Wireless Pressure Sensor System for Intracranial Pressure Monitoring

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Healthy Aims Partner
Hydrocephalus describes state of excessive accumulation of CSF within the fluid system of the head causing high intracranial pressure.

- Therapy: draining CSF from the CNS by shunts
- NPH market: 375,000 cases each year in the U.S., $500 Mio market size
- Approx 40 per 100,000 Individuals have shunts in place
- Shunt failure
  - 40% shunts fail in 1st year, 50% by 2nd year
  - Shunts are revised about two times in the first ten years of use per patient!
- There is currently no practical way to measure shunt performance in vivo!
ICP monitoring in the management of severe head injury

Today’s techniques use strain gauge tip transducers and intraventricular catheters

Main pitfalls of today’s techniques

<table>
<thead>
<tr>
<th>Tip transducer</th>
<th>Increasing drift over time</th>
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<tbody>
<tr>
<td></td>
<td>High risk of infection</td>
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<td></td>
<td>Reduction of patient mobility</td>
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<table>
<thead>
<tr>
<th>Intraventricular catheter</th>
<th>High risk of infection</th>
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<tbody>
<tr>
<td></td>
<td>Catheter occlusion</td>
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<td>Needs reposting of transducer level with change in head position</td>
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Neurosurgical Applications

1. ICP monitoring in the clinical management of severe head injury and other conditions causing high ICP
   - Alternative approach to conventional tip transducers

2. Continuous monitoring of ICP in hydrocephalus patients
   - Monitor shunt performance in-vivo
   - Therapy optimization

3. Closed-loop hydrocephalus shunts
   - Feedback-controlling
   - Event-driven therapy
Requirements

- Miniaturized and flexible for minimal invasive delivery
- Wireless communication
- No battery or internal power source
- Highly biocompatible
- Wave form analysis
- Minimal drift and temperature stable
- Easy measurement at home
System Overview

Interface
Modulation
Voltage regulator
AC
DC
Power
RF-transmitter
Demodulator
Pressure
Interface
Signal processing
Reference
Pressure sensor
Internal telemetry unit
Modulation
External telemetry unit
Wireless power and data transmission
Skin
Base station
Interface
Pressure sensing tip
Interface
System Overview (Cont.)

Inductive coupling

RF communication
Prototypes

Flexible substrate

Electronics FC/SMD on flex

Encapsulation into polymer
Device Characteristics

- Telemetric powering and data read-out
- Intraventricular or parenchymal measurement
- ‘Drift-free’ capacitive pressure sensor
- Temperature stable readings
- Dynamic measurement possible
- Easy to insert and position; flexible
Device Benefits

- Scalp barrier reduces risk of infection
- Minimal drift of sensor
- Prolonged monitoring possible
- No replacement required
- Independent from shunt therapy
- Home monitoring
- Therapy control and optimization
Development Roadmap

Clinical trials and regulatory approval process
Frenchay Hospital, UK

2nd prototype
System optimization and Design validation

Bench testing
System design verification, in bench tests and animal model

1st prototype
SMT & FC on flex circuit; Polymer encapsulation & Biocompatible barrier coating

Functional demonstrator
Complete assembly: SMT & FC on flex circuit

Spin-off applications

EU Market launch

P1 | P2 | P3 | P4 | P5 | P6 | P7 | P8
---|---|---|---|---|---|---|---
2004 | 2005 | 2006 | 2007

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Spin-Off Applications

- Monitoring endoluminal stent-grafts in abdominal aortic aneurysm repair
- Home monitoring of patients suffering from congestive heart failure
- Wireless monitoring of urinary bladder pressure
- …
- Feed-back systems for gentle control and therapy-optimization
Conclusion

- Implantable telemetric sensor systems will be of significant value for cost-effective continuous monitoring of therapeutic procedures even under everyday life conditions.
- Close collaboration with clinical end-users guarantees development closely along the market needs and medical requirements.
- High integration of technology partners during development enables the introduction of new add reliable products.
- First prototypes have raised high expectations and are currently being validated in bench tests.
- Opportunity for new commercial partner
Thank you

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