

Free Papers B

[O24] GENTAMICIN CONTAINING BONE SUBSTITUTE TO PREVENT INFECTIONS DURING BONE RECONSTRUCTION SURGERY

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Aim: The demand for a synthetic bone substitute that can build bone and at the same time kill bacteria is high. The aim of this study was to compare the elution of gentamicin from a new synthetic bone substitute *in vitro* with the performance in clinical applications.

Method: Gentamicin release was measured from a synthetic bone graft substitute, comparing *in vitro* and *clinical* conditions:

1) elution in Ringers solution. The bone graft substitute contained 175mg gentamicin per 10mL. The material was introduced either as paste or as pre-set beads with a high or low surface areas, >100cm² and 24cm² respectively. The gentamycin release was measured by daily collection of samples.

2) elution in patients treated for trochanteric hip fractures(n=6) or uncemented hip revisions(n=5) 7,3±1,1mL of substitute was implanted and drainage was collected at 6h,12h,24h,30h,36h post-op. Blood serum was collected every hour for the first 6h and thereafter every 6h until 4 days post-op, urine - daily for the first 7 days post-op.

3) elution in patients treated after bone tumor resection(n=8), 12,1±5,5mL of substitute was implanted and both drainage and blood serum were collected daily until 2 days post-op. Gentamicin concentrations were analyzed using antibody technique.

Results: In the *in vitro* study, there was an initial peak in the gentamicin concentration (GC) for all the samples and at a level above 4mg/L, which is the MIC break point, during the whole test period of 28 days. All gentamicin was released during the test period and more than 95 % had been released after 2-4 days independently of the surface area of the material, or if it was pre-set or paste. In the clinical studies similar results were found. Gentamicin was detected in the drainage until 2 days post-op. and the hip patients 40% less GC - compared to the tumor patients. In the blood serum with higher GC in the tumor patients and non-detectable levels after 2 days post-op for the hip patients. The GC was significantly lower than maximum systemic level recommended of 12 mg/L. In the urine, GC was above the MIC of 4mg/L for the first seven days post-op.

Conclusions: A reliable *in vitro* test method has been identified for the future development of additional new and effective antibiotic containing bone substitutes. The new bone regenerating carrier gives very high local antibiotic release for a controlled short time after surgery and high systemic serum concentrations are avoided.