

Early experience with the ATTUNE Total Knee Replacement System

Stefano Giarretta¹, Mattia Berti², Gian Mario Micheloni¹, Alberto Ceccato²,
Francesco Marangoni¹, Alberto Momoli¹

¹Orthopedic and Traumatology Unit, San Bortolo Hospital, Vicenza, Italy; ²Department of Orthopedics and Trauma Surgery, University of Verona, Verona, Italy

Summary. *Background:* Modern TKA implants promise to improve functional outcomes, stability, patient satisfaction and operating room efficiency. The purpose of this retrospective study is to evaluate our short-term clinical and radiological results and survival using the ATTUNE Total Knee Replacement System. *Methods:* The authors reviewed 228 primary cemented TKAs using ATTUNE Total Knee Replacement System which were implanted between 2014 and 2018 concerning short-term clinical and radiographical outcomes and survival. Clinical evaluation was performed using the Knee injury Osteoarthritis Outcome Score (KOOS), the Oxford Score and a Numeric Rating Scale (NRS) for pain. Radiographic analysis was performed using the Modern Knee Society Score Evaluation System. *Results:* The means of the clinical results as measured with KOOS score were Pain 82,7, Symptoms 79, ADL 78,3, Sport & recreation 51,8 and QOL 78,6. The mean Oxford score was 35 and NRS 2. The mean ROM was 113,4 (SD 9,4 range 90-130). Radiographically mean mechanical axis was 1,97° of Varus and radiolucent lines were detected in 43 knees (22,4%). The survival rate is 98.4% at 2 years and 97.4% at 5 years. *Conclusion:* At short-term follow-up the ATTUNE Knee Replacement System provide excellent clinical and radiographical outcomes and good results regarding revision rate. Due to high incidence of radiolucent lines, those patients should be closely monitored even though they show no clinical evidence for loosening. (www.actabiomedica.it)

Key words: TKA, ATTUNE Total Knee Replacement, Radiolucency

Introduction

Total knee arthroplasty (TKA) is believed to be one of the most successful and effective surgical procedures for end-stage osteoarthritis with survivorship more than 94% at 16 years after surgery (1-3). However the incidence of patient dissatisfaction after TKA varies in literature and has been reported to be as high as 20% (4, 5).

There is a constant race between different health-care companies to advance the technology employed in prostheses to further improve patient outcomes. Newer implants are regularly introduced, or design features of current implants are adjusted in an effort to achieve this (6).

In order to improve functional outcomes, stability, patient satisfaction and operating room efficiency the ATTUNE Total Knee Replacement system was launched as a modified version of a previous prosthesis (Press Fit Condylar Sigma). The theoretical advantages of this prosthesis suggested by the providers are increased conformity between the femoral component and the polyethylene insert with a gradually reducing femoral radius, an innovative s-curve design of the posteriorly stabilized cam for gradual femoral rollback and stability, an extensive range of sizes for a diverse population, optimization of the patellofemoral tracking, an improved polyethylene insert locking mechanism and incorporation of an antioxidant polyethylene insert.

However, despite such advantages, there are some design features that might cause problems.

The thickness of the patellar component is greater and hence the residual bone stock should be shallow with the increased possibility of patella fractures (7). Furthermore, the tibial component stem is located relatively posterior e this might increase the risk of injury to the posterior tibial cortex (8).

Finally recently early aseptic failures at the implant-cement interface were reported in a retrospective study based on data from Manufacturer and User Facility Device Experience (MAUDE) database (9).

The purpose of this retrospective study is to evaluate our short-term clinical and radiological results and survival using the ATTUNE Total Knee Replacement System. Our primary objective is to compare our tibial aseptic loosening rate with previous reported studies. Secondly, we show our clinical and radiographic findings with those reported in literature

Material and methods

Patients

All consecutive patients who underwent TKA using ATTUNE between January 2014 and January 2018 were enrolled in this study. For all patients the indication for surgery was based on patient history and physical examination combined with anteroposterior and lateral radiography.

All TKAs were performed by 3 surgeons with certified experience in total joint arthroplasty. All implants were cemented posterior stabilized.

For all patients follow-up, sex, age at operation, revision and revision date, complications, the presence of rheumatoid arthritis, diabetes, smoking status and body mass index (BMI) were registered.

If patients were still alive at follow-up, they were invited to fill out two questionnaires and a pain score as described below.

Operative technique and rehabilitation

All operations were conducted with the patient under spinal or general anaesthesia using the same

technique of medial parapatellar approach and capsulotomy with patellar eversion. Femoral and tibial bone resection were made with a modified measured resection technique.

The transepicondylar axis was used as a reference for femoral component rotation. The tibial resection was set to be 0°-3° of posterior slope in sagittal plane. The reference line for tibial rotation was accurately aimed to pass through the medial third of tibial tubercle and the second metatarsal bone. All osteophytes were removed, and any contracted medial or lateral soft tissue was carefully evaluated and selectively released when required.

The bone surface was irrigated with 0.9% saline with a pulsatile high-pressure lavage system (Pulsavac Plus, Zimmer, Warsaw, Indiana, USA) for at least 1 min. After irrigation, preparation of bone cement was initialized according to manufactures specifications. All TKA were implanted with surface cemented components using high-viscosity bone cement (Palacos, Heraeus Medical, Wehrheim, Germany). The bone cement was applied on the tibial bone surface and on the implant surface via cement gun pressurization. The tibial component was then inserted and impacted. The femoral component was inserted and impacted in the same manner. Implantation of tibial and femoral component was performed in a single step. The patella was never replaced.

Patients started with mobilization on the day after surgery dependent on pain. Normal expectancy was unaided walking after 4 weeks of rehabilitation.

Clinical and Radiographic Evaluation

Clinical evaluation at follow-up was performed using the Knee injury Osteoarthritis Outcome Score (KOOS)(10) questionnaire, an Oxford(11) questionnaire and an 11-point Numeric Rating Scale (NRS) for pain ranging from 0 to 10.

The KOOS is a 42-item site specific questionnaire, resulting in five 0-100 scores (higher is better) for Pain, Symptoms, activities of daily life (ADL), Sport & Recreation and quality of life (QOL). The Oxford is a 12-item site specific score, ranging from 0 to 48 (higher is better).

The ROM was measured using a long-armed goniometer.

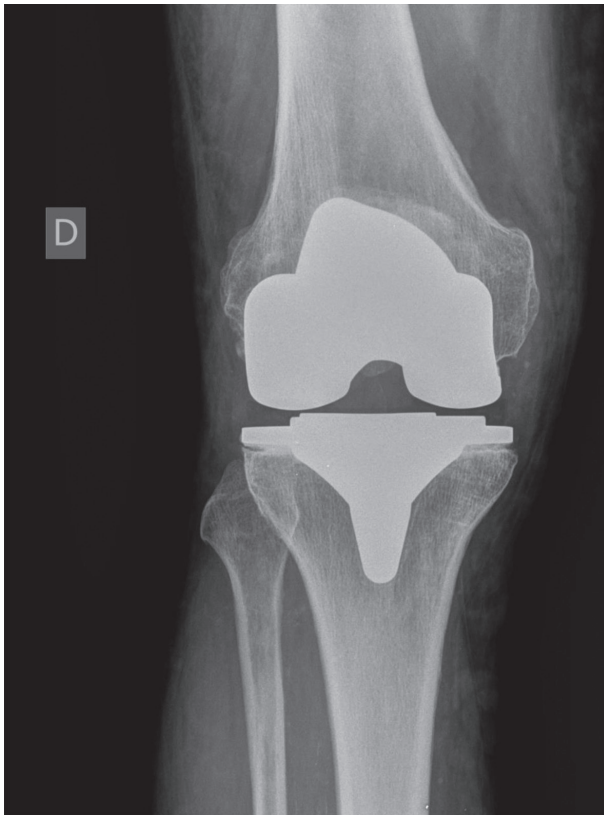


Figure 1A. Radiolucent lines (AP view)

Radiographic evaluation was performed with anterior-posterior (AP) and lateral x-ray of the knee joint as well as full-length standing AP-radiograph to assess correction of alignment. Detailed analyses of AP and lateral radiographs were conducted on the basis of the Modern Knee Society Radiograph Evaluation System(12) dividing each component in different zones for a standardized documentation of radiolucent lines. Radiolucencies were documented for each radiograph.

Statistical analysis

Statistical analysis was performed using Microsoft Excel (2017 version).

Results

During the period considered in the study 228 TKAs were performed with this prosthesis in 218 pa-



Figure 1B. Radiolucent lines (Lateral view)

tients, 89 males and 129 females with a mean age of 70,3 years (SD 6,52; range 43-85).

The mean follow-up was 3,16 years (SD 1,16) ranging from 1 to 5,4 years.

Three patients were deceased at the time of the current study, 22 patients (25 TKAs) were lost to follow-up and 8 withdrew consent. A total of 185 patients and 192 TKAs remained.

The demographic data of the patients are summarized in table 1.

Clinical results

The means of the clinical results as measured with KOOS score were Pain 82,7 (SD 14,4 range 44,4-97,2), Symptoms 79 (SD 13,8 range 39,3-100) ADL 78,3 (SD 15,8 range 38,2-98,5) Sport & recreation 51,8 (SD 26,3 range 20-85) and QOL 78,6 (SD 20,9 range 31,2- 97,7). The mean Oxford score was 35 (SD 14,6 range 20-48) and NRS 2 (SD 1,7 range 1-5). The mean ROM was 113,4 (SD 9,4 range 90-130).

Table 1. Patient demography

Sex	Male: n=89 (40.8%) Female: n=129 (59.2%)
Side	Right: n=121 (53.1%) Left: n=107 (46.9%)
Age	70.3 y \pm 6.52
Body height	167 cm \pm 8 cm
Body weight	86 kg \pm 15.2 kg
Body Mass Index	28.6 \pm 3.95
Follow up	3,16 years \pm 1,16 years
Smoke	Yes: n=17 (7.8%) No: n=201(92.2%)

Radiographic results

Radiographically, the mean mechanical axis was $1,97^\circ$ of Varus.

Radiolucent lines were detected in 43 knees (22,4%). Table 2 display the incidence in dependence on the location of the radiolucent lines.

Complications

Revision surgery for tibial aseptic loosening was performed in 2 cases (1%), respectively 7 and 13 months after surgery, with intra operative finding of failure at tibial implant-cement interface in all cases.

Two patients (1%) developed a periprosthetic infection at 2 and 3 years after surgery respectively and were treated with implant revision in two-stage surgery.

In one patient (0,05%) patient revision surgery was performed for component malposition.

In one case (0,05%) a partial lesion of the patellar tendon during rehabilitation (confirmed with sonography) was observed(13). The patient was treated with 20 days of immobilization in an extended brace. After this period a progressive program of rehabilitation lead to a complete functional recovery.

Table 2. Summary of all radiolucent lines in the anterior-posterior (AP) tibial, lateral tibial and lateral femoral radiograph

Location, radiolucency	
Tibial AP	n=25 (13%)
Tibial Lateral	n=17 (8.8%)
Femur Lateral	n=23 (12%)

Other complications included 2 (1%) patients who developed wound infections. Both were superficial and successfully eradicated with antibiotic administration. Following surgery, 3 (1,5%) knees required one manipulation under anesthesia and 1 knee was treated with arthroscopic lysis of adhesions.

Discussion

Aseptic loosening remains a common reason for early revision also with contemporary TKA system(14, 15). Loosening in short-term analyses most likely reflects failure to gain fixation. Retrieval studies have shown that bone resorption stimulated by polyethylene wear particles and stress shielding play an important role in aseptic loosening.(16, 17). Even debonding of the tibial implant-cement interface as a result of cement type and application methods is a reported cause of aseptic loosening (15, 18).

Early aseptic loosening in ATTUNE Total Knee Replacement System is still debated.

Bonutti (9) reported high rate of early tibial aseptic failures at the implant-cement interface in a study based on data from Manufacturer and User Facility Device Experience (MAUDE) database.

In contrast, the Australian registry and the National Joint Registry of the United Kingdom (NJR) reported low rates of aseptic loosening with excellent survivorship rates (19, 20).

Even several recent studies analyzing short-term outcome of ATTUNE implant reported low revision rates (7, 8, 21-23).

In addition, Turgeon used radiostereometric analysis of the components to assess the stability of the ATTUNE prosthesis and showed secure fixation of the tibial baseplate within the first two postoperative years (24).

In this study, the revision rate for tibial aseptic loosening is 1% while overall revision rate is 2.6%. The survival rate is 98.4% at 2 years and 97.4% at 5 years.

These results are congruent with those reported in previous studies and, according to the literature, are acceptable values for primary TKA (14, 25, 26).

However, in our case series, a high number of radiolucent lines was detected at the radiographic analysis. Reasons for the high incidence of radiolucencies remain a matter of speculation.

Staats (21) reported an increased number of radiolucent lines in ATTUNE-patients than PFC Sigma-patients, especially on the tibial component. He hypothesized that it was mostly due to technique-related issues, in particular he assumed that the implant itself may allow too much movement during cement interlocking-phase. He suggested to proceed the cementation of the tibial and femoral component in two separated steps.

Another reason that can explain this high number of radiolucent lines is attributable to the design of this prosthesis, in particular in relation to the cement pockets.

In a recent study peer-reviewed digital imaging method was used to investigate cement adhesion on the ATTUNE tibial tray (27). None of the prosthesis examined in this cohort showed cement attachment at the tibial tray backside and the authors concluded that it may be related to the absence of separate cement pockets.

In the meantime, the company has launched a revised tibial component with additional cement pockets and optimized surface conditions on the tibial base that will have to be studied in the further future.

Literature about the outcome of the ATTUNE Knee Replacement System is scarce due to its recent availability.

Anyhow Ranawat (22) showed excellent clinical results in 90.7% of ATTUNE-patients after 2 years' follow up with less anterior knee pain and less crepitation than PFC Sigma-patients.

Molloy (23) reported no difference in physical function and most outcomes between ATTUNE and PFC Sigma at short-term follow-up.

Song (7, 8) in his two studies showed more favorable clinical results using the ATTUNE prosthesis than using PFC Sigma prosthesis. However, they reported an increased risk of posterior tibial cortex injury and residual patellar injury with use of the ATTUNE prosthesis.

Additionally, Takagi (28) showed that the gradually reducing radius design of the ATTUNE prosthesis minimized paradoxical anterior slide in a navigation-based in vivo knee kinematics.

According to our findings we can confirm that this system achieves excellent outcomes at short-term follow-up.

However, the radiographic analysis of the present study doesn't allow to exclude that the tibial component may have problems even though no evidence for a higher revision rate could be detected in our study.

Conclusion

At short-term follow-up the ATTUNE Knee Replacement System provide excellent clinical and radiographical outcomes and good results regarding revision rate. Due to high incidence of radiolucent lines, those patients should be closely monitored even though they show no clinical evidence for loosening. Further studies with large cohort and long-term follow up are needed to evaluate and improve the application of this modern TKA-system.

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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Correspondence:

Stefano Giaretta

Orthopedic and Traumatology Unit, San Bortolo Hospital

Viale Rodolfi 37 - 36100 Vicenza (Italy)

Tel.+39 0444752823

Fax +39 0444752824

E-mail: Stefano.giaretta@gmail.com