Prospective Randomized Study on the Outcome after Osteosynthesis in AO Technique vs Minimally Invasive Intramedullary Osteosynthesis by "Photodynamic Bone Stabilization" in Distal Fibula Fracture

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Introduction/Purpose: The aim of the study is to clarify whether a novel, minimally invasive intramedullary osteosynthesis system to be implanted leads to an improvement of surgical care in terms of a reduction of postoperative complications after fracture of the distal fibula in older patients. Considering that the population of patients in the western world is getting older and older, a soft tissues-friendly surgical method can not only improve the clinical outcome, the length of stay but also prevent possible postoperative infections.

Methods: In our prospective randomized study two study arms were considered. The first arm represents the control group conventionally treated with ORIF in AO technique. Patients in arm 2 were stabilized using the minimally invasive intramedullary Photodynamic Bone Stabilization System (IlluminOss®). The primary target parameter of the clinical outcome is the functionality of the ankle joint, objectified by the Olerud score. Secondary target parameters are the type and severity of postoperative complications. These were divided into minor complications: Superficial wound infection, delayed wound healing, mechanically prominent implant, skin irritations and major complications requiring surgical revision: Deep wound infection, material loosening, loss of reduction. Included were patients > 65 years, with a Charlson comorbidity index = 1 and a distal fibula fracture (according to AO 44 B1.1, B1.2, B1.3), which met the criteria for surgical treatment. Clincal and radiological controls were performed 6 weeks, 12 weeks, 6 months and 1 year postoperatively.

Results: 16 patients (10W/6M), age of 77 J (± 6.65) have been included. Charlson comorbidity index was 2 (±1). Ten patients were treated minimally invasively (62.5%), six patients using the AO technique (37.5%). No minor complications (0%) occurred In the IlluminOss® group. Three minor complications (50%) were detected in the AO group. One patient of the IlluminOss® group (10%) showed a loss of reposition and the procedure changed to the AO treatment. In one case (16%) in the AO group a material loosening with deep wound infection which resulted in a material removal could be detected. At each control time a significantly better olerud score could be obtained in the IlluminOss® group. The length of stay also showed a significant advantage for the minimally invasive group.

Conclusion: Our first results are quite positive. We could demonstrate not only the fact that a good clinical function was shown in the IlluminOss® group, but also the absence of minor complications suggests a gentle surgical treatment. The reduced postoperative complication rate has the consequence that the elderly patients can be discharged more quickly into their home environment, the patient's mobility can be restored faster and the costs for the health care system decrease significantly. However, further investigations and completion of the ongoing study must be awaited.

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