A Low-Cost In-Line Device for Early Detection of Peritonitis in Peritoneal Dialysis Patients

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Problem:
High infection rates in PD patients
- Over 26,500 peritoneal dialysis (PD) patients in the US
- Affects nearly 13% of PD users annually
- Only preventative measures are strict sanitary practices
- Subjective infection symptoms lead to lengthy detection times

Consequence:
- Scarring prevents patients from using PD
- Responsible for the deaths of approximately 16% of PD patients
- Affects nearly 13% of PD users annually
- Hospitalization costs from severe peritonitis are $100 million per year in the US
- PD can be used for up to 10 years, but patients often switch to HD after 2-3 years due to repeated episodes of infection

Solution:
- Detect peritonitis before patient awareness
  - Uses optical methods to detect infectious levels of white blood cells (WBCs) in dialysis waste fluid
  - Automatically measures and reports the patient’s WBC count
  - Minimizes scarring of the peritoneum

Benefits:
- Earlier treatment intervention
- Reduces acute hospitalizations and associated costs
- Minimizes scarring of the peritoneum
- Improves PD longevity
- Reduces burden on patients and caretakers to evaluate symptoms

Our Solution: OpticLine

2-step set-up

Results

OpticLine Concentration Determination

<table>
<thead>
<tr>
<th>Calculated Concentration (WBCs/mm³)</th>
<th>Effluent Fluid Concentration (WBCs/mm³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy</td>
<td>0</td>
</tr>
<tr>
<td>Intermediate</td>
<td>100</td>
</tr>
<tr>
<td>Infected</td>
<td>200</td>
</tr>
</tbody>
</table>

We tested OpticLine’s ability to count WBCs in flowing PD effluent fluid dosed with known WBC concentrations ranging from 0 to 300 cells/mm³. Our results (shown with ±SEM) indicate that OpticLine is able to accurately calculate WBC concentrations in conditions representative of its intended use. OpticLine can distinguish between healthy and pathological concentrations of WBCs with extremely high significance (p < 0.0001), suggesting with confidence that it will be a useful tool for aiding diagnosis.

Conclusions
We have designed, built, and validated a device that is capable of detecting peritonitis before patient awareness, and can be easily integrated with the current PD set-up in under 30 seconds. Early detection of peritonitis can reduce peritonitis-related death rates and acute hospitalization among PD patients, and increase the amount of time patients can remain on PD by reducing peritoneal scarring. We hope that OpticLine will be integrated into standard PD set-ups as part of routine practice.

Currently, a majority of incoming dialysis patients are hesitant to use PD because of the risks of infection. If widely adopted, we believe this device will increase the attractiveness of PD and result in a shift away from hemodialysis. This will be crucial for fulfilling the 2019 executive order to have 80% of new ESRD patients in 2025 receiving either at-home dialysis or a kidney transplant.

Future Directions
For further validation, clinical trials could be conducted to test OpticLine during patients’ PD sessions to inform usability and help identify additional effluent solutes that could confound our current WBC detection algorithm. Cloud-based methods for information transmission can be developed to streamlines physician-patient communication, such as a smartphone application that displays WBC counts over time. The application can also be used as an educational resource for PD patients by displaying daily reminders for best sanitary practices and linking to outside educational sources. Future work also includes adapting the device to accommodate PD patients who use continuous ambulatory peritoneal dialysis (CAPD), in which the OpticLine viewing chamber could be integrated right above the CAPD drain bag.

References
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6. White House
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