, while CT scans expose patients to harmful doses of radiation which have been associated with latent development of hematologic and neurologic cancers. Both of these methods are most useful with prior imaging and have poor accuracy for diagnosis of presumptive malfunctions. Radionuclide shunt patency studies (RSPS) and shunt aspirations have poor diagnostic accuracy and are uncomfortable to patients. Newer entrants have attempted ice mediated cooling, with equivocal clinical studies alongside patient discomfort. More accurate and non-invasive methods of shunt failure diagnosis are necessary.

Research Objectives

We demonstrate the use of a simple, non-invasive sensor platform providing a low-cost and comfortable means for the assessment of flow through ventricular shunts. This is enabled by materials science advances allowing for development of soft, stretchable , 'epidermal' electronics capable of precise heat mapping on skin.

Methods

Device Design

Metallic, resistance temperature detectors (RTD's) are rendered in ultrathin formats (<100 nm) allowing millikelvin precision temperature measurements and simultaneous low-power Joule heating of mechanically coupled tissue. The combination of targeted heating and sensing allows for measurements of transient tissue thermal response to directly yield skin thermal transport with established algorithms. Strategic configurations of these sensing and actuating elements can generate heat maps tracking thermal anisotropy induced by blood vessels or fluid flowing through subdermal implants like catheters. Novel algorithms combine finite element analysis with analytical scaling laws to yield quantitative flow rates. This allows for over 100, individually addressable sensors to create detailed heat maps measuring flow in subdermal ventriculoperitoneal (VP) shunts in hydrocephalic patients.

Study Design

Patients were recruited from the neurosurgical practice of Northwestern Memorial Hospital in 2017. 5 patients were selected undergoing de novo shunt placement or during evaluation for presumptive shunt malfunction. Patients underwent sensor measurement after shunt placement, prior to shunt revision, and after shunt revision when applicable. Sensor readings were obtained on locations on and off of the shunt tubing for negative control. Measurements were performed at the level of the clavicle, where tubing is most superficial, then processed and compared with ultimate clinical course.

Table 1: Patient Demographics

Trial	Underlying Condition	Age	Sex	Malfunction Present	Flow Detected (pre-intervention)	Flow Detected (post-intervention)	Imaging Correlate	Skin Irritation
1	Aneurysmal subarachnoid hemorrhage	66	F	N	Y	N/A	N/A	N
2	Chiari I malformation	53	F	N	Y	N/A	N/A	N
3	Pseudotumor cerebri	36	F	Y	N	Y	Y	N
4	Glioblastoma multiforme	32	M	N	Y	N/A	N/A	N
5	Glioblastoma multiforme	58	F	Y	N	Y	Y	N
6	Post-hemorrhagic	30	F	Y	Y	N/A	Y	N

Figure 1: Sensor Design

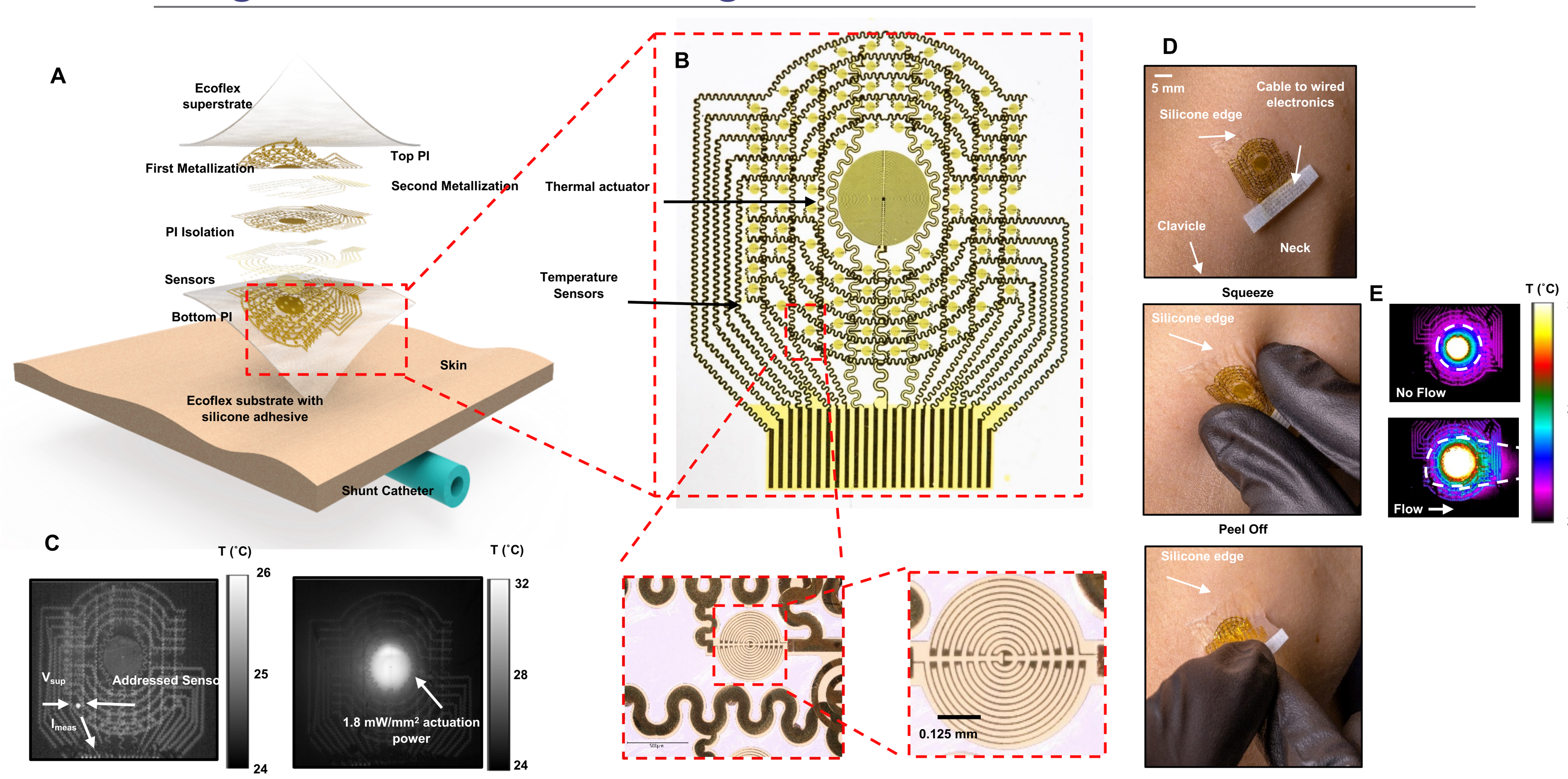

Figure 1. Soft wearable device for the evaluation of shunt functioning. A. Exploded view illustration of 100-sensor device over skin with underlying shunt catheter. **B.** Optical micrograph of device, illustrating sensors **C.** Infrared (IR) thermographs illustrating addressing of an individual sensor (left), and thermal actuation from central heater with 1.8 mW/mm2 actuation power. **D.** Optical images of device on neck, over location of shunt, under different deformation modes. **E.** IR thermographs with color and contrast enhancement showing thermal isotropy in the absence of flow (top) and anisotropy in the presence of flow (bottom), with flow going towards the right of the page.

Results

5 patients with existing or newly placed shunt systems with varying pathologies were evaluated in a clinical setting. Patient 1 was initially assessed prior to corrective surgery, and as in Fig. 2, clearly had a shunt malfunction, consistent with ELA measurements (0.01 ∓ 0.01 ml min-1). Measurements made after a surgical revision revealed a flow rate of 0.06∓ 0.02 ml min-1. Patients 2 and 3 were not suspected of shunt malfunction and exhibited flow rates of 0.36 ∓0.04 ml min-1 and 0.13 ∓0.02 ml min-1 respectively, well within established ranges for healthy CSF flow. Patient 4 was initially measured to have occluded flow (0.013 ∓0.002 ml min-1). The patient had experienced severe and prolonged constipation for the past week and clinically deteriorated due to a likely pseudo-obstruction. After administering a rigorous bowel regimen, the patient's mental status improved, and a subsequent measurement revealed healthy flow (0.16 ∓ 0.02 ml min-1). Patient 5 was suspected to have shunt malfunction, and thermal measurements revealed highly occluded flow (0.027∓0.005 ml min-1), which was later surgically confirmed.

Figure 2: Clinical Application

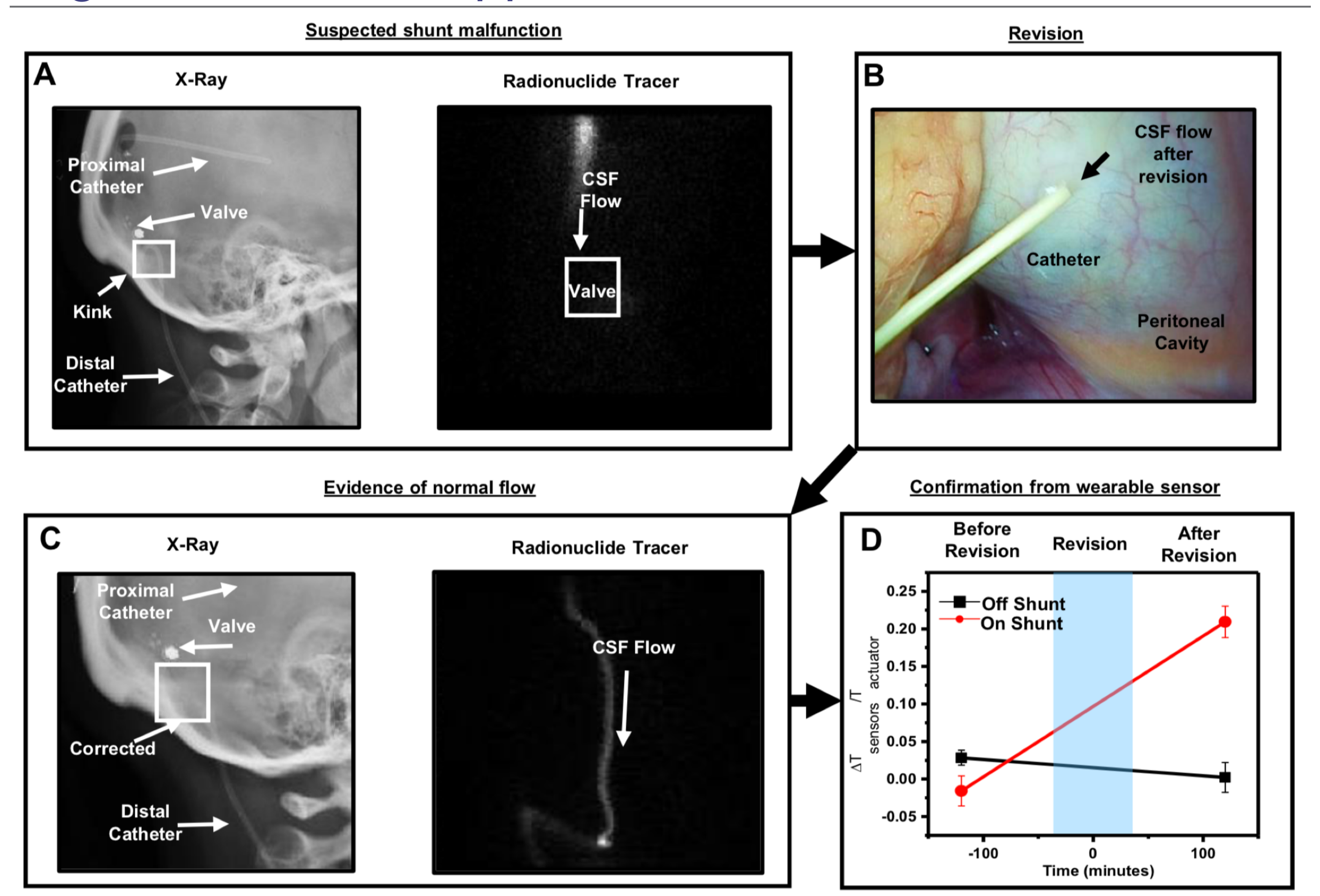

Figure 6. Case study of patient with shunt malfunction. A. X-Ray and radionuclide tracer showing kinking and occlusion of catheter. **B.** Optical image of patient's peritoneal cavity immediately after surgery showing flow in repaired shunt. **C.** X-ray and radionuclide tracer confirming working of repaired shunt. **D.** ΔTsensors/Tactuator measured by ELA before and after revision, at locations over (on) and adjacent to (off) shunt, before and after revision, confirming results from X-Ray and Radionuclide tracer.

Conclusions

Noninvasive thermal detection of shunt flow may be a valuable adjunct in the diagnosis and treatment of ventricular shunt malfunction. Larger scale studies are required to determine efficacy compared to standard of care diagnostic modalities.

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