Validation of an Acidity Sensor for Early Periprosthetic Joint Infection Detection

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Summary

Periprosthetic joint infection (PJI) causes over 2% of implants to fail, leading to severe complications and revision surgeries. A key indicator of PJI is a decrease in synovial fluid acidity. To improve early PJI detection, this study aims to validate an acidity sensor for continuous long-term monitoring of the synovial fluid following implantation. The UriMoni™ system acidity sensor's performance was tested under simulated foreign body response conditions. Testing involved solutions with varying protein compositions under different flow rates, temperatures, and durations. Preliminary results showed stable sensitivity, but reproducibility and response time declined over longer periods. These findings are promising evidence that the system is capable of real-time infection detection *in vivo*.

Introduction

Periprosthetic joint infection (PJI) causes over 2% of implant failures [1]. Early detection can reduce complications and delay or prevent revision surgeries [2]. A key indicator of PJI is a decrease in joint fluid acidity from approximately a pH level of 7.4 to 6.7 [3, 4]. To improve early PJI detection, Wijayaratna et al. described a hydrogel-based pH sensor placed in the joint that can be read using X-ray imaging [4]. However, this approach is limited to periodic measurements rather than continuous monitoring. This study aims to validate a pH sensor for continuous long-term *in vivo* monitoring of the synovial fluid following implantation. Specifically, studying the effects of protein adhesion, due to the foreign body response, on the sensor characteristics: sensitivity, reproducibility, and response time and comparing this to the required characteristics for *in vivo* use.

Materials & Methods

The acidity sensor which was tested is part of the UriMoni™ system (Paramedir, NL). It was tested in four different solutions: phosphate buffered saline (PBS) as the control, a combination of bovine albumin (BAl) and PBS, porcine gastric mucin (PGM) and PBS, and a combination of all three (BAl, PGM and PBS). The experiments were performed under three different conditions: 0.3 mL/hour fluid flow at room temperature, static fluid at room temperature, and static fluid at 40°C. Tests were conducted at 1, 2, and 3 days for all conditions, and 21 days for experiments with fluid flow. Before and after each test a calibration of the system was performed using three buffers with a pH level of 4.01, 7.00, and 10.01 (Thermo Fisher Scientific, USA). All tests were performed three times. From each test the change in sensor characteristics was assessed by comparing the calibrations done before and after each test using the software Calibration 19 (Paramedir, NL). The accuracy needed to distinguish between a healthy and infected joint is 0.1 decade of pH.

Results and Discussion

The preliminary results showed a mean sensitivity of the first calibration (when the sensor is clean) of 55.8mV/decade. The sensitivity differed marginally across conditions, with the highest variance being -4.7 mV/decade for the fluid flow tests after 21 days and +5.4mV/decade for the static tests after 3 days. This translates to respectively a difference of -0.084 and +0.097 decade from the actual value. Which means the reproducibility decrease over time, but the largest variance found is smaller than the necessary accuracy described earlier. The change in response time for all tests with a duration of 1, 2, and 3 days at room temperature varied at most +/-40 seconds from the PBS group. For the 21 days experiment and the 3-day experiment at 40°C the average response time increased with respectively 154 and 135 seconds for the BAl, PGM and PBS group compared to PBS.

Conclusions

The preliminary results indicate that the UriMoni™ system's reproducibility and sensitivity stay sufficiently accurate over time, but the response time increases to a maximum of 200 seconds, after protein adhesion while under the specific *in vitro* conditions used. Even with this slower response, the indication of infection will be faster than using the most used indicator: patient reported pain. Additional studies are needed to confirm the sensor's performance under a broader range of biological processes. After which it could be further developed for integration into implants for early infection detection.

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