Improved Detection of Clinically Relevant Wound Bacteria Using Autofluorescence Image-Guided Sampling in Diabetic Foot Ulcers

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INTRODUCTION
Chronic wounds negatively affects patient quality of life and strain already burdened global health care systems. Standard of care for diagnosing wound infections involves bedside assessment of clinical signs and symptoms (CSS). In CSS-positive wounds, identification and quantification of bacterial species and antibiotic susceptibility are achieved by wound sampling. Standard Levine technique swabbing samples the wound bed, however treatment-relevant bacteria in the wound periphery or other regions are not collected or identified. Moreover, microbiology reports are typically not available for 3-5d after swabbing, at which point the biology and bioburden of the wound is no longer the same. In cases of asymptomaticity, CSS are insufficient for identifying bacterial loads and early opportunities to treat and improve outcomes are missed. The clinic need to ameliorate microbiological sampling. CSS plus Levine techniques swabbing of the same wound. During the clinical assessment of DFUs compared to standard K2 device to visualize bacteria and guide wound swabbing.

To evaluate real-time autofluorescence (AF) imaging using the handheld K2 device:
- detects clinically significant moderate and/or heavy growth of bacteria based on endogenous red AF
- more accurately samples wounds compared to standard of care (78% vs. 52%), and
- performs well as a diagnostic test (DOR = 7.67, p = 0.00022)

AF imaging allows for a more objective assessment of wound bioburden, making it more accurate and reproducible between different users at the point-of-care.

FUTURE PLANS
Prospective randomized controlled trial to evaluate the effect of AF-guided intervention (guided-swabbing and -debridement) on complete wound healing at 12 wks.

TABLE 1. Participant & sample summary

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>CSS (n = 27)</th>
<th>AF Imaging (n = 27)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TP</td>
<td>8</td>
<td>7</td>
<td></td>
</tr>
<tr>
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<td>3</td>
<td>2</td>
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<tr>
<td>TP</td>
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Sensitivity = 0.73 (0.41,0.91)
Specificity = 0.58 (0.54,0.91)
Accuracy = 0.52 (0.34,0.74)
DOR (adj.) = 3.07 (0.93, 10.14)

For CSS-/AF+ swabs:
- Adjusted for repeat visits within a patient.
- Not including swabs with P. aeruginosa only.

OBJECTIVE
To evaluate real-time autofluorescence (AF) imaging using the K2 device to visualize bacteria and guide wound swabbing during the clinical assessment of DFUs compared to standard CSS plus Levine techniques swabbing of the same wound.

METHODS
Prospective single centre trial in 29 patients with 31 DFUs. CSS positives were swabbed at 7 days. Up to 4 swabs were taken from wound areas not identified as positive for CSS of infection. Swabs were obtained at a patient’s initial visit (n = 128 swabs) from the wound center or periphery using CSS or AF imaging, respectively. DOR calculated for all visits (n=128 swabs).

CONCLUSIONS
1. There is a clear unmet need for improved standardized and objective methods for identifying infected wounds and guiding sampling (Levine, z-technique, or biopsy) at the point-of-care.

2. AF imaging of DFUs performed at the bedside using the handheld K2 device:
- detects clinically significant moderate and/or heavy growth of bacteria based on endogenous red AF
- more accurately samples wounds compared to standard of care (78% vs. 52%), and
- performs well as a diagnostic test (DOR = 7.67, p = 0.00022)

3. AF imaging allows for a more objective assessment of wound bioburden, making it more accurate and reproducible between different users at the point-of-care.

4. AF imaging directs clinicians to swab in wound areas not typically targeted by standard of care.

5. AF imaging is ~7x more likely to indicate a swab is required (red AF) when moderate/heavy growth of bacteria is present than it is to indicate that a swab is required in an area of no/occasional/light bacterial load in a wound.

SUPPORT
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