

Functionalized orthopaedic implant as pH electrochemical sensing tool for smart diagnosis of hardware infection

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CLINICAL NEED & STUDY DESIGN

INTRODUCTION

Hardware infection can drive non-union, revision surgery, prolonged antimicrobial treatment and systemic infection. Diagnosis may be delayed or culture-negative. Because bacterial biofilm acidifies the peri-implant microenvironment, local pH is a plausible real-time biomarker.

STUDY AIM - DUAL-FUNCTION IMPLANT

To determine whether a standard fixation implant can act simultaneously as fracture hardware, a pH-sensing working electrode and a tool for early local diagnosis of hardware infection.



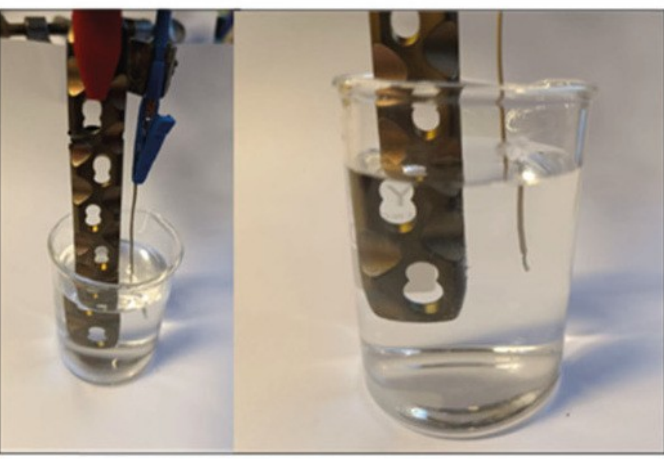
Concept: a titanium fixation implant functionalized with iridium oxide detects peri-implant acidification.

MATERIALS & METHODS

Preclinical laboratory proof-of-concept

- Screen the hardware**
Stainless steel, titanium alloy and commercially pure titanium screws/implants.
- Functionalize the surface**
Electrodeposit a pH-sensitive iridium oxide film directly on the implant.
- Miniaturize the reference**
Select a flexible Ag wire and connect the 2-electrode system to a portable potentiostat.
- Stress-test performance**
pH 4-8, BSA, interferents, hysteresis, drift, recovery and healthy synovial fluid.

Readout: <10 s.
Current: no measurable leakage >20 nA.
Platform: CP titanium implant + IrO_x + Ag wire.



The implant itself is the sensing surface: no additional bulky sensing scaffold is required.

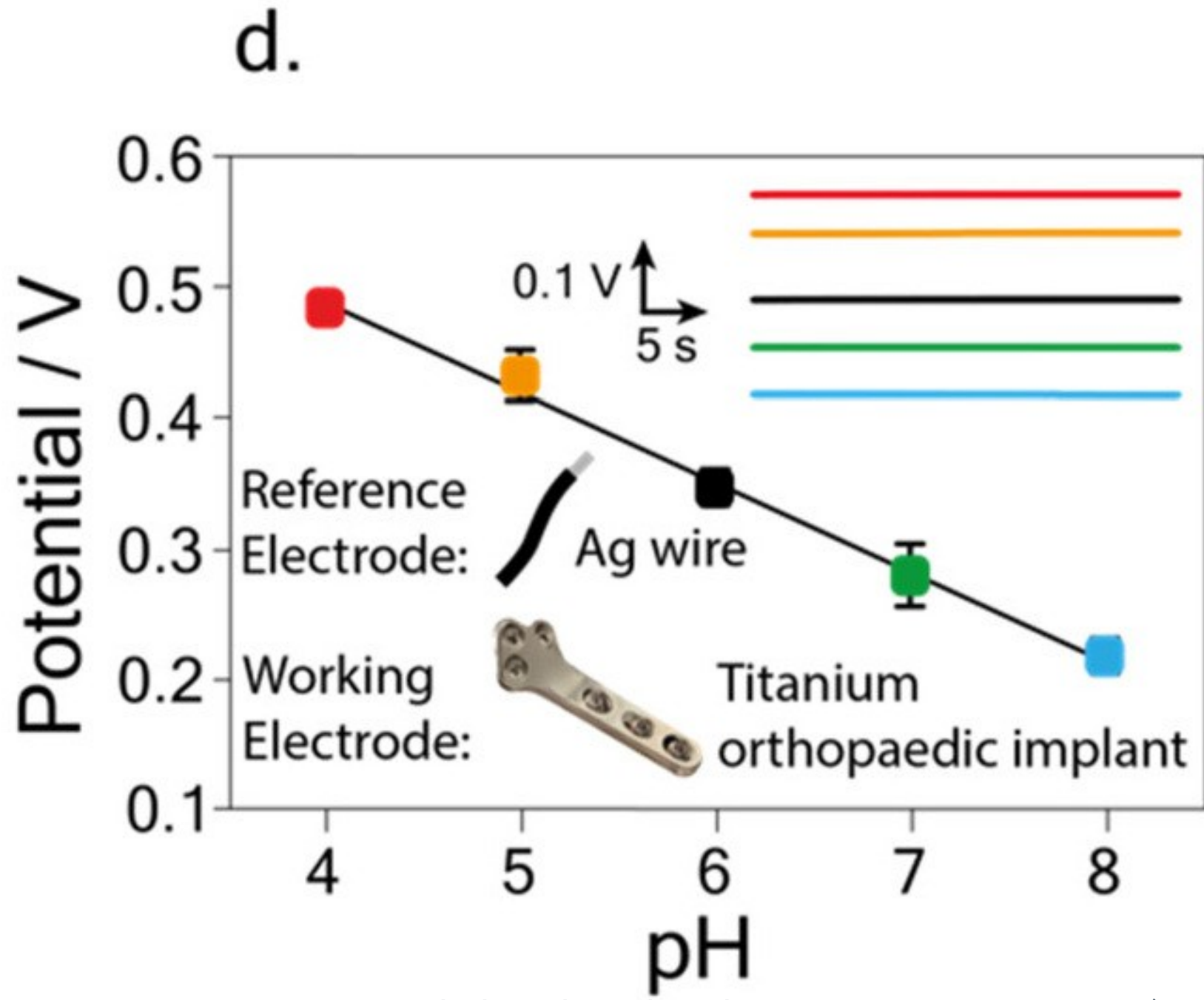
ORTHOPAEDIC VALUE PROPOSITION

Local sensing: monitors the biochemical microenvironment at the fixation site.
Hardware-compatible concept: uses a conventional titanium implant as the transducer.
Earlier reassessment: peri-implant acidification could trigger timely clinical, imaging and microbiological work-up.
Complementary role: intended to support - not replace - established hardware-infection criteria.

RESULTS & TRANSLATIONAL RELEVANCE

FINAL SENSOR CONFIGURATION

Commercially pure titanium plate + electrodeposited IrO_x working surface + Ag-wire reference electrode.



Linear potentiometric response with the selected implant/Ag-wire configuration (source figure cropped from the supplied article).

CORE ANALYTICAL PERFORMANCE

pH 4-8

linear operating range

R² 0.996

Ag-wire configuration

-68 ± 2

mV per pH unit

<10 s

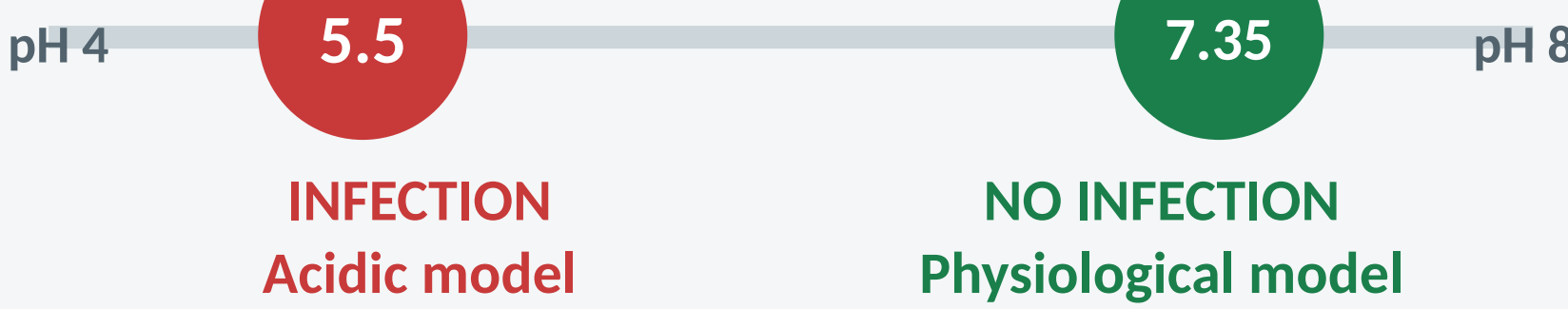
signal acquisition

ACCURACY IN A PROTEIN MATRIX

BSA calibration: R² = 0.999; slope -70 ± 1 mV/pH.
Recovery at pH 5.5 (infection): 99.2 ± 0.3%.
Recovery at pH 7.35 (no infection): 99 ± 2%.
Reproducibility: 1.7% intra-implant and 8.6% inter-implant RSD.
Selectivity: no significant effect from tested ions, BSA, glucose or urea; no hysteresis.

LOCAL pH WINDOW

Modeled peri-implant conditions



CONTINUOUS MONITORING

Signal drift after 7 days remained small in both modeled conditions: 0.013 V at pH 5.5 and 0.014 V at pH 7.35.

0.013 V

7-day drift · infection

0.014 V

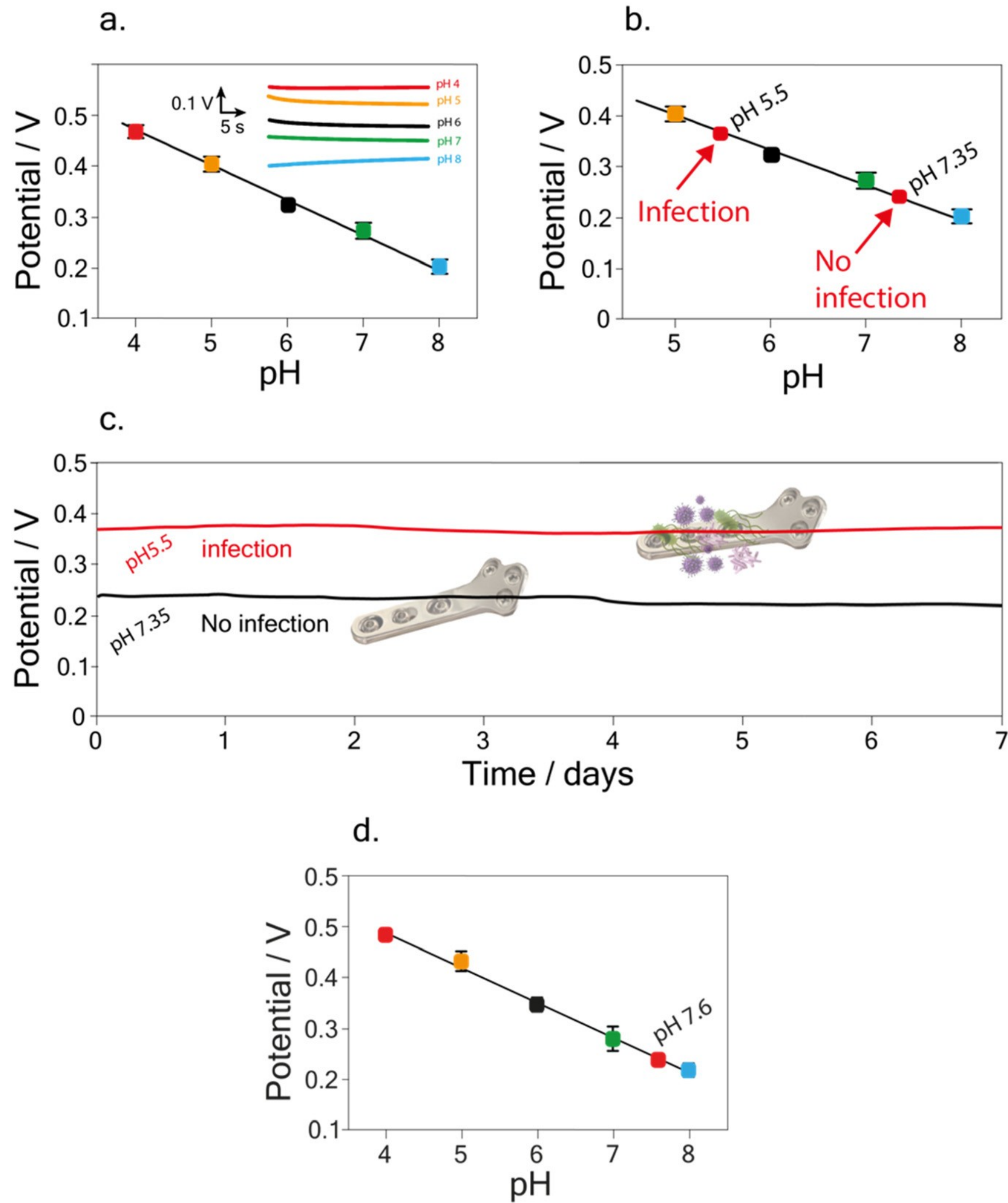
7-day drift · no infection

SYNOVIAL-FLUID CHECK

Healthy synovial fluid
7.7 ± 0.1 sensor | 7.9 ± 0.1 pH-meter

The close agreement supports matrix compatibility, but does not establish diagnostic accuracy in infected patients.

BIOLOGICAL-MATRIX VALIDATION



Recovery at infection/no-infection pH, one-week continuous monitoring and healthy synovial-fluid comparison.

LIMITATIONS & NEXT STEPS

Proof-of-concept only: bench testing and healthy synovial fluid; no infected-patient sensitivity/specificity.
Implant validation: sterilization, fatigue strength, coating durability and long-term biocompatibility remain to be demonstrated.
System integration: battery-free wireless acquisition and clinically usable alert thresholds are required.
Clinical studies: in vivo models followed by prospective hardware-infection cohorts.

CONCLUSION

A standard titanium fixation implant can be converted into a pH-sensitive working electrode through direct iridium oxide functionalization.

The device rapidly distinguished modeled infection (pH 5.5) from physiological conditions (pH 7.35), retained accuracy in a protein-containing matrix and remained stable during 7-day monitoring.

ORTHOPAEDIC IMPLICATION: the fixation implant itself may become a local interface for earlier diagnosis and monitoring of hardware infection. In vivo and prospective clinical validation remain essential before clinical use.

SELECTED REFERENCES

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