Diagnosis of Fracture Related Infection

KEYWORDS

- ❑ EARLY DIAGNOSIS
- ❑ PROTEIN BIOMARKERS
- ❑ SPECTROSCOPIC MARKERS
- ❑ FRACTURE INFECTIONS
- ❑ INFRARED SPECTROSCOPY

AREA

- ❑ BIOMEDICAL

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Patent Type
Patent for invention

Co-Ownership
Sapienza 33,3%, Purdue University 33,3%, Indiana University 33,3%

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Industrial & Commercial Reference
Biomedical applications and clinical diagnostics. Possible extension also to the prosthesis and implants sector.

Time to Market
TRL 3 – experimental proof of concept. TTM could be 1.5/2 years.

Availability
Licensing, Research, Development, Experimentation, Collaboration, Start-up and Spin-off.

Fig. 1 X-ray of patient that developed fracture related infection in the leg that had been repaired with metallic implants.

Fig. 2 X-ray of a patient that had fracture above the ankle that had been repaired with bone plate and screws and developed a fracture related infection.

Abstract
The invention applies the discovery of a combination of biomarkers that accurately identify the presence of a fracture-related infection (FRI). FRIs are generally seen in patients after surgery to introduce, replace or adjust an implant and their identification for subsequent treatment requires analysis of a blood sample, imaging, biopsy from two separate locations, tissue culture and histological analysis. The invention provides a method for detecting an FRI by analyzing a blood sample and quantifying the concentration of some proteins or recording an IR spectral profile.

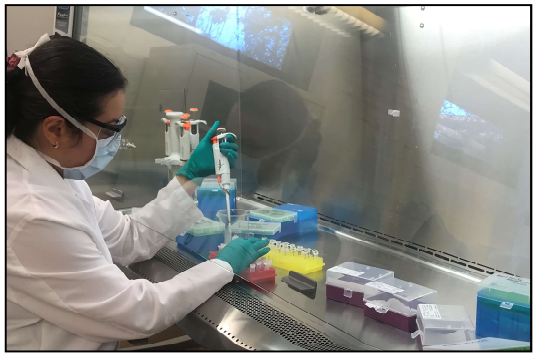

Fig. 3 Patient blood samples being processed for spectral analysis.

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Diagnosis of Fracture Related Infection

Technical Description

Embodiments of the invention include a system for detecting an FRI using antibodies, spectroscopic profiles or both, as well as methods for treating patients who have been identified as having an FRI.
To simplify and reduce the number of tests required to diagnose an FRI, the invention provides a method for detecting and analyzing biomarkers with specificity for FRI. In one implementation, the method involves the determination of some protein biomarkers. Each biomarker can be detected at a concentration threshold above or below a control concentration.
In another embodiment, the spectroscopic profile in the mid infrared (MIR) of a plasma sample can be used through the construction of multivariate predictive models.

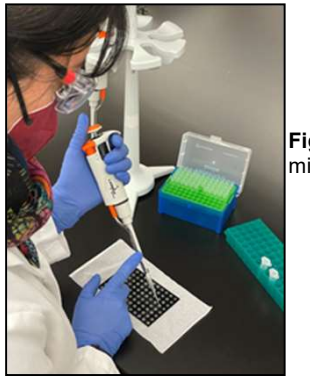

Fig. 4 Sample application on microplate.

Technologies & Advantages

Fracture infections are a serious complication following bone injuries, the incidence of which varies widely depending on the injury. Despite the significant socio-economic impact, the ability to diagnose FRI remains a challenge. Infection work-up is largely based on history and physical examination, white blood cell count (WBC), erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), radiographs and occasionally on advanced imaging. Unfortunately, these diagnostic tools are of limited use.
Furthermore, only a few studies have evaluated other biomarkers, such as the cytokine IL-6, which, however, proved insufficient in terms of both sensitivity and specificity.
The invention represents a method capable of accurately detecting a fracture-related infection by means of biomarkers with high specificity and sensitivity. Furthermore, the spectroscopic implementation represents a potential diagnostic screening tool for the point of care, thanks to the advantage of not requiring adjuvants and the greater cost-effectiveness.

Applications

With regard to possible applications, the main target is the early diagnosis of the onset of fracture-related infections, possibly already during the postoperative course after surgery to introduce, replace or adjust an implant. Therefore, the main applications all fall within the biomedical-diagnostic field. Furthermore, although the approach is specific for the diagnosis of FRI, the invention lends itself to being generalized and extended to the diagnosis of other related pathologies.
Finally, the spectroscopic implementation could take advantage of the possibility of adopting portable instruments, in order to be used at the points of care.

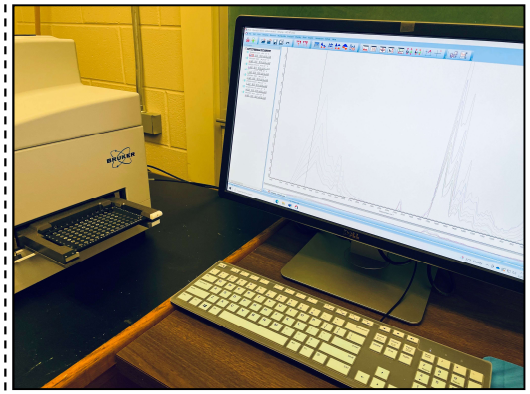

Fig. 5 The microplate is run in the machine and spectral data is collected and displayed for further analysis.

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