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Wound Status Early Outcome Sensor and 3D Construct Development

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14. ABSTRACT Early identification of the specific proteins, which indicate delayed healing are critical to long-term success of the patient and the development of new treatments. It is the objective of this research to correlate changes in the proteome of wounds with clinical outcome and develop technology to sense these changes. Protein Imprinted Xerogels with Integrated Emission Sites (PIXIES) and porous polymer photonic bandgap (PBG) structures are being integrated to sense the wound bed in real time. Flexible structures have been developed to conform to the anatomy of the wound bed.					
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INTRODUCTION

Early identification of the specific proteins, which indicate delayed healing are critical to long-term success of the patient and the development of new treatments. It is our hypothesis that real time sensing of the wound proteome can be used to predict wound outcome, resulting in tailored treatment that improve acute and chronic wound healing. The focus of this proposal is to correlate protein targets and wound outcome and develop a technology that can sense the microenvironment in acute and chronic wounds.

BODY

Statement of Work

Technical Objective 1:

Develop technologies for sensing multiple proteins in the wound microenvironment, in real time.

Subtask 1.1 Develop xerogel-based elements.

Subtask 1.2 Develop PBG-based sensor platforms.

Subtask 1.3 Sensor design and evaluations using wound fluids

Technical Objective 2:

Test the suitability of our technology for the detection of multiple proteins from acute and chronic wounds in vitro and in vivo, and correlate results with clinical outcomes.

Subtask 2.1 Collect fluid from subjects with pressure ulcers.

Subtask 2.2 Collect samples from wounds in porcine model

Subtask 2.3 Proteomic analysis of wound fluid

Technical Objective 1:

Subtask 1.1 Develop xerogel-based elements. Completed.

Subtask 1.2 Develop PBG-based sensor platforms. Completed

Subtask 1.3 Sensor design and evaluations using wound fluids

Task is in progress. Delayed enrollment of human subjects has delayed the completion of this task. Enrollment is ongoing, an additional site has been added to increase enrollment.

Technical Objective 2:

Subtask 2.1 Collect fluid from subjects with pressure ulcers.

Enrollment of human subjects is improving. The modification to the inclusion criteria and the addition of a site have increased the rate of enrollment significantly.

Subtask 2.2 Collect samples from wounds in porcine model Completed

Subtask 2.3 Proteomic analysis of wound fluid

The task has been delayed due to slow human subject enrollment. We anticipate beginning the broad survey analysis the first quarter of 2014 and continuing with analysis as the year progresses.

The current research is novel with respect to current published research in the field. There are no published studies utilizing PIXIES to evaluate the biochemistry of wounds during healing. Differential protein expression between healing and non-healing pressure ulcers has identified proteins, which may serve as indicators of wound healing. It is anticipated that some of the proteins identified will be significant with regard to our understanding of the healing of chronic wounds, as well as serving as potential biomarkers of healing. These biomarkers will serve as the basis of the array for the technology for sensing the wound bed in real time.

KEY RESEARCH ACCOMPLISHMENTS

- Xerogel-based sensor elements developed.
- PBG-based sensor platforms developed.
- PIXIES platform developed and verified for cytokine detection of both *in vitro* and *in vivo* (thermally injured normoglycemic pig) wound fluids.

REPORTABLE OUTCOMES

- Pilot studies (not funded by this award) are being conducted to evaluate genomic methodology to identify genes involved with proteins present in healing and non-healing wounds. Sample type (fluid vs. tissue) is also being assessed. This line of inquiry will build on the results from the current study and hopefully lead to a better understanding of the non-healing wound.

CONCLUSION

The development of a technology to real-time sense the proteome of a wound bed is ongoing. The fabrication of flexible sensors is significant in the development of a point of care sensing device. The evaluation of wounds in a porcine model allows refinement of the system while the future enrollment of human subjects will allow confirmation for the relevant proteins for the sensing platform for this novel technology. Ultimately this work may allow the development of personalized wound care based on the real-time characteristics of the wound.