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Proof of concept: efficacy of surgical titanium implants coated with linear gentamicin against osteomyelitis in pigs

Mickael Riou¹, Aurélien Voisin², Nathalie Kasal-Hoc¹, Céline Barc¹, Christelle Rossignol³, Hans Adriaensen⁴, José Delaval⁵, Anne-Lyse Lainé⁶, Sandrine Mélo³, Marie-Pierre Foulc²

¹UE-1277 Plateforme d'Infectiologie Expérimentale (PFIE), INRA, Nouzilly, France,

²Rescoll, Pessac, France,

³UE-1282 Infectiologie et Santé publique, INRA - Université de Tours, Nouzilly, France,

⁴Plateforme Chirurgie et Imagerie pour la Recherche et l'Enseignement, INRA, Nouzilly, France,

⁵Laboratory Touraine, Parçay-Meslay, France,

⁶UMR-0085 Physiologie de la Reproduction et des Comportements, INRA - CNRS - HARAS NATIONAUX - IFCE - Université de Tours, Nouzilly, France

Background: Implant infections in human surgery are serious clinical conditions that result in high mortality rates. The treatment of these infections almost systematically requires the combination of long-term antibiotic treatment and concomitant surgical treatment, as well as implant replacement. However, standard antibiotic treatment protocols have a low efficacy for this type of infection and the surgical procedure is often complex. These practices represent a high risk to the patient and a significant cost to society. It is necessary to find alternative solutions, such as using a surface treatment on titanium to deliver antibiotics locally only in case of infection. To meet this objective, it is therefore essential to develop an animal model for the surgical placement of titanium implants with bone infection and to measure the antibiotic efficacy of coated implants.

Materials/methods: The objective of this study is therefore to demonstrate the concept of the efficacy of gentamicin-coated surgical implants against *S. aureus* osteomyelitis in pigs. We have defined two sizes of titanium cylinder implants (4 and 8 mm length by 4 mm diameter). Double and bilateral partial osteotomy surgery of the porcine tibia was performed, followed by local bone infection with *S. aureus* SAHOS (human bone clinical isolate) at two different concentrations (10^2 CFU and 10^6 CFU). Once the bacteria have been deposited in the bone hole, the 4 mm and/or 8 mm titanium implant with or without coated gentamicin were deposited.

Results: Clinical and bacteriological results from implants with or without gentamicin confirmed local bone infection at both concentrations tested, as early as 7 days post-infection. However, a significant reduction in bacterial load is observed in the presence of gentamicin-coated implants. In both cases, inflammation of the implanted bone area was observed through clinical and medical imaging (MRI) follow-up and confirmed by the increase in cytokines. As with bacteraemia, the results show that the clinical condition of the pigs is better and inflammation is less spread in the presence of gentamicin coated implants.

Conclusions: This porcine model therefore validates the proof of concept on the therapeutic efficacy of biomedical implants coated against acute postoperative osteomyelitis for human use.

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