Introduction
Robotic systems are referred to as active systems of Computer Assisted Orthopaedic Surgery (CAOS). They serve as a delivering tool of a surgical procedure planned off-line on a computer prior to the surgery. The approach is very much similar to a Computer Numerical Control-milling machine (CNC-machine): the shape of the object or cavity is stored in the control computer of the machine and executed on demand.

The discussion whether the usage of a robotic system improves the clinical success of THR or not is being held on very emotional and subjective grounds. Only the superior fit of a cavity reamed by a robotic system when compared to manual reaming is established. Whether this aspect is important or not was not shown. The purpose of this study was to provide objective information regarding the differences in clinical outcome between robotic assisted and conventional manually implanted THR using the same prosthesis type.

Materials and Methods
Inclusion criterion was the diagnosis of osteoarthritis. 154 patients (54 men / 100 women) volunteered to participate in the study. They were informed about their participation in the study and gave their consent. The average age at operation was 70 ± 7.8 years. All patients were provided with a modular S-ROM® prosthesis with a cobalt-chromium head (Ø28mm). A spherical cementless press-fit-cup provided with a modular S-ROM® was used with two reference pins. Patients assignment to either group or surgeon was randomized. The robotic / manual group consisted of 74 / 80 patients (Tab.1).

For the robotic group the ROBODOC® (Fig.1) with the complementing planning computer ORTHODOC® 3 was used with two reference pins implanted. A Helical-CT® was carried out according to the manufacturer specified protocol. Then the CT-data were transferred to the ORTHODOC® and transformed into a 3-D reconstruction. The planning of the S-ROM® prosthesis was carried out with an anteverision of 15°. For the patients of the manual group a pre-operative planning sketch was drafted with the usual X-ray templates taking into account the leg-length. All patients were examined clinically and Xrayed pre-operatively as well as post-operatively after 3, 6, 12 and 24 months. The functional hip scores according to Harris, Merle d’Aubigne and the Mayo-score (clinical) were calculated. The X-ray results were also considered for the post-operative Mayo-score (radiological). Furthermore, the difference between prosthesis axis and femur-axis was calculated from the post-operative X-ray. After 6 months the leg-length of the standing patient was assessed. Statistical analysis was performed by means of analysis of variance (ANOVA). All statistical tests were performed with a confidence interval of 95% (α=0.05).

Results
Surgery had to be converted in 13/74=18% of the robotic surgeries to manual due to failure of the system. Surgery duration was higher in the robotic group (107.1±29.1 vs. 82.4±23.4 min, robotic vs. manual, p<0.001). Leg length equality (0.18±0.30 vs. 0.96±0.93 cm, p=0.001) and stem varus-valgus-orientation (0.34±0.67 vs. 0.84±1.23°, p<0.001) were better in the robotic group. After 6 months slightly more ossifications were seen in the robotic group. After 6 months the robotic group showed a better Mayo-score (63.6±15.0 vs. 56.0±16.8, p=0.01) and Harris-score (85.9±12.0 vs.73.2±16.9, p<0.001), whereas after 24 month no differences were found any longer. In the robotic group dislocation was more frequent (11/61=18% vs. 3/80=4%, p<0.001, Tab.1). Recurrent dislocation and pronounced massive limping was the indication for revision surgeries in the robotic group (non-infectious etiology, 9/61=15% vs. 7/80=9%, p=0.001). During reoperation rupture of the abductor muscle tendon (pseudoparalysis similar to the rupture of rotator-cuff) was observed.

Discussion
The robotic assisted technology showed advantages in pre-operative planning and accuracy of intra-operative procedure. Disadvantages are the high revision rate, the amount of muscle damage responsible for the higher dislocation rate and the longer surgery duration. It cannot be the goal to show that the robotic approach “reaches” the quality of the manual approach. The additional time and investment in machinery required as well as the additional burden for the patient (e.g. CT-scan) can only be justified by a clearly better performance. This study clearly shows that the described robotic approach, in its current form, is an endangerment to the THR patient. A neural injury rate of 7%, a dislocation rate of 18% and a revision rate within two years of key operation of 15%, such as demonstrated with the robotic group, are well below today’s (and even those of 25 years ago) standards for primary THR.

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Table 1: The different hip scores at the different assessment time points.

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Figure 1: The ROBODOC® surgical robot.

a DePuy, a Johnson & Johnson Company, Leeds; UK
b ESKA Implants, Luebeck, Germany
c Integrated Surgical Systems (ISS), Sacramento, USA
d Siemens AG, Muenchen, Germany

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