Evaluation of The Safety And Efficacy of Fully Automated Active Robotic System In Robotic Assisted Total Knee Arthroplasty

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DISCLOSURES

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INTRODUCTION

- Despite improvements in the implants and surgical techniques, about 20% of patients remain dissatisfied with their primary Total Knee Arthroplasty (TKA).

- Accurate implant size/ alignment and limb alignment are necessary for the long term survival of the implant and successful outcome.

- Implant overhang/ under sizing and limb mal-alignment is associated with sub-optimal patient reported outcome measures and increased chances of revision.

- Use of semi-active and active robotic system for performing TKA is increasing. The novel fully automated active robotic system performs milling of the bone surfaces with a high speed burr.

AIMS AND OBJECTIVES

- To study the safety of the fully automated active robotic system by comparing the incidence of adverse events to the literature control values associated with conventional manual TKA.

- To study the effectiveness of the system in predicting the implant size/alignment and limb alignment and to compare it with the literature control values for conventional manual TKA.

MATERIAL AND METHODS

- This is single center, same surgical team prospective study involving patients undergoing RA-TKA for end stage (grade 4) arthritis of the knee joint.

- The sample size was estimated to be 28 patients for anticipated 20% decrease in the composite adverse events associated with the conventional manual TKA with alpha error of 0.05 and beta error of 0.2 with power of study being 80%.

- ***Inclusion Criteria:*** Patients undergoing primary TKA with fully automated active robot.

- ***Exclusion Criteria:*** Patients undergoing conventional TKA, revision TKA, patients with body mass index >40 kg/m2, patients with any type of metallic implants in the to be operated knee.

- A pre-defined list of RA-TKA adverse events was employed to study the safety of the system.

- The safety endpoint was assessed against the composite rate of adverse events incidence rate of 7.6 %. The adverse events associated with the manual TKA reported in the literature are medial collateral ligament injury (2.7%), extensor mechanism injury(2.1%), nerve injury /palsy(1.3%), femoral/ tibial condyle fracture(0.68%) , patello-femoral mal-alignment (0.5%), knee subluxation/ dislocation (0.2%) and popliteal vessels injury(0.15%) .

- Efficacy was judged by comparing the planned versus achieved Implant size, alignment and limb alignment on post-operative radiographs.

- The post-operative clinical evaluation was done by an independent observer who was not part of the operating team.
- The primary safety hypothesis was tested using a one sided exact binomial test.
- The primary efficacy hypothesis was tested using Chi-squared test.
- The P value < 0.05 was considered significant.

RESULTS

- A total of 30 patients (21 females and 9 males) were studied. The average age of the patients was 69 years.
- The average body mass index of the patients was 29.1 with a range of 20.1–38.5.
- All the patients were followed up at 6 weeks, 3 and 6 months.
- None of the 30 patients suffered any of the pre-defined procedure related adverse events.
- The pre-operative 3D templating was successful in accurately predicting the femur implant in 100% of cases. It accurately predicted the tibial implant in 96.67% of cases.

- The time taken in conventional TKA for application of appropriate zigs and execution of the bone cuts and soft tissue releases and in RA-TKA group for the insertion of registration pins, bony registration, bone milling with robot and required soft tissue release was 24.77 ± 1.92 and 25.03 ± 3.27 respectively which is statistically non-significant (p value 0.7086).

- According to Peek's criteria no femoral or tibial implant was found to be undersized/oversized. The limb alignment was found to be optimal in all cases. No femoral component had anterior cortical notching, and a >2 mm gap between the anterior cortex of femur and the implant was not observed in all cases.

- All femoral implants restored the posterior condylar contour. As regards the tibial base plate there was no lateral overhang or <50% cortical contact.

- The primary safety hypothesis is met as none of the patients had any predefined adverse events (P value < 0.001).

- The primary effectiveness hypothesis is also satisfied as all the 30 patients had achieved pre-planned limb alignment on the post-operative x-rays. (0% mal-alignment as against literature control rate of 32% for manual TKA, P value < 0.05).

- The pre-operative Oxford Knee Score 19.47±1.57 improved to 35.65 ±1.35 at 6 months follow up. (Statistically significant, students *t*-test, P value < 0.001).

Figure 1: The Femur and Tibia points being registered in the computer.

Figure 2: Fully automatic robotic arm performing distal femur and proximal tibia bone cuts.

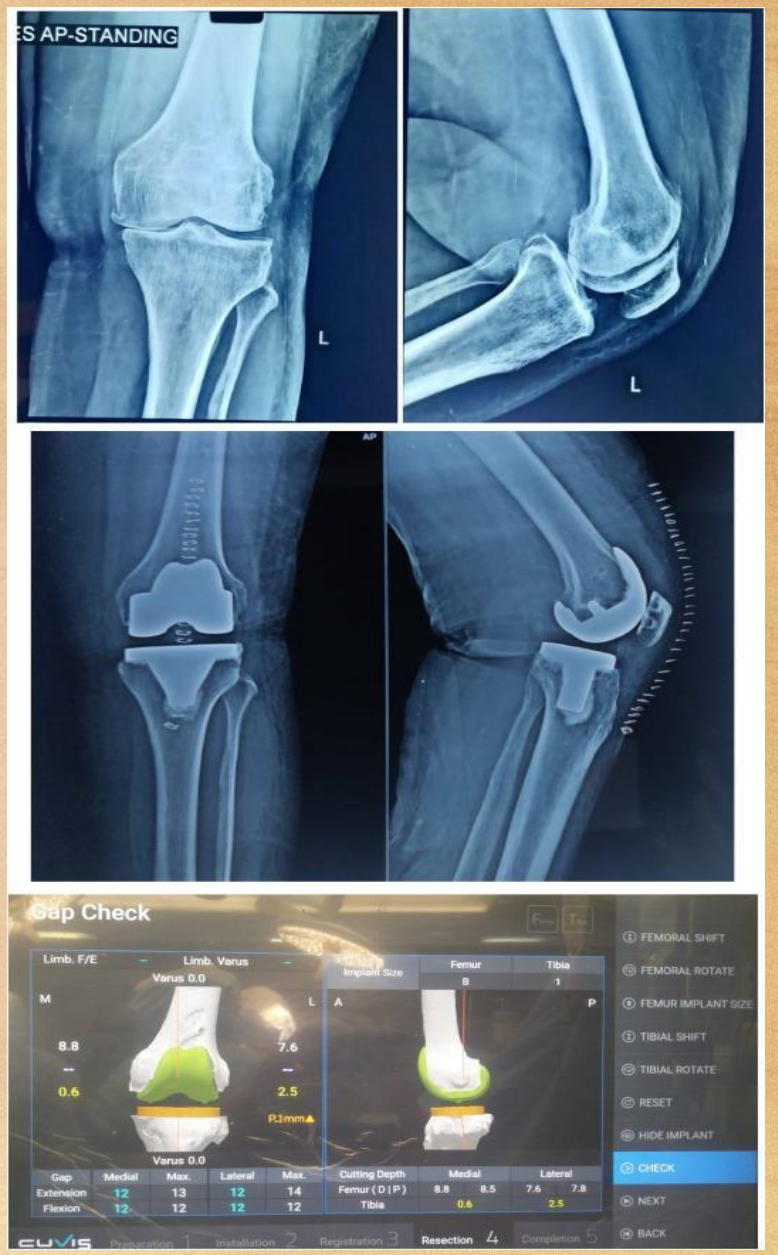

Figure 3: Pre-Operative and Post-Operative X-Rays and Intra-operative measurement estimation.

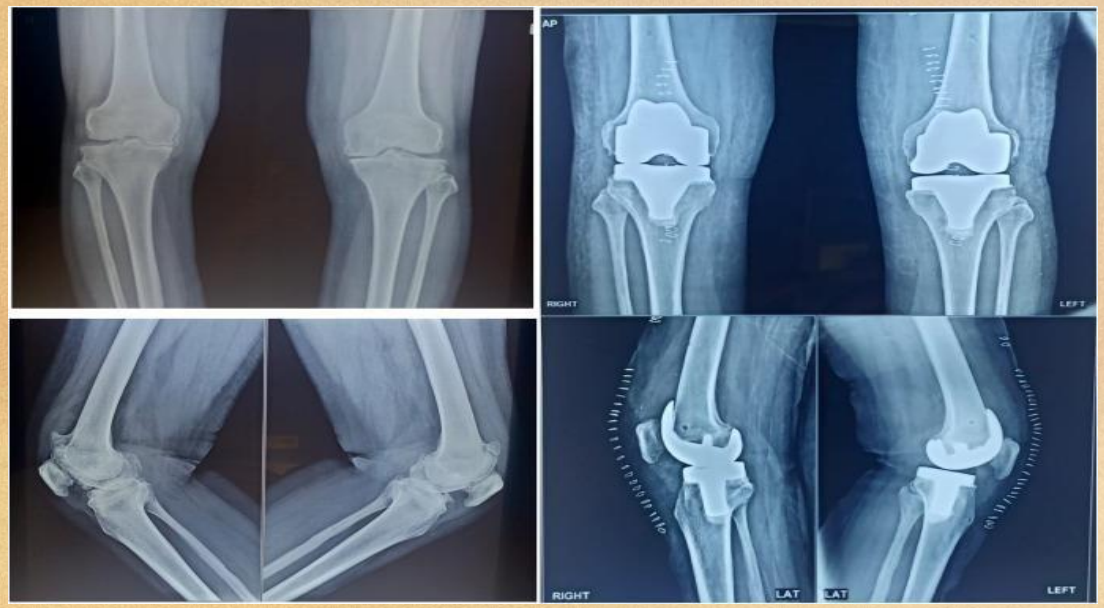

Figure 4: Pre-operative and post-operative X-Rays

CONCLUSION

- The results of our study clearly demonstrate the safety of the fully automated active robotic system by comparing the incidence of adverse events to the literature control values associated with conventional manual TKA.

- Also the study shows the effectiveness of the system with the pre-operative 3 D CT scan-based templating in accurately predicting the actual femur and tibia implant sizes and achieving optimal implant position and limb alignment.

- This may have a potential to improve the implant longevity, clinical outcomes and patient satisfaction.

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