Biocompatibility Assessment of a Smart Bacteria-Responsive Colorimetric Nanofiber Membrane

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Introduction

Early detection of wound infection remains a significant challenge in both clinical and home-care settings. Conventional diagnostic methods, such as swabbing and bacterial culture, are time-consuming, require specialized personnel, and often delay clinical intervention. Consequently, by the time visible symptoms appear, bacterial populations may have already exceeded critical thresholds, increasing the risk of complications and systemic infection. To address this limitation, we developed an ***in situ*** **colorimetric nanofibrous membrane** capable of real-time detection of bacterial activity at concentrations below infection-level thresholds. The biocompatibility of this smart nanofibrous membrane was evaluated according to **ISO 10993 standards** to assess its safety and potential for future clinical application.

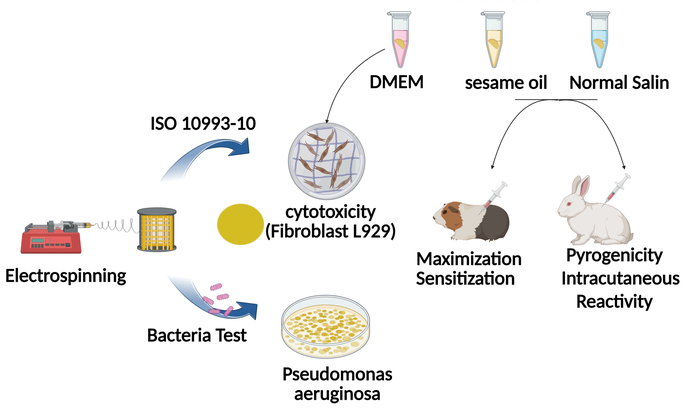
Objectives

- ✓ **Evaluate the active surface area of the membranes.**
- ✓ **Assess cytotoxicity, sensitization, pyrogenicity, and intracutaneous reactivity assessments.**

Aims

1) To determine the active surface area of the nanofibrous membrane.
2) To achieve high cytocompatibility in accordance with biocompatibility standards.
3) To ensure the membrane does not induce irritation, sensitization, or pyrogenic responses.
4) To enable rapid bacterial detection at concentrations below infection-level thresholds

Methodology



Results

Morphology of Nanofibrous Membranes

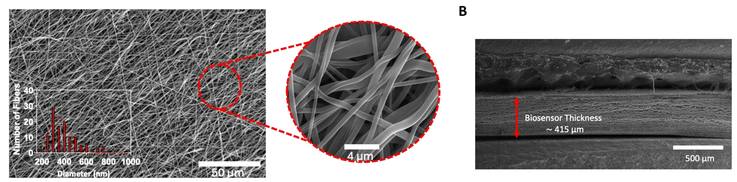


Figure 1. A)The morphology of nanofibrous membranes and B) Thickness of the membrane.

Color Changing Response to Bacteria

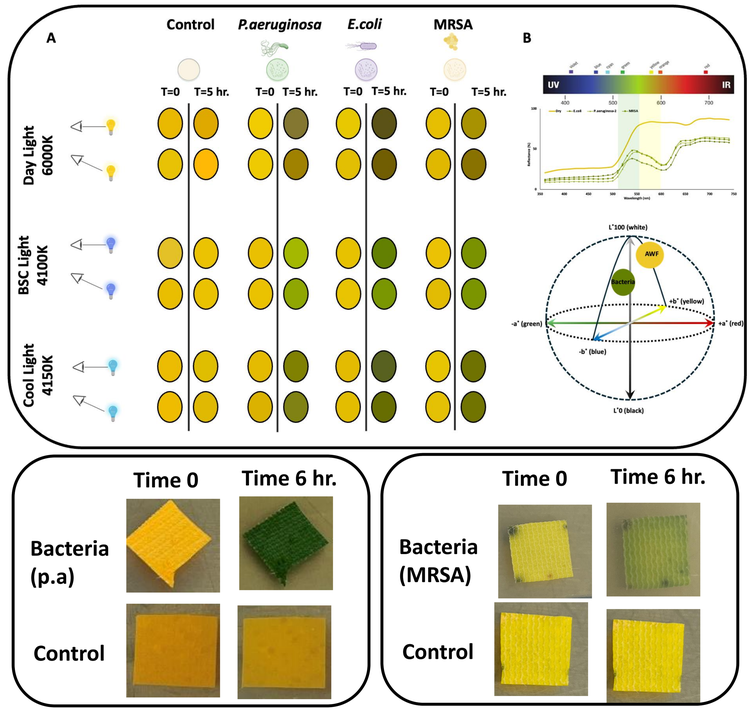


Figure 2. Bacteria results (digitalized data) and real time images.

Cytotoxicity

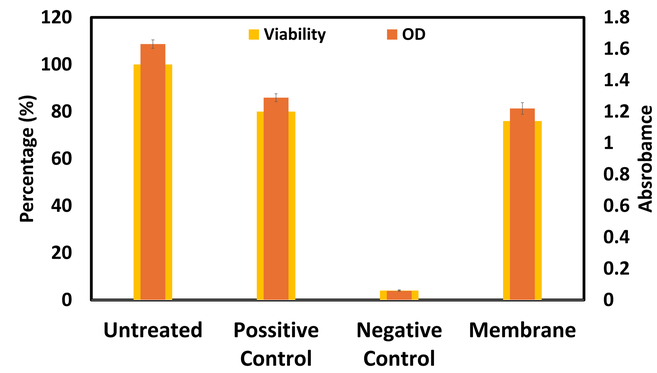


Figure 3. cell viability (Fibroblast from mice L929) in the presence of membranes extract after 72 hrs.

In vivo assay

Skin Sensitization

Sample	24 hr Score
Control	0
Membrane	0
Sample	**48 hr Score**
Control	0
Membrane	0

Patch Test Reaction	Grading Scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

Intracutaneous Reactivity Test

Sample NS	24 hr Score
Control	0
Membrane	0
Sample SSO	**24 hr Score**
Control	1
Membrane	1
Sample NS	**48 hr Score**
Control	0
Membrane	0
Sample SSO	**48 hr Score**
Control	1
Membrane	1

Grading Scale	Erythema	Edema
0	No erythema	No edema
1	Very slight erythema	Very slight edema
2	Well-defined erythema	Well-defined edema
3	Moderate erythema	Moderate edema
4	Severe erythema	Severe edema

Pyrogenicity Test

Sample	Raised Temp
1	0.04
2	0.07
3	0.04

Raised less than 0.5 °C means no pyrogenicity

Figure 4. Results of in vivo tests.

Conclusion

Collectively, the *in vitro* and *in vivo* evaluations confirm that the colorimetric, bacteria-responsive nanofibrous membrane provides rapid and visually distinct detection of pathogenic bacteria while meeting key biocompatibility requirements. These findings support its potential for safe and effective clinical integration in early infection monitoring.

Take Away Message

- ✓ **This *in situ* nanofibrous colorimetric membrane offers a promising solution for early bacterial detection in wounds, reducing risks and financial burdens on patients and healthcare systems. Its simplicity, accuracy, and adaptability make it suitable for various applications, including hospitals, home care, and battlefield settings, empowering even untrained users to monitor wound infections effectively before it progresses to a systemic infection or damage adjunct tissues.**

References

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