International Journal of Orthopaedics Sciences

E-ISSN: 2395-1958
P-ISSN: 2706-6630
IJOS 2020; 6(3): 773-777

www.orthopaper.com
Received: 19-05-2020
Accepted: 03-08-2020

Thomas Kozak
Department of Orthopaedic Surgery, Royal Perth Hospital, Australia

Moreica Pabbruwe
Centre for Implant Technology and Retrieval Analysis, Department of Medical Engineering and Physics, Royal Perth Hospital, Australia

Alan Kop
Centre for Implant Technology and Retrieval Analysis, Department of Medical Engineering and Physics, Royal Perth Hospital, Australia

Gavin Clark
St John of God Hospital, Subiaco, Perth WA 6008, Australia

Corresponding Author:
Thomas Kozak
Department of Orthopaedic Surgery, Royal Perth Hospital, Australia

Forensic analysis of retrieved score knees: A failure of fixation?

Thomas Kozak, Moreica Pabbruwe, Alan Kop and Gavin Clark

DOI: https://doi.org/10.22271/ortho.2020.v6.i3l.2284

Abstract
Background: The SCORE total knee arthroplasty (Amplitude, France) has a deep trochlear groove designed to reduce polyethylene wear, risk of loosening, and patellofemoral complications. In 2014, the AOANJRR reported a higher revision rate when implanted cementless compared to cemented. The aim of the study was to forensically examine retrieved SCORE TKA's and determine failure modes.
Methods: Retrieval analysis was performed at the Centre of Implant Technology and Retrieval Analysis (Royal Perth Hospital). 27 SCORE primary total knee implants from 26 patients requiring revision were forensically analysed for failure mode. Macroscopic examination and quantitative assessment of tissue ingrowth was combined with clinical record findings and radiographic analysis. Statistical analysis was performed.
Results: On average the patients were relatively young (mean age 65.5 years) and obese (mean BMI=32.5) with almost equal numbers of male and females and a mean short time of service (2.4 years). The majority of the implants were cementless and without patella resurfacing. Secondary analysis of patient demographics found no difference in age, BMI, gender and activity levels between the patients with loose femoral components and the population as a whole. Radiological analysis revealed an overall satisfactory alignment using the Knee Society TKA Roentgenographic Evaluation and Scoring System. Although six uncemented femoral components (22%) were found grossly loose at time of revision, only one was identified pre-operatively from plain x-rays. Macroscopic analysis confirmed coating delamination and deposition of fine metallic debris on tissue attached to components. Polyethylene inserts had a degree of wear greater than expected with embedded metal debris. Histomorphometric analysis revealed poor bony ingrowth on both uncemented femoral and tibial components.
Conclusions: Retrieval analysis revealed a higher than expected rate of cementless femoral loosening in SCORE TKAs. Clinically, surgeons should be aware of patients with this implant presenting with pain that femoral loosening cannot be excluded as a diagnosis by imaging.

Keywords: Arthroplasty, knee, retrieval analysis

1. Introduction
Primary total knee arthroplasty (TKA) is a common operation with over 55,000 cases in the last year in Australia and over 600,000 cases in the United States. Due to an aging population, this number is expected to increase almost four times by 2030. TKA has an overall low failure rate when the primary diagnosis is osteoarthritis, with the Australian Orthopaedic Association Joint Replacement Registry (AOANJRR) reporting a revision rate of 5.3% at 10 years. Despite this, patellofemoral complications remain a major issue encountered post-operatively, with patellofemoral pain accounting for 10.4% of all revisions. These complications are usually caused by a combination of surgical (e.g. implant positioning, soft tissue balancing, patellar resurfacing) and implant factors (e.g. trochlear depth, sagittal curvature, and patella component design). Various patellofemoral systems exist in the current market, however there is evidence to suggest that a number of these models exhibit characteristics of trochlear dysplasia. In general, newer TKA designs have more anatomic trochlear geometries than earlier models.
The SCORE TKA (Amplitude, France) was designed with a deep trochlear groove in an attempt to recreate normal anatomy and reduce patellofemoral complications. This device has a rotating tibial plateau and uses a specific computer-assisted navigation system. Cemented and cementless options are available as well as the option for patellofemoral resurfacing. In the cementless version, the implant has a dual-coating of plasma-sprayed titanium (80μm) and hydroxyapatite (80μm).

In 2014, the AOANJRR reported a higher than expected revision rates in SCORE TKAs when used without patellar resurfacing, however the exact mechanism of failure was not apparent. A survey of the literature revealed a limited number of studies looking at long-term performance and post-marketing surveillance of this implant. As such, the aim of this study was to forensically analyse retrieved SCORE TKAs and determine failure modes.

2. Materials and methods

2.1 Patient Demographics

This research has been approved by the Ethical Committees of the authors' affiliated institutions. Routine retrieval analysis of all arthroplasty implants in Western Australia is performed at the Centre for Implant Technology Retrieval Analysis (CITRA). From the retrieval collection of 11,800 devices in our collection, 27 SCORE knees were identified and analysed. The retrievals were collected from 5 different institutions and the revision surgeries were performed by 11 surgeons. The retrieval forms supplied at the time of revision included clinical information (age, sex, weight, and activity levels), causes of failure and observation at the time of surgery. Additional clinical notes were gathered from the surgeon retrospectively. In particular, the documented indications for revision and possible contributory factors were noted. Intra-operative observations were also collated from operative reports, noting findings including the fixation of femoral and tibial components to bone, gross loosening, metallosis, bone resorption, and scar tissue formation. Implants were described as loose if they were pulled out without significant force. A summary of the patient demographics and clinical data is presented in Table 1.

Table 1: Summary of patient demographics including reasons for removal and observations at retrieval

Demographics	
Time in situ (years)	2.39 ± 1.7
Age (years)	65.6 ± 8.8
F : M ratio	1 : 1
BMI	32.5 ± 7
High activity levels	48%
Fixation Method	
Cementless	20
Cemented	6
Hybrid	1
Patella resurfacing	6
Reasons For Removal (% value)	
Pain	56
Joint instability	37
Loosening	37
Infection	15
Stiffness	7
Osteolysis	7
Observations At Removal (% value)	
Loose femoral	26
Loose tibial	22
Loose patella	7
Scar tissue/Granulation	44
Metallosis/Debris	30
Bone resorption	22
Infection	11

Statistical analysis was performed to look for differences in age, gender, BMI and activity levels between the patients with femoral loosening and the population as a whole (2-tailed, unpaired t-test) as shown in Table 2.

Table 2: Basis statistic on Patient demographics: t-test

Statistical Analysis of Patient Demographics (t-test)	
Age	p = 0.552
BMI	p = 0.276
Gender	p = 0.279
High activity	p = 0.804

2.2 Radiographic findings

TKA position was assessed from antero-posterior and lateral knee radiographs. Plain radiographs taken post primary arthroplasty were analysed according to the Knee Society Roentgenographic Evaluation System (α-angle formed medially by the mechanical axis of femur and bicondylar axis, β-angle formed by the line tangent to the medial tibial plateau and the mechanical axis of tibia, γ-angle on the lateral view between the supratrochlear cortex and the prosthetic trochlea, and δ-angle between the line tangent to the posterior edge of the tibial plateau and the axis of the tibia). In patients with multiple radiographs the earliest post-operative film was used. In addition, radiographs, CT scans and bone scans performed pre-revision surgery were reviewed for signs of loosening based on the Radiologist's report.

2.3 Retrieval Analysis

Retrieved femoral and tibial components were inspected and photographed upon arrival then analysed using a stereomicroscope (M80, Leica, Germany). Any particular features were photographed using the M80 stereomicroscope. Wear on the polyethylene inserts was described following the wear mechanisms (pitting, scratching, burnishing, embedded debris, abrasion, delamination and plastic deformation) proposed by Hood and colleagues.

2.4 Histomorphometry

Histomorphometric analysis was performed to evaluate tissue ongrowth to femoral and tibial cementless components. The total area of bone, fibrous and total tissue ongrowth on femoral and tibial components was measured and calculated using digitised images and image analysis software (Magnification, Orbicule, USA). The calculation of tissue ongrowth on the tibial tray was performed using an orthogonal view of each component while for the femoral component three images were taken for anterior, posterior and distal regions.

3. Results

3.1 Patient Demographics

27 SCORE TKAs were retrieved from 26 patients (13 men and 13 women) with an average implantation time of 2.4 years. The mean age was 65.6 years with a mean weight of 94.9kg. The mean BMI was 32.5. The method of fixation included 20 cementless implants, four cemented, and three hybrids (cemented tibial and uncemented femoral component). Six patients had patella resurfacing (four cementless and two cemented). Activity levels documented by the revising surgeon were noted as 'high' in 48%. When additional analysis of demographics comparing the patients with observed loose components and the study group as a whole (Table 2), there was no significant difference in age (p=0.552), gender (p=0.279), BMI (p=0.276) or activity levels (p=0.804).

The most significant observation at removal was seven (26%) loose femoral components, of which six were cementless. Two of these cases had infection that may have contributed to loosening. Loose tibial components were noted in six (22%)

cases of which five were cementless. Loose patella components were found in two (9%) components.

3.2 Radiographic findings

All 27 SCORE TKAs were analysed for radiological position from x-rays taken in the immediate post-operative period. Using the Knee Society Roentgenographic Evaluation System, it was found that all the implants were well positioned. The average α-angle was 94.8, the β-angle was 87.4, γ-angle was 3.01, and δ-angle was 87.6 (Table 3). Examination of radiological imaging performed in the work-up for revision arthroplasty revealed that 26 of the 27 SCORE TKAs had x-rays. Of these 26 x-rays, only one was reported as having a radiolucent line indicative of prosthetic loosening (patient no. 2). Ten patients had CT scans, and of these only one was reported as having a loose tibial component (patient no. 5). Ten patients had technetium bone scans, and these revealed two loose femoral and two loose tibial components (patient's no. 1, 2, 16, 17). Demonstrated below is an x-ray of patient no. 10, who had an x-ray reporting no signs of loosening however was found to be grossly loose on retrieval (Figure 1).

Table 3: Radiographic analysis of x-rays post primary arthroplasty

Radiographic Parameters	
α-angle	94.9 ± 3.5
β-angle	87.3 ± 2.2
γ-angle	3.29 ± 2.7
δ-angle	87.6 ± 1.8
Insall-Salvati ratio	1.04 ± 0.1

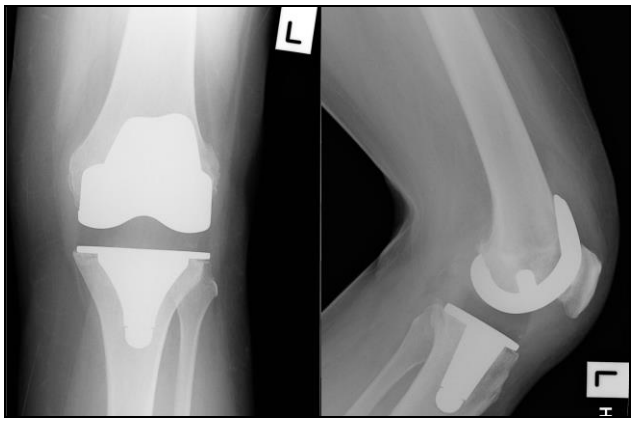

Fig 1: Prior to revising this SCORE TKA at 2.7 years in this 71-year-old female patient (patient no. 10), x-ray was reported without evidence of prosthetic loosening. On retrieval, the femoral component was noted to be grossly loose.

3.3 Retrieval Analysis

The examination of all the components revealed common features that differed in the degree of the degradation (from minimal to extensive). Femoral components showed deep longitudinal scratches on the bearing surfaces (Figure 2a). Tibial components had concentric scratches on the bearing surface (Figure 2b). Peeling or delamination of the cementless coating on cementless explants was also a common feature on a number of implants (Figure 2c) resulting in the generation of numerous particles seen within attached tissue of nine (39.1%) explants, a potential source for third body wear (Figure 2d).

Wear of the polyethylene insert was assessed as per the seven wear categories described by Hood and colleagues. The superior bearing surface on the majority of the sample showed longitudinal scratching. Wear on the inferior surface consisted of concentric scratching on the posterior surfaced expected in a mobile bearing prosthesis. Both bearing surfaces showed embedded metal debris (Figure 2e) and severe pitting wear on cemented components likely from bone cement particles (Figure 2f).

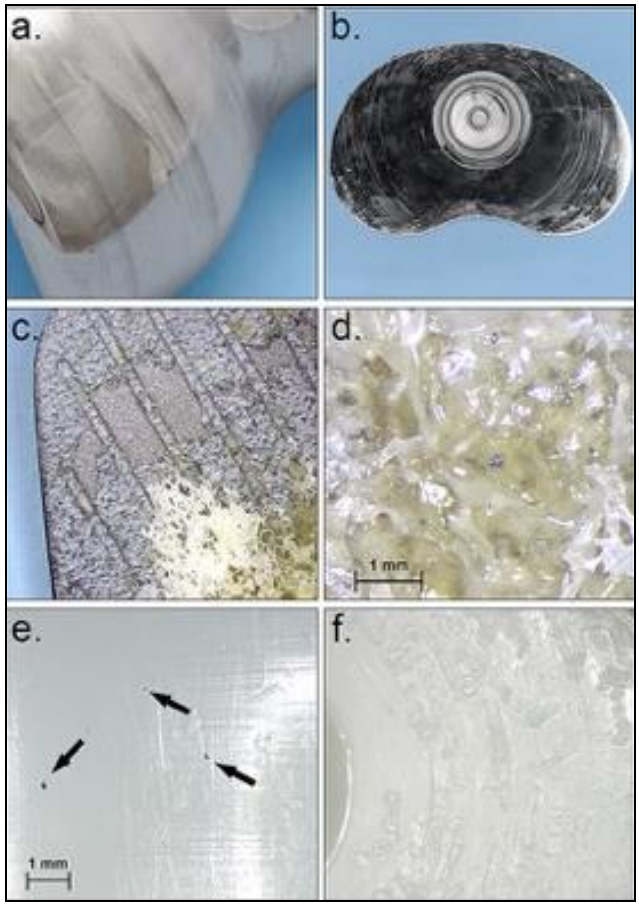

Fig 2: Common features found on retrieval samples in the study group. (a) Extensive scratching on femoral component (b) Concentric scratches on the bearing on bearing surface of tibia trays, typical of mobile bearing (c) Delamination of the cementless femoral coating in an implant revised after 10 months in situ (d) Multiple fine metallic particles on tissue attached to cementless femoral component (e) Fine metallic particles embedded in the polyethylene insert (f) Severe pitting and concentric scratches on posterior bearing surface of PE insert.

3.4 Histomorphometry

Histomorphometric analysis was performed on twelve (12) cementless SCORE TKAs that revealed minimal tissue apposition to both femoral and tibia components (Figure 3). The amount and type of tissue attached to both components is very similar and in most cases there is mostly bone not fibrous tissue.

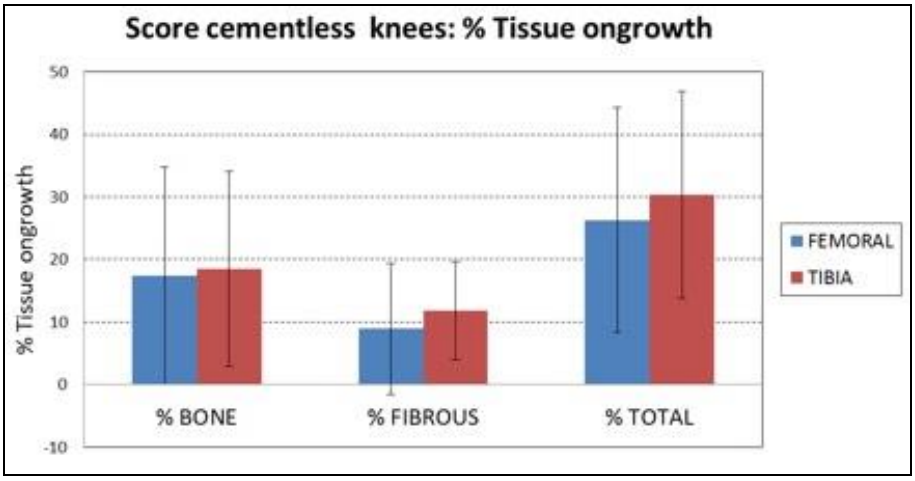

Fig 3: Average tissue ingrowth of femoral and tibial components

4. Discussion

The AOANJRR reports a total of 3982 SCORE TKAs implanted in Australia, comprised of 731 cemented, 2034 cementless, and 1217 hybrid implants. The cumulative revision rate at 5 years for each combination is 2.4% (cemented), 7.6% (cementless) and 5.4% (hybrid). This is compared to a cumulative 5-year revision rate of 3.5% for all TKA implants, and 4.2% for all minimally stabilised primary cementless TKAs for osteoarthritis. In 2014 the SCORE TKA was recognised by the AOANJRR as having a higher than expected rate of revision when implanted without patellar resurfacing. At the time it was also noted that SCORE TKAs with cementless fixation had a higher revision rate than cemented implants. This was acknowledged by the Australian Therapeutic Goods Association in their 2015 report. More recently, the AOANJRR have reported a cumulative revision rate at 10 years of 12.9% for the SCORE TKA when used cementless.

The patients in this series had typical characteristics of those undergoing joint replacement, although were noted to have an average BMI of 32.5. Obesity has been shown to increase risk of mechanical failure and aseptic tibial loosening when BMI is above 35, hence our cohort should not have been at higher risk for this failure mechanism.

Radiological analysis found implant position to unlikely be a factor contributing to failure in this series, and subsequent analysis of radiography prior to revision found that component loosening was not consistently detected prior to revision. Only one patient of the patients with a loose cementless femoral component had a radiolucent line seen on x-ray. This is important as x-ray is generally one of the first line investigations used to evaluate TKAs post-operatively. Other investigations such as SPECT/CT have been shown to have superior sensitivity and specificity to diagnose prosthesis loosening and hence may need to be considered in addition to x-ray. To our knowledge there are no studies reporting on loose femoral components not detected on x-rays.

The most significant observation at removal was six cases of loose cementless femoral components. This was an unexpectedly high number for the number of cases in our series and it was poorly detected with radiographic imaging. Only one patient in this series had a radiolucent line on x-ray indicating component loosening, and moreover loosening was not consistently seen with CT or technetium bone scan. Aseptic loosening is the failure of the bond between an implant and bone in the absence of infection. It can be the result of inadequate fixation, mechanical failure over time, or the loss of biological fixation from particle-induced Osteolysis. The AOANJRR reports that aseptic loosening accounts for 25% of all primary TKA revisions. The Norwegian Arthroplasty register found that tibial implant loosening accounts for around 17% of primary TKA revision, compared to less than 5% for femoral loosening. Importantly, we observed 22% of cementless femoral and 19% of tibial loosening in our cohort. The findings from our series differ from the two largest series of SCORE TKAs, both authored by the creators of the device. In these studies, Chatain (n=447) and Ouanezar (n=138) reported no cases of aseptic loosening. The only study reporting poor results of the SCORE TKA by Akakpo and colleagues found a high rate of revision of 19 SCORE TKAs, and suggested that unique trochlear design puts high loads on the patella implant with protrusion of the trochlear and this may contribute to failure.

Another new knee implant with a similarly designed deep trochlear groove is the HLS Noetos (Gloucestershire, UK), which has also been identified by the AOANJRR as having a higher than expected revision rate of 13.7% at 10 years. To our knowledge there are no other primary TKAs with a similarly designed deep trochlear groove. A longstanding successful cementless TKAs is the LCS (Depuy) mobile bearing TKA with 5-year revision rates of 4%. Despite the theoretical advantages of mobile bearing TKAs, recent systematic reviews have not proven superiority to fixed bearing TKAs. The AOANJRR reports a cumulative revision rate of 4.5% at 5 years for all rotating mobile bearing primary TKAs, compared with 3.3% for fixed bearings.

Histomorphometric analysis in our series revealed overall low levels of tissue ingrowth. The exact reason behind the cases of poor biological fixation is unclear to us, especially given the generalised success of all other cementless TKAs. The cementless SCORE TKA is coated with plasma-sprayed titanium and hydroxyapatite, similar to other cementless TKA designs. Our findings of coating delamination suggest that suboptimal coating characteristics may be contributing to the higher than expected rate of loosening and revision of cementless Score knees. This could either involve the bonding of the titanium coating to the cobalt chromium base material or the bonding of the titanium coating to bone. Given that generally bone was observed on the affected coating it is suggested that the adhesive strength at the coating-substrate interface may be of concern, and this also supports the radiological findings of a lack of bone lucency. Further studies are needed to further characterise the Titanium/Hydroxyapatite coating. Other unique patient factors including biological and mechanical may have also

played a role in bone ingrowth. The limitations of this study include the retrospective nature of the study and small number of patients.

5. Conclusion

Forensic examination of 27 retrieved Score TKA indicates that a higher than expected rate of loose cementless femoral components related to coating characteristics that was poorly detected with radiographic imaging and associated with poor tissue ingrowth. We advise an awareness that patients with the SCORE total knee arthroplasty are unable to have femoral loosening excluded as a diagnosis by imaging.

6. Acknowledgements: Nil

7. References

1. Australian Orthopaedic Association National Joint Replacement Registry. Hip, Knee & Shoulder Arthroplasty Annual Report 2019. Adelaide: AOA, 2019.
2. Losina E, Thornhill TS, Rome BN, Wright J, Katz JN. The dramatic increase in total knee replacement utilization rates in the United States cannot be fully explained by growth in population size and the obesity epidemic. J Bone Joint Surg Am. 2012; 94(3):201-7.
3. 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):780-5.
4. Australian Orthopaedic Association National Joint Replacement Registry. Hip, Knee & Shoulder Arthroplasty Annual Report 2018. Adelaide: AOA, 2018.
5. Healy WL, Wasilewski SA, Takei R, Oberlander M. Patellofemoral complications following total knee arthroplasty. Correlation with implant design and patient risk factors. J Arthroplasty. 1995; 10(2):197-201.
6. Ostermeier S, Buhrmester O, Hurschler C, Stukenborg-Colsman C. Dynamic *in vitro* measurement of patellar movement after total knee arthroplasty: an *in vitro* study. BMC Musculoskelet Disord. 2005; 6:30.
7. Varadarajan KM, Rubash HE, Li G. Are current total knee arthroplasty implants designed to restore normal trochlear groove anatomy? J Arthroplasty. 2011; 26(2):274-81.
8. Dejour D, Ntagiopoulos PG, Saffarini M. Evidence of trochlear dysplasia in femoral component designs. Knee Surg Sports Traumatol Arthrosc Off J ESSKA. 2014; 22(11):2599-607.
9. Châtain F, Gaillard TH, Denjean S, Tayot O. Outcomes of 447 SCORE® highly congruent mobile-bearing total knee arthroplasties after 5-10 years follow-up. Orthop Traumatol Surg Res OTSR. 2013; 99(6):681-6.
10. Australian Orthopaedic Association National Joint Replacement Registry. Hip, Knee & Shoulder Arthroplasty Annual Report 2014. Adelaide: AOA, 2015.
11. Ewald FC. The Knee Society total knee arthroplasty roentgenographic evaluation and scoring system. Clin Orthop. 1989; (248):9-12.
12. Hood RW, Wright TM, Burstein AH. Retrieval analysis of total knee prostheses: a method and its application to 48 total condylar prostheses. J Biomed Mater Res. 1983; 17(5):829-42.
13. Administration AGD of HTG. Score Knee Prosthesis [Internet]. Therapeutic Goods Administration (TGA). 2015 [cited 2017 Jun 22]. Available from: https://www.tga.gov.au/alert/score-knee-prosthesis
14. Abdel MP, Bonadurer GF, Jennings MT, Hanssen AD. Increased Aseptic Tibial Failures in Patients with a BMI ≥35 and Well-Aligned Total Knee Arthroplasties. J Arthroplasty. 2015; 30(12):2181-4.
15. Gunst S, Fessy M-H. The effect of obesity on mechanical failure after total knee arthroplasty. Ann Transl Med [Internet]. [cited 2019 Feb 26]. 2015; 3(20). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC466931/
16. Murer AM, Hirschmann MT, Amsler F, Rasch H, Huegli RW. Bone SPECT/CT has excellent sensitivity and specificity for diagnosis of loosening and patellofemoral problems after total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc Off J ESSKA. 2019, 1.
17. Abu-Amer Y, Darwech I, Clohisy JC. Aseptic loosening of total joint replacements: mechanisms underlying osteolysis and potential therapies. Arthritis Res Ther. 2007; 9(1):S6.
18. Dyrhovden GS, Lygre SHL, Badawy M, Gøthesen Ø, Furnes O. Have the Causes of Revision for Total and Unicompartmental Knee Arthroplasties Changed During the Past Two Decades? Clin Orthop. 2017; 475(7):1874-86.
19. Ouanezar H, Franck F, Jacquel A, Pibarot V, Wegrzyn J. Does computer-assisted surgery influence survivorship of cementless total knee arthroplasty in patients with primary osteoarthritis? A 10-year follow-up study. Knee Surg Sports Traumatol Arthrosc Off J ESSKA. 2016; 24(11):3448-56.
20. Akakpo A, Dereudre G, Fouilleron N, Pasquier G, Migaud H. Poor short-term outcomes after computer-assisted rotating-platform total knee arthroplasty with a deep-trochlear-groove femoral component: analysis of 19 patients. Orthop Traumatol Surg Res OTSR. 2013; 99(2):183-90.
21. Gaillard R, Lustig S, Peltier A, Villa V, Servien E, Neyret P. Total knee implant posterior stabilised by a third condyle: Design evolution and post-operative complications. Orthop Traumatol Surg Res OTSR. 2016; 102(8):1061-8.
22. Australian Orthopaedic Association. Identified and No Longer Used (Supplemental Report for AOANJR Annual Report) [Internet]. Adelaide, 2018. Available from: https://aoanjrr.sahmri.com/documents/10180/276222/HLS%20Noetos%20%26%20HLS%20Noetos%20Combination
23. Capella M, Dolfin M, Saccia F. Mobile bearing and fixed bearing total knee arthroplasty. Ann Transl Med [Internet]. [cited 2019 Mar 3] 2016; 4(7). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC484239/
24. Van der Voort P, Pijls BG, Nouta KA, Valstar ER, Jacobs WCH, Nelissen RGHH. A systematic review and meta-regression of mobile-bearing versus fixed-bearing total knee replacement in 41 studies. Bone Jt J. 2013; 95-B(9):1209-16.
25. Aprato A, Risitano S, Sabatini L, Giachino M, Agati G, Massè A. Cementless total knee arthroplasty. Ann Transl Med [Internet]. [cited 2019 Jan 14]. 2016; 4(7). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC484239/
26. Bone ingrowth and total knee replacement – Science Direct [Internet]. [Cited 2019 Jan 14]. Available from: https://www-sciencedirect-com.smhslibresources.health.wa.gov.au/science/article/pii/0968016094900574