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Abstract:

New TKA are designed to optimise patient outcomes and improve implant longevity, such as the Attune TKA. Concerns have been raised regarding a potentially high rate of early de-bonding at the implant–cement interface of the tibial component. Our study aimed to prospectively assess the clinical outcomes and radiographs of a consecutive series of patients undergoing either Attune TKA or another modern TKA for OA to establish failure rates and compare radiological abnormalities.

96 Attune TKA performed by three surgeons at our local centre were matched to 96 control TKA (PFC/Vanguard) performed between 2015 and 2017. Day one, one year and two year post surgery radiographs were analysed by two independent, blinded assessors. Clinical outcome was assessed using the Oxford Knee Score and survival of the implant recorded. Patients were contacted two years from surgery, 93 Attune and 92 control TKAs attended for clinical and radiological assessment by the same independent assessors.

No TKA in either group were revised. No significant radiolucencies (≥ 2mm) at the cement-bone or implant-cement interfaces were encountered in either group. The incidence of radiolucencies (<2mm) across both interfaces was similar between both groups and did not affect clinical outcome. There was no significant difference between the incidence, progression and extent of radiolucencies at two years follow-up in either of the groups as compared with one year.

No clinically relevant adverse radiographic features were found in this prospective cohort study comparing a consecutive series of Attune TKA with a matched group of

established, modern TKA designs.

Key words:

Attune TKA; Early aseptic loosening; Tibial de-bonding; Radiolucency

Introduction

Total Knee Arthroplasty (TKA) is a financially and clinically effective treatment for managing symptomatic end-stage knee arthritis. TKA demand is expected to increase significantly over the coming years, with an estimated increase of up to 637% between 2005 to 2030 in the USA [1,2]. This is due to a combination of factors, including an ageing population, changing patient expectations and increasing population BMI [1,3]. TKA's popularity is due to its association with improvement in mobility and better quality of life [4] , although the improvement is not uniform and many patients report residual symptoms. A study of 10,000 patients included in the England and Wales National Joint Registry (NJR), found that a significant proportion had on-going issues: 57% had problems with kneeling, 20% had persistent pain and 17% had pain on walking [5]. Less than 10% of patients reported no knee problems following TKA. Nearly 20% of patients were not satisfied with the outcome of their surgery and similar findings in other studies have driven the push for further development of TKA systems [6,7].

The Attune TKA system was developed by DePuy, (DePuy Synthes, Raynham, Massachusetts, United States) with changes to the tibial base, femoral radius, polyethylene formulation, and patella-femoral articulation. The developments were aimed to improve the performance of the knee in deep flexion, optimize patella tracking and enhance implant longevity. There have been positive reports in the literature reflecting improved performance of Attune TKA system. Carey and Harty found that more Attune knees achieved minimum clinically important difference in Patient Related Outcome Measure (PROM) score compared with control implants in the contralateral knee of the

same patient [8]. Webb et al described a reduced incidence of lateral release in Attune TKA as compared with the Press-Fit Condylar (PFC) and Sigma knees [9], and Whittaker et al showed that learning curve had no effect on PROM whilst using the Attune system [10]. However, concerns have been raised of high rates of early tibial loosening. Bonutti et al published a case series of 15 knees revised in three community hospitals due to early aseptic loosening of the tibial component at the implant-cement interface [11]. Most presented with anterior knee pain, with pain on weight bearing, a knee effusion and decreased range of motion. The average time to revision was 19 months (range, 1-34 months), and in each case at the time of revision surgery, a loose tibial implant devoid of cement was found. The authors suggested that adaptations in the Attune TKA system resulted in inferior outcomes, a cause for concern for implanting surgeons. Although the authors did not provide an actual incidence of tibial loosening, such early failures are worrying, and this has caused apprehensions amongst arthroplasty surgeons across the world. The work of Deen *et al* who have reported an incidence of proximal tibial resorption of 35% as soon as 6.9 months following implantation of the Attune TKA [12], added to concerns about the long term implant survival. As have Cerquiiglini *et al* who found no evidence of any cement attachment on any of the 11 tibial trays they retrieved [13], yet the majority of retrieved PFC trays were also found to be devoid of cement attachment in their study. Some centers have stopped using the Attune system whilst others have embarked on a prospective audit of their patient cohort to establish clinical outcomes, with an RCT comparing the Attune TKA to Sigma PFC TKA run through the Leiden University, Netherlands, predicted to take until mid 2023 for results to be available [14].

Incidence of early component loosening needing revision is typically low and therefore surrogate measures such as change in patient symptoms and/or changes in radiographic appearance are used to establish the incidence. To understand if a particular implant is associated with higher incidence of residual clinical symptoms and/or have abnormal radiographic findings, it is important to compare the data of the implant under scrutiny with a well-established implant. Clinical and

radiological outcomes depend upon many factors including patient demographics, surgical technique, implant used and post-operative regime. It is important to minimize the bias by ensuring that patient demographics, surgical technique and post-operative regime are similar between the two groups.

The aim of this cohort study is to compare the occurrence of aseptic loosening as determined by revision rates, clinical outcomes and radiological evidence in a consecutive series of Attune TKA matched with a cohort of patients who underwent TKA using established TKA systems implanted by the same surgeon.

Material and methods

To investigate the incidence of early tibial aseptic loosening and the overall clinical performance of the Attune TKA at our local center, a prospective, cohort study was designed with formal approval from our local clinical governance department.

200 primary cemented TKAs were performed between 2015 and 2017 by three consultant arthroplasty surgeons. A consecutive series of 100 primary Attune TKA were paired with 100 primary non-Attune TKAs [Sigma PFC (DePuy Synthes, Raynham, Massachusetts, USA) or Vanguard, (Zimmer Biomet, Warsaw, Indiana, USA)] each performed by the same surgeon, at our local center. It should be made clear to avoid confusion that the Attune TKA in our study were all original Attune baseplates and not the Attune S+ baseplates, a later development. Pre-operative diagnosis, extent of deformity, BMI, ASA status, patient's age and gender were recorded, as was the type of implant, extent of constraint (CR vs PS), size of each component, component alignment and whether the patella was resurfaced or not.

All cases underwent same pre-operative work up, pre-operative counseling and templating, surgical steps, post-operative regime including the same DVT prophylaxis, standardized physiotherapy and similar analgesia. All surgeries were performed under tourniquet with a midline incision and medial parapatellar arthrotomy. Measured resection technique was used to achieve a balanced knee which could be fully extended and flexed to at least 120^{o} without any component lift off. Bony surfaces were prepared as per standard surgical technique and irrigated with 0.9% saline using a pulstatile high-pressure lavage system (JetLavage, Endocon, Heidelberg, Germany) for at least 1 minute (flow rate 1200 ml/min). After irrigation, preparation of bone cement was initialized according to the manufacturer's specifications. All TKAs were fully cemented using 80 grams of high-viscosity bone cement, The bone cement was prepared using a vacuum mixing system (Palamix, Heraeus Medical, Wehrheim, Germany). The bone surface was dried, and the mixed bone cement applied to the tibial bone surface, tibial keel canal and on the implant surface. Implantation of tibial and femoral components was performed in a single step from a single mix. The leg was then held in full extension with axial compression until the cement was set. There were no differences in cementing technique between the two groups. Tourniquet was released prior to closure to ensure adequate haemostasis and the wound closed in layers. All patients received the same standard postoperative care. They were encouraged to mobilize as tolerated on the day of surgery. On day one post-surgery, anterior-posterior (AP) and lateral standing radiographs of the operative knee were obtained. Patients typically stayed in the hospital until the wound was dry, there were no peri-operative complications, pain was well controlled, and patients were considered safe for discharge. A standard post-discharge protocol was used. All patients were contacted on day 30 of surgery to establish whether they had needed any readmission, or any hospital visit, and reasons recorded. All patients were seen in a consultant-led outpatient clinic at 12 weeks, one year and two years post-surgery when patient reported Oxford Knee Score (OKS) [15] and an up to date weight bearing AP

and lateral standing radiographs of the operated knee were obtained. OKS was used from 0 to 48 with 0 being the worst outcome and 48 the best [16].

The one day, one-year and two-year post-operative radiographs were analyzed according to the 'Knee Society Reporting Protocol' [17] to identify radiolucency either at implant-cement or cement-bone interface and standardize their reported location (diagram 1). In addition, any adverse features such as fracture, component malposition, retained loose body (cement or bone) were recorded. The radiographs were reviewed by two independent orthopedic surgeons who were blinded to the clinical outcome. The assessment was recorded on a standardized form and in case of a discrepancy, the radiographs were reviewed by the senior author (who was not involved in any of the surgeries) and consensus reached. In addition, 35% of the radiographs were re-examined independently by each reviewer and data compared to establish inter and intra-observer reliability. Thickness of the tibial baseplate was used as reference to establish magnification and thereby quantify the thickness of radiolucencies.

Aseptic loosening necessitating revision was recorded as our primary end point. Incidence of significant radiolucency on either the post-operative or one-year post-operative radiographs was compared between the two groups as a secondary end point. A radiolucency (either at implant-cement or at cement-bone interface) was considered significant if it was 2mm or more in depth or progressive. Non-significant radiolucencies (less than 2mm) were also recorded for analysis. The location of radiolucencies was documented according to the Knee society reporting protocol in AP zones 1-7 and lateral zones 1-3 [17]. Two-year post-operative radiographs were used to monitor for progression of radiolucencies.

Statistical analysis was performed on RStudio (RStudio, Inc., Boston, Massachusetts, USA). Pre-operative data, patient demographics, surgical parameters were compared to identify any

differences in the baseline data. Wilcoxon rank-sum test were used for all non-parametric data analysis and the significance for all analyses was set at $p<0.05$, with 95% confidence intervals (CIs) as appropriate.

Results

Of the 100 Attune TKA, 96 cases were available with complete data for analysis including one-year radiograph and OKS. These cases were matched to 96 control TKA (Sigma PFC n=41, Vanguard n=55). From this cohort, 93 Attune TKAs and 92 control TKAs (Sigma PFC n=40, Vanguard n=52) were available for clinical and radiological follow-up at two years.

All pre-operative characteristics, except gender, were well matched across the two arms with regard to age, gender, ASA, number of patella re-surfacings and pre-operative deformity (table 1). Inter-observer reliability was 96% whilst intra-observer reproducibility was 97%.

Clinical outcomes:

No patient died or needed readmission during the follow-up period. None of the patients underwent further surgery in either of the groups. No patient was lost to follow up at one year, although 4 patients in the Attune arm did not complete OKS at their review, their radiographs did not exhibit any concerning features but as their data remained incomplete, they were not included in the analysis. None of the patients in either groups had noticed significant knee effusion or suffered from increasing knee pain and/or loss of knee flexion at the time of their annual review. At two years, 3 further patients in the Attune arm and 4 patients on the control arm were not available for full follow-up, but had not died, been re-admitted or undergone further surgery on their operative knees.

Median OKS at one-year post-surgery was 36 (IQR 25.75 – 43) in the Attune arm and 36.5 (IQR 26 – 44) in the control arm. This difference was not statistically significant, p=0.61. The distribution in different subgroups [18] based on OKS was also not statistically significant, (table 2A). Median OKS at two-year post-surgery was 37 (IQR 26-44) in the Attune arm and 37.5 (IQR 27 – 44.5) in the control arm. This difference was not statistically significant, p=0.62. The distribution in different subgroups [18] based on OKS was also not statistically significant, (table 2B).

Radiographic evaluation and clinical correlation:

None of the cases in either group exhibited implant loosening. There were no cases of significant radiolucency either at the implant-cement or cement-bone interfaces in either groups on the post-operative radiographs. There were no cases of significant radiolucency either at implant-cement or cement-bone interfaces in either groups on one-year and two-year radiographs. There was no significant difference between the two groups when component alignment was compared (table 3). None of the radiolucencies at implant-cement or cement-bone interfaces in either groups seen on the one-year radiographs progressed on the two-year radiographs.

Radiolucencies at the cement-bone interface:

The overall incidence of TKAs with radiolucencies <2mm observed at the cement-bone interface between the two groups not significantly different (34 in the Attune arm and 28 in the control arm; p=0.51). 44 radiolucencies (all <2 mm) were observed at the cement-bone interface in 34 knees in the Attune group, the median OKS at one-year follow up for this cohort was 36.5 (IQR 27.25-42.5).

The presence of radiolucencies at the cement-bone interface in the Attune TKA did not affect performance when compared to Attune TKAs without radiolucency at the cement-bone interface. The median OKS at one-year follow up for this cohort (no radiolucency at cement-bone interface at one-year) was 34.5 (IQR 23.5-43.0). The difference between the two groups was not statistically significant (p=0.69). 35 radiolucencies (all < 2mm) were observed in 28 knees at the cement-bone interface in the control group. The median OKS at one-year follow up for this cohort was 38.5 (IQR 26.0-46.0). The presence of radiolucencies at the cement-bone interface in the control group did not affect performance when compared to control TKAs without radiolucency at the cement-bone interface. The median OKS at one-year follow up for this cohort (no radiolucency at cement-bone interface at one-year) was 35.5 (IQR 26.0-43.25). The difference between the two groups was not statistically significant (p=0.37). Graph 1 displays the position of the cement-bone lucencies across both groups. Similar results were observed at the two-year follow-up.

(Figures 1 and 2.)

Radiolucency at the implant-cement interface:

The frequency of TKAs with radiolucencies <2mm observed at the implant-cement interface between the two groups was not statistically significant with 26 in the Attune arm, 20 in the control arm; (p=0.42).

Radiolucencies were present on the post-operative radiograph at the implant-cement interface in both the groups, yet none were significant (>2mm) and none of these progressed. 28 radiolucencies (all <2 mm) were observed at the implant-cement interface in 26 knees in the Attune group, the median OKS at one-year follow up for this cohort was 31.5 (IQR 21.0-40.0). The presence of radiolucencies at the implant-cement interface in the Attune TKA did not affect performance when

compared to Attune TKAs without radiolucency at the implant-cement interface. The median OKS at one-year follow up for this cohort (no radiolucency at implant-cement interface at one-year) was 37 (IQR 26.25-43.75). The difference between the two groups was not statistically significant (p=0.11). 29 radiolucencies (all < 2mm) were observed in 20 knees at the implant-cement interface in the control group. The median OKS at one-year follow up for this cohort was 36.5 (IQR 26.0-40.25). The presence of radiolucencies at the implant-cement interface in the control group did not affect performance when compared to TKAs without radiolucency at the implant-cement interface. The median OKS at one-year follow up for this cohort (no radiolucency at implant-cement interface at one-year) was 36.5 (IQR 26.0-44.0). The difference between the two groups was not statistically significant (p=0.52). Details of the location of lucencies seen at the implant-cement interfaces are shown in graph 2. Similar results were observed at the two-year follow-up.

(Figures 3 & 4.)

(Figures 5 & 6.)

Of note, lateral zone 3 in the Attune TKA had notably more lucencies than the control arm. 57% (n=16) of radiolucencies seen at the implant-cement interface in the Attune group were seen in lateral zone three, anterior to the keel; their median OKS was 32.5, (IQR 26.75-40). There was no statistically significant difference in OKS between those Attune TKAs where there was lucency anterior to the keel at the implant-cement interface and those where it was absent, median 36.0, (IQR 25-43.25) (p=0.51).

Discussion

This cohort study confirms that patients with Attune TKA have similar outcomes at two-year follow up as compared to Sigma PFC or Vanguard TKA. No difference was found in the incidence of radiolucency occurrence at either cement-bone or implant-cement interface between the two cohorts and patient reported outcome measures were similar between the two groups. Reassuringly, no evidence of increased aseptic loosening was found in this study either clinically, radiographically or as an indication for revision in the Attune cohort as compared with established TKA systems. Non-significant radiolucencies (< 2 mm) occurred with similar frequency in both the cohorts and these had no effect on clinical outcomes.

Developments in TKA systems focus on improving patient satisfaction, implant survival and surgical efficiency. Some developments in TKA system designs have previously been reported to lead to increased incidence of tibial component aseptic loosening. Foran et al studied 529 TKAs using the Nexgen Tibial Component developed for minimally invasive surgery in 460 patients implanted by a single surgeon over the course of 18 months [19]. Eight patients initially experienced a pain-free postoperative period, then developed pain on weight-bearing with a clinical effusion and radiographical findings indicative of loosening. Other authors have noted aseptic loosening in tibial component developed for minimally invasive surgery, the majority at the implant-cement interface [20, 21], while further reports disagree and find no increased rates of loosening [22].

Tibial loosening generally presents with symptoms and/or with radiological evidence of implant loosening [11]. Symptoms of loosening are identified at clinical review, and clinical deterioration objectively quantified by use of Patient Reported Outcome Measures (PROMs). OKS is a popular and validated PROM and is routinely used by NJR of England and Wales. OKS generally reaches a postoperative peak followed by a plateau at one year. Although a gradual decline following this has

been observed in the literature, no statistically significant difference is usually seen within the first five years [23]. We therefore used OKS at one-year as a benchmark to assess clinical outcome. In addition, we followed the patients up at two years to ensure there was no deterioration in PROMS, as well as no new adverse features identified on the radiological review.

Implants can loosen at either the implant-cement or cement-bone interface. Presence of a radiolucency at either of these interfaces can be suggestive of loosening provided it meets certain criteria. Goodfellow et al suggested that the pathological radiolucencies i.e. those which are abnormal and typically associated with infection or aseptic loosening are progressive, poorly defined and over 2 mm thick, while physiological radiolucencies (i.e. a normal finding) develop within the first post-operative year, become stable thereafter and are no more than 2mm [24, 25]. The latter are thought to indicate suboptimal fixation and represent a layer of fibrocartilage which develops at the cement-bone interface [26]. These physiological radiolucencies have been shown to have no correlation with clinical outcome, are typically seen with cemented rather than cementless implants and are at the cement-bone interface [27].

Radiographical appearances, particularly the implant-cement and cement-bone interfaces can be influenced by cementing technique. There is a lack of consensus in the literature and orthopedic community with respect to the accepted method of cementing. Cement viscosity, application time and application method have all been shown to influence cement penetration and degree of radiolucency, and all may vary between surgeons [28-30]. To achieve clinically relevant conclusions, it is necessary to compare clinical and radiological data with another TKA system which has a proven track record with long-term clinical data confirming its safety and efficacy and has been implanted by the same surgeon. We therefore conducted this study comparing radiographs of Attune TKA with well-established TKA systems implanted by the same group of arthroplasty

surgeons in patients with similar characteristics and all joint replacements performed with a standardized surgical technique.

Bonutti et al suggested a concerning possibility of increased rates of aseptic loosening in Attune TKA systems in their case series but there are significant limitations to their study [11]. All revision cases reported were following primary TKAs referred from other institutions and the authors were therefore unable to provide a rate of aseptic loosening. In addition, the retrospective nature of the study prevented the authors from being able to account for confounding factors such as patient demographics, individual surgeon technique, post-operative care and institutional differences, or compare with control cases. Our study has tried to overcome this limitation by comparing two cohorts with identical surgical techniques as well as standardized post-operative care. We have not seen a single case of aseptic loosening in this study in either of the cohorts and none of the patients have undergone revision surgery or are awaiting revision. A recent independent report based on UK National Joint Registry data found no difference in overall revision rate in Attune TKA systems as compared with all other TKAs, or in revision rate specifically for aseptic tibial loosening [31][28].

In a study similar to ours, Staats et al investigated 276 Attune TKA systems and found a significantly increased frequency of radiolucencies as compared with PFC controls (35.1% of Attune TKA vs 7.5% of PFC TKA) [32]. The authors also noted that the majority of the radiolucencies occurred at the implant-cement interface in the Attune group. Their study did not record patient-reported clinical outcomes, although survival analysis found no difference in revision-free survival or revision rate at the time of last follow-up. The authors found the largest proportion of radiolucencies at the cement-implant interface anterior to the keel (in zone 3 on lateral radiograph) at 12 months. They advised close monitoring and clinical correlation in these patients. Contrary to their observations, we did not find a significant difference in incidence of radiolucencies at cement-bone or implant-cement interface in the Attune group as compared with

controls at two-year follow-up. In addition, we also assessed patient-reported clinical outcomes at one and two years; this was similar in both groups. It is not possible to explain the differences between our results and those reported by Staats, with reference to the incidence of radiolucency. The two studies are quite similar in the study design as well as methodology. Our sample size is smaller, but we have looked at PROM and it does confirm that these radiolucencies have no impact on the clinical outcome, at least in the short term.

Our findings and possibly more importantly data from the UK registry provide some assurance that early tibial loosening does not seem to be an issue with the Attune TKA system as suggested by the study by Bonutti et al. Aseptic tibial loosening is a rare event and can occur at any time frame post-arthroplasty. New tibial implants tend to have shorter keels, increased conformity and are possibly less forgiving than conventional TKA systems. Since the start of our study DePuy have launched an alternative option; the Attune S+ tibial tray. This offers increased surface roughness, 45 degrees undercut pockets to enhance mechanical fixation and the ability to use a rotating platform. None of the TKA in our study used the Attune S+ tibial base plate. Attention to detail in cementing as well as surgical technique is likely to be more critical with the newer designs than with the conventional systems. Restoration of native tibial slope, meticulous preparation of the bony surfaces prior to cementing, adequate application of bone cement on both the cancellous bone as well as the under surface of the implant are some of the key steps in achieving a stable bond between implant-cement and cement-bone interface. A standardized cementing technique needs to be followed to ensure stable fixations. In spite of following all the key steps in cementing, our cohorts did show occurrence of radiolucency at both implant-cement as well as cement-bone interfaces. The former is likely to be associated with the surgical technique whilst the latter are physiological with no clinical relevance. The importance of the presence of a small (< 2mm) radiolucencies at the implant-cement interface, which does not progress, is not known but is likely to be of little consequence.

There are some limitations to this study. Pre-operative OKS were not available. The relative change in PROM score therefore cannot be compared between Attune and control arms. The study cannot determine rate of aseptic loosening with certainty as no cases were revised for aseptic loosening. We used clinical and radiological outcomes as surrogate measures of loosening in this study. However, clinical outcomes quantified by PROM scores are subjective, and aseptic loosening is not always evident radiologically [11]. Similarly, aseptic loosening may occur before symptoms become apparent [29]. These surrogate measures may therefore be relatively crude. For more rigorous assessment of the incidence of aseptic loosening in Attune knee systems, a longer follow-up period with greater sample size is required.

Reference list:

1. Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am. 2007;89(4):780-785. doi:10.2106/JBJS.F.00222

2. Culliford D, Maskell J, Judge A, et al. Future projections of total hip and knee arthroplasty in the UK: results from the UK Clinical Practice Research Datalink. Osteoarthr Cartil. 2015;23(4):594-600. doi:10.1016/j.joca.2014.12.022

3. Sharkey PF, Lichstein PM, Shen C, Tokarski AT, Parvizi J. Why are total knee arthroplasties failing today--has anything changed after 10 years? J Arthroplasty. 2014;29(9):1774-1778. doi:10.1016/j.arth.2013.07.024

4. Bourne RB, Chesworth BM, Davis AM, Mahomed NN, Charron KDJ. Patient Satisfaction after Total Knee Arthroplasty: Who is Satisfied and Who is Not? Clin Orthop Relat Res. 2010;468(1):57-63. doi:10.1007/s11999-009-1119-9

5. Baker PN, van der Meulen JH, Lewsey J, Gregg PJ, National Joint Registry for England and Wales. The role of pain and function in determining patient satisfaction after total knee replacement. Data from the National Joint Registry for England and Wales. J Bone Joint Surg Br. 2007;89(7):893-900. doi:10.1302/0301-620X.89B7.19091

6. Parvizi J, Jain N, Schmidt AH. Periprosthetic knee fractures. J Orthop Trauma. 2008;22(9):663-671. doi:10.1097/BOT.0b013e31816ed989

7. Scott CEH, Oliver WM, MacDonald D, Wade FA, Moran M, Breusch SJ. Predicting dissatisfaction following total knee arthroplasty in patients under 55 years of age. Bone Joint J. 2016;98-B(12):1625-1634. doi:10.1302/0301-620X.98B12.BJJ-2016-0375.R1

8. Carey BW, Harty J. A comparison of clinical- and patient-reported outcomes of the cemented ATTUNE and PFC sigma fixed bearing cruciate sacrificing knee systems in patients who underwent total knee replacement with both prostheses in opposite knees. Journal of Orthopaedic Surgery and Research. 2018;13(1):54. doi:10.1186/s13018-018-0757-6

9. Webb JE, Yang HY, Collins JE, Losina E, Thornhill TS, Katz JN. The Evolution of Implant Design Decreases the Incidence of Lateral Release in Primary Total Knee Arthroplasty. The Journal of Arthroplasty. 2017;32(5):1505-1509. doi:10.1016/j.arth.2016.11.050

10. Whittaker J-P, Dwyer KA, Howard J, et al. Learning curve with a new primary total knee arthroplasty implant: a multicenter perspective with more than 2000 patients. Arthroplasty Today. July 2018. doi:10.1016/j.artd.2018.05.004

11. Bonutti PM, Khlopas A, Chughtai M, et al. Unusually High Rate of Early Failure of Tibial Component in ATTUNE Total Knee Arthroplasty System at Implant-Cement Interface. J Knee Surg. 2017;30(5):435-439. doi:10.1055/s-0037-1603756

12. Justin T. Deen, MD *, Terry B. Clay, MD, Dane A. Iams, MD, Proximal tibial resorption in a modern total knee prosthesis. Arthroplasty Today 4 2018, 244-248 doi: 10.1016/j.artd.2017.10.005

13. A. Cerquiglini, J. Henckel, H. Hothi, P. Allen, J. Lewis, A. Eskelinen, J. Skinner, M. T. Hirschmann, A. J. Hart. Analysis of the Attune tibial tray backside: A comparative retrieval study. Bone Joint Res 2019;8:136–145. doi: 10.1302/2046-3758.83.BJJ-2018-0102.R2

14. US NATIONAL LIBRARY OF MEDICINE ClincalTrials.gov, [online] USA, September 17, 2019, viewed 10/03/2020, https://clinicaltrials.gov/ct2/show/NCT04037735

15. Dawson J, Fitzpatrick R, Murray D, Carr A. Questionnaire on the perceptions of patients about total knee replacement. J Bone Joint Surg Br. 1998;80(1):63-69.

16. Murray DW, Fitzpatrick R, Rogers K, et al. The use of the Oxford hip and knee scores. J Bone Joint Surg Br. 2007;89(8):1010-1014. doi:10.1302/0301-620X.89B8.19424

17. Ewald FC. The Knee Society total knee arthroplasty roentgenographic evaluation and scoring system. Clin Orthop Relat Res. 1989;(248):9-12.

18. Kalairajah Y, Azurza K, Hulme C, Molloy S, Drabu KJ. Health outcome measures in the evaluation of total hip arthroplasties--a comparison between the Harris hip score and the Oxford hip score. J Arthroplasty. 2005;20(8):1037-1041. doi:10.1016/j.arth.2005.04.017

19. Foran JRH, Whited BW, Sporer SM. Early aseptic loosening with a precoated low-profile tibial component: a case series. J Arthroplasty. 2011;26(8):1445-1450. doi:10.1016/j.arth.2010.11.002

20. Kajetanek C, Bouyer B, Ollivier M, Boisrenoult P, Pujol N, Beaufils P. Mid-term survivorship of Mini-keel™ versus Standard keel in total knee replacements: Differences in the rate of revision for aseptic loosening. Orthop Traumatol Surg Res. 2016;102(5):611-617. doi:10.1016/j.otsr.2016.05.007

21. Ries C, Heinichen M, Dietrich F, Jakubowitz E, Sobau C, Heisel C. Short-keeled cemented tibial components show an increased risk for aseptic loosening. Clin Orthop Relat Res. 2013;471(3):1008-1013. doi:10.1007/s11999-012-2630-y

22. Yoo J-H, Park B-K, Han C-D, Oh H-C, Park S-H. Minimum 5-year Follow-up Results of Minimally Invasive Total Knee Arthroplasty Using Mini-Keel Modular Tibial Implant. Knee Surg Relat Res. 2014;26(3):149-154. doi:10.5792/ksrr.2014.26.3.149

23. Williams DP, Blakey CM, Hadfield SG, Murray DW, Price AJ, Field RE. Long-term trends in

the Oxford knee score following total knee replacement. Bone Joint J. 2013;95-B(1):45-51. doi:10.1302/0301-620X.95B1.28573

24. Goodfellow JW, O'Connor JJ, Dodd CAF, Murray DW. In: Unicompartmental Arthroplasty with the Oxford Knee. Oxford, UK: Oxford University Press; :117-128.

25. Gulati A, Chau R, Pandit HG, et al. The incidence of physiological radiolucency following Oxford unicompartmental knee replacement and its relationship to outcome. J Bone Joint Surg Br. 2009;91(7):896-902. doi:10.1302/0301-620X.91B7.21914

26. Pandit H, Liddle AD, Kendrick BJL, et al. Improved fixation in cementless unicompartmental knee replacement: five-year results of a randomized controlled trial. J Bone Joint Surg Am. 2013;95(15):1365-1372. doi:10.2106/JBJS.L.01005

27. Ecker ML, Lotke PA, Windsor RE, Cella JP. Long-term results after total condylar knee arthroplasty. Significance of radiolucent lines. Clin Orthop Relat Res. 1987;(216):151-158.

28. Cawley DT, Kelly N, McGarry JP, Shannon FJ. Cementing techniques for the tibial component in primary total knee replacement. Bone Joint J. 2013;95-B(3):295-300. doi:10.1302/0301-620X.95B3.29586

29. Hazelwood KJ, O'Rourke M, Stamos VP, McMillan RD, Beigler D, Robb WJ. Case series report: Early cement-implant interface fixation failure in total knee replacement. Knee. 2015;22(5):424-428. doi:10.1016/j.knee.2015.02.016

30. Kopinski JE, Aggarwal A, Nunley RM, Barrack RL, Nam D. Failure at the Tibial Cement-Implant Interface With the Use of High-Viscosity Cement in Total Knee Arthroplasty. *J* Arthroplasty. 2016;31(11):2579-2582. doi:10.1016/j.arth.2016.03.063

31. Beyond Compliance. Implant Summary Report for: DePuy Attune Cemented (CR&PS, Fixed Bearing Only).; 2018.

32. Staats K, Wannmacher T, Weihs V, Koller U, Kubista B, Windhager R. Modern cemented total knee arthroplasty design shows a higher incidence of radiolucent lines compared to its predecessor. Knee Surg Sports Traumatol Arthrosc. September 2018. doi:10.1007/s00167-018-5130-0

Table caption/Figure legends:

Diagram 1. The Knee Society total knee arthroplasty roentgenographic evaluation and scoring system.

Table 1 – Characteristics across the study arms

Table 2A – Stratification of Oxford Knee Score (OKS) at one year: Poor <27, Fair 27-33, Excellent ≥34

Table 2B – Stratification of Oxford Knee Score (OKS) at two years: Poor <27, Fair 27-33, Excellent ≥34

Table 3 – Comparison of component alignment

Figure 1. Attune radiograph showing lucency at the cement-bone interface in AP zone 1.

Figure 2. Control (Vanguard) radiograph showing lucency at the cement-bone interface in AP zone 1.

Graph 1. Lucencies less than 2mm observed at the cement-bone interface

Graph 2. Lucencies less than 2mm observed at the implant-cement interface

Figure 3. Attune radiograph showing lucency at the implant-cement interface in AP zone 1.

Figure 4. Attune radiograph showing lucency at the implant-cement interface in lateral zone 3.

Figure 5. Control (PFC) radiograph showing lucency at the implant-cement interface in AP zone 1.

Figure 6. Control (PFC) radiograph showing lucency at the implant-cement interface in lateral zone 3.