Treatment of Infected Femoral Non-union using Ultrathin Silver-Polysiloxane-Coated Implants

Maximilian M Mueller, Celia Maxima Niclassen, Sidney Schaeffer, Craig E. Klinger, Arndt Peter Schulz, Karl-Heinz Frosch, Rita Schoop-Schmetgens

INTRODUCTION:
Development of an infected non-union is considered a severe complication following femoral shaft fractures. Furthermore, recurrence is common, particularly among chronic infections, necessitating multiple surgical revisions to achieve long-term bony stability.
In terms of adjuvant therapy to improve treatment success, use of silver implant coatings as a bactericidal and fungicidal substance is promising, as hardly any resistance mechanisms are known. In contrast to clinically established silver coatings (e.g., MUTARS®-protheses; Implantcast, Buxtehude, Germany), a silver-polysiloxane coating, developed based on a unique manufacturing process (HyprotectTM, Bio-Gate® AG, Nuremberg, Germany) is reported to have a significantly reduced amount of silver, offering improved biocompatibility while maintaining effectiveness. While the anti-infective effect of this silver-polysiloxane coating has been described in individual case reports, case series or comparative studies have not yet been published.

The study purpose was to report short- and mid-term outcomes following treatment of infected femoral shaft non-union and investigate if an ultrathin silver-polysiloxane-coating of implants improved treatment success rate at 1-year follow-up. It was hypothesized that use of silver-coated implants would lead to a significantly higher rate of treatment success compared to conventional, un-coated implants at 1-year follow-up.

METHODS:
This prospective, controlled study included patients with a minimum follow-up of one year who were treated for infected femoral shaft non-union from 2013 to 2024 either with an uncoated or silver-polysiloxan-coated implant. Clinical, radiological and biochemical follow-up were performed at 3, 6 and 12 months (2- and 5-years pending). The primary endpoint was defined as successful treatment at 1-year follow-up (no re-infection, bony consolidation, and full weight-bearing). Secondary outcomes included clinical, blood serum analysis (including silver-ion concentration), radiographic outcomes, and patient reported outcome measures (in SC-cohort only) including Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Lower Extremity Functional Scale (LEF-S), and EuroQol-Visual Analogue Scale (EQ-VAS).

RESULTS:
The mean follow-up of the 70 included patients was 3.7±2.8 years (8 coated, 62 uncoated; mean age 49±14 years; median age 39 vs. 52 years; 75% male). With a median bone defect size of 4.1 respectively 5cm (circular), successful treatment at 1-year follow-up was achieved significantly more often in the silver-coated group (100% vs. 61.3%, p= 0.04). In the first postoperative year, in 19 cases (30.6%) after conventional treatment (39% at final follow-up) either re-infection or persistant non-union was found. At final follow-up, successful treatment was achieved in 91.2% of cases after conventional treatment. The serum silver ion concentration reached a maximum of 0.014 mg/l without clinical signs of argyria. In 35.7% of cases, multiresistent or ‘difficult-to-treat’ bacteria were detected. An improvement in lower extremity function (WOMAC, p= 0.3; LEF-S, p= 0.1) and quality of life (EQ-VAS, p<0.001) (n=8) as well as a significant reduction of the treatment costs (33886€ vs. 48937€, p= 0.048) were observed in the silver-coated group at 1-year FU.

DISCUSSION AND CONCLUSION:
This study presents comprehensive short-term and mid-term data on treatment of patients with infected femoral non-union. Application of a silver-polysiloxane coating on implants for internal stabilization resulted in a significantly higher treatment success rate at the 1-year follow-up compared to conventional implants.

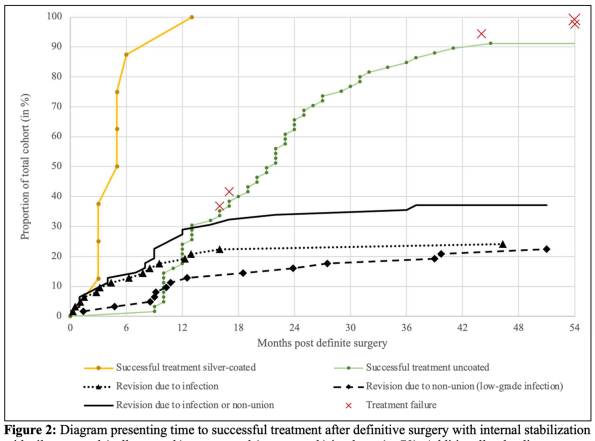

Figure 2: Diagram presenting time to successful treatment after definitive surgery with internal stabilization with silver-coated (yellow graph) or uncoated (green graph) implants (n=70). Additionally, the diagram demonstrates time to treatment failures (red cross) as well as time to revision surgery due to infection (black dotted graph), non-union (black dashed graph) and combined (whatever happened first, infection or non-union; black graph).

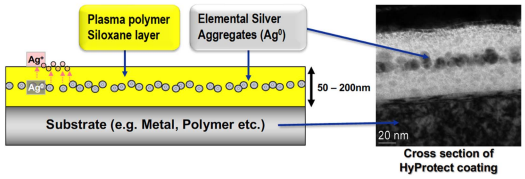

Figure 1: Schematic representation of the plasma silver-polysiloxane coating. Elemental Silver aggregates are embedded in a plasma polymer siloxane layer applied onto the implants (provided by BioGate® AG). Nm, nanometer; Ag, silver ions