

Quantification of polyethylene degradation in mobile bearing knees

A retrieval analysis of the Anterior-Posterior-Glide (APG) and Rotating Platform (RP) Low Contact Stress (LCS) knee

Alan M Kop and Eric Swarts

Department of Medical Engineering and Physics, Royal Perth Hospital, Perth, Western Australia

Correspondence AMK: alan.kop@health.wa.gov.au

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Background Routine qualitative observations of more than 850 polyethylene fixed and mobile bearings at our institution have noted minimal wear of mobile bearings. The APG mobile bearing is the most recent design variant of the LCS knee, allows multi-directional movement at the tibiofemoral articulation, and is posterior cruciate sparing. Even though it is difficult to perform, quantitative wear measurement is important in determining the likely longevity of new arthroplasty devices, and is especially relevant because of increasing numbers of new mobile bearing designs.

Patients and methods We analyzed 10 retrieved APG and 7 retrieved RP tibial bearings (De Puy) with a mean implantation period of 33 (9–70) months. We used coordinate-measuring techniques to quantitatively determine linear penetration, and optical and scanning electron microscopy to assess wear mechanisms qualitatively.

Results The mean total volume loss (superior and inferior articulations) of the APG and RP designs was 85 mm³/year and 77 mm³/year, respectively. Burnishing was the predominant wear mechanism, and to a lesser extent scratching, abrasion and pitting. Multidirectional scratching and abrasion were noted on the APG inserts inferiorly, whereas there was circumferential scratching on the RP inserts.

Interpretation Our short-term results for the APG and RP mobile bearing designs are similar and compare more than favorably with reported values for fixed-bearing designs. However, increased backside wear due to multidirectional movement may predispose the APG design to greater wear in the long term. ■

Retrieval studies of implant components play a pivotal role in determining the efficacy of new designs that are introduced onto the market, and provide an invaluable resource for laboratory investigations that cannot be performed in vivo (Hailey et al. 1994, Williams et al. 1998). Analysis of retrieved devices that have been recently introduced onto the market can be useful in proving the worth of designs, materials and manufacturing methods, and can elucidate clinical factors that are important for successful implantation (Jones et al. 2001, Morberg et al. 2002, Muratoglu et al. 2004).

Since 1977, there has been increased interest in mobile bearing designs because of their potential to reduce stress at the implant-bone interface, minimize polyethylene wear, and thus improve implant longevity (Jones et al. 2001, Huang et al. 2002, Kilgus 2002, Kuster and Stachowiak 2002). The DePuy RP LCS knee (DePuy Orthopaedics Inc., Warsaw, IN) allows internal and external rotation of the knee with essentially linear-directional motion at the superior tibiofemoral articulation. In 1996, the Anterior-Posterior-Glide (APG) LCS knee was introduced to spare the posterior cruciate, reduce the potential for impingement, and possibly improve the range of motion of the knee by allowing multidirectional movement at the polyethylene bearing surface of the inferior tibial insert (Figure 1).

Routine observations at our institution have qualitatively noted minimal wear of LCS mobile bearings compared to fixed-bearing designs. Thus,

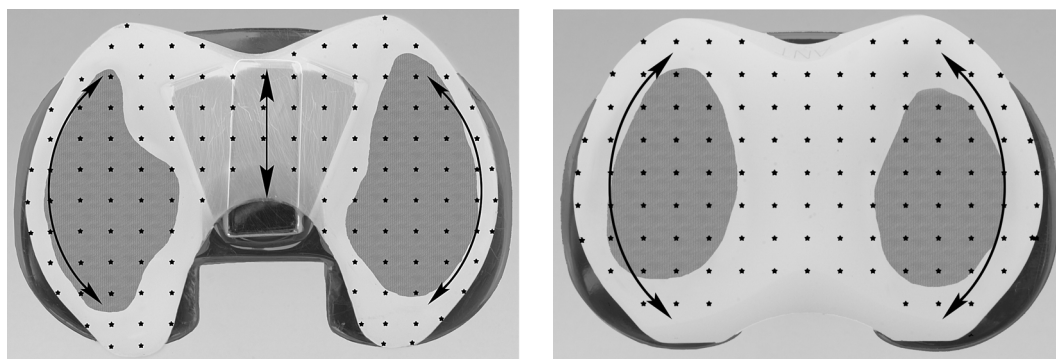


Figure 1. Measurement methodology (APG bearing left, RP right; shaded area worn). Arrows indicate direction of movement.

the primary aim of the study was to quantify and compare the wear on the superior tibiofemoral and inferior surface of retrieved RP and APG LCS polyethylene tibial inserts, and to determine the mechanisms of operative wear. The study examined all APG and RP implants referred to our laboratory for routine retrieval analysis. The limited number of investigations that have quantitatively assessed wear in TKA, and difficulty associated with measuring minimally worn components, led to the need for a new methodology to quantify the wear.

Material and methods

719 APG knees and approximately 1400 RP knees, both cemented and porous-coated types, have been implanted locally in Perth since 1998. Over this time we have received 17 LCS retrievals (APG and RP), all from local hospitals, with 6 senior surgeons conducting the original surgery (Table 1).

Average implantation time for the retrievals was 33 (9–70) months, and the most common reason for revision was pain and loosening. Other reasons included pain and stiffness, and infection. In most 12 cases only the tibial tray was revised, and generally to a cemented device. Each of the devices was processed according to our retrieval protocol, including cleaning, ethylene oxide sterilization, identification, failure analysis, reporting, and storage.

The LCS tibial polyethylene insert is essentially based upon a spherical superior medial and lateral tibiofemoral bearing and planar inferior bearing. This allowed quantitative analysis to be carried

Table 1. Summary of patient demographics and retrieval cases

	Anterior-posterior glide	Rotating platform
No. of tibial inserts	10	7
Women:men	6:4	5:2
Mean age (range)	63 (52–78)	56 (36–73)
Mean weight (range)	83 (70–112)	96 (90–100)
Mean time in situ (range)	31 (10–51)	36 (9–70)
Activity level (LM:MH)	6:3	3:3
Pain and loosening	7	4
Cemented:uncemented	1:9	1:6

LM: low to medium activity level;
MH: medium to high activity level.

out after implantation without design drawings, and also alleviated difficulties associated with pre-insertion measurement.

Specifically, we used a coordinate measuring (CMM) technique and a simple geometric model to determine the wear (Figure 1). We measured the superior surface at discrete points in a 5 mm × 5 mm grid pattern using a CMM technique (Brown and Sharp, North Kingston, RI) with a 3-sigma accuracy of 6 µm. We then marked out the worn and unworn bearing area using a stereo microscope. By taking the measurements in the unworn areas, the entire unworn bearing surface, i.e. the surface at the time of implantation (time = 0), was described mathematically. Subtraction of the data measured in the worn areas from the corresponding “point” at time = 0 resulted in a measurement of linear penetration. Similarly, on the inferior insert surface, by taking the perpendicular distance from the worn

Table 2. Intended bearing radii compared to measured values (mm)

Size	Intended value	Measured value ^a
Small +	32.7	32.8
Large	41.4	41.0
New RP	35.7	35.8 ^b
New APG	41.4	41.4 ^b

^a Measured value: the bearing radii were calculated from unworn areas on retrieved devices.

^b The method and model was verified using new inserts.

point to the unworn point (time = 0) an assessment of inferior wear resulted. Volumetric wear was estimated by measuring the area over which the wear occurred and the average penetration depth.

Using a stereo microscope at 20× magnification, we determined the wear mechanism(s) and severity of the bearing surfaces using a point scoring method (1 = slight, 10 = severe) (Hood et al. 1983). The 7 wear categories assessed were: surface deformation, pitting, embedded particles, scratching, burnishing, abrasion, and delamination. We used scanning electron microscopy (SEM) (Philips XL 30 scanning electron microscope) on selected bearings and tibial trays to aid in the determination of modes of wear.

Results

Quantitative wear: superior and inferior articulation

We validated the methodology to measure the tibiofemoral wear using new APG and RP inserts (Table 2). Comparison of results from worn inserts and values obtained from the manufacturer (DePuy Pty. Ltd., Australia) showed good agreement in light of the measurements being conducted on retrieved inserts subject to normal in vivo kinematic loading, surgical removal, cleaning, and sterilization.

There were no statistically significant differences between the wear rates of the inserts from patients with low and high activity levels, or between the wear rates of the APG and RP inserts regarding either superior or inferior wear (Table 3; Figure 2).

Table 3. Average penetration rate and volume loss for APG and RP LCS inserts

Insert type	Penetration rate (mm/year) mean (range)	Volume loss (mm ³ /year) mean (range)
APG superior	0.052 (0.007–0.110)	49 (6.2–109)
APG backside	0.039 (0.001–0.097)	36 (1.9–52)
Total wear		85
RP superior	0.054 (0.015–0.089)	44 (25–72)
RP backside	0.037 (0.014–0.051)	33 (1.7–91)
Total wear		77

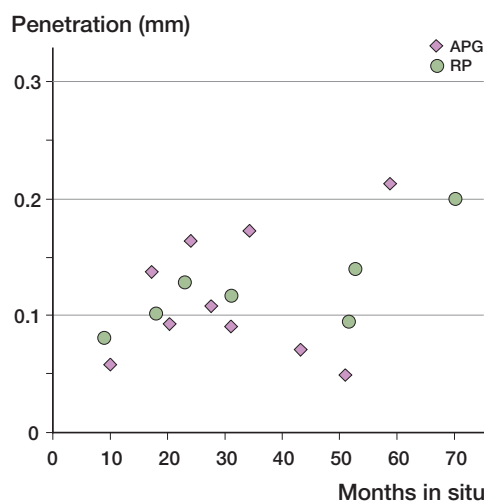


Figure 2. Average linear penetration for the seventeen inserts.

Wear mechanism assessment of the superior and inferior articulations

Figures 3 and 4 summarize the quantitative assessment of each of the seventeen LCS inserts for each of the seven mechanisms of damage. We noted that none of the LCS samples retrieved showed any sign of delamination wear or surface deformation, or eccentric or malaligned wear patterns. Asymmetric wear was also minimal, the average difference between the worn area on the medial and lateral bearings being 11% (0.1–31).

We noted that the original machining marks on the inferior surface of the RP platform are concentric with the central peg, and therefore run circumferentially with rotational bearing motion. In contrast, the APG machining marks are approximately orthogonal to anteroposterior motion and

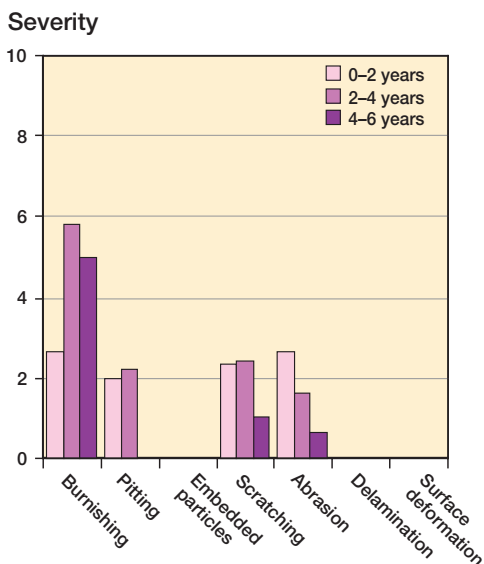


Figure 3. Severity of wear of the superior LCS bearing surface.

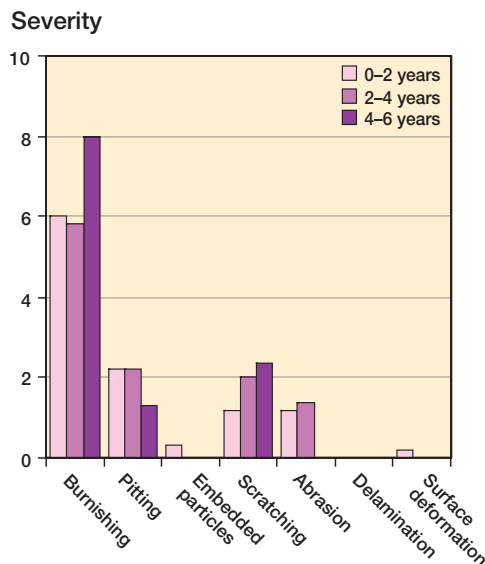


Figure 4. Severity of wear of the inferior LCS bearing surface.

oblique to knee rotational motion. Even though the inferior bearings of the RPs were worn, the original machining marks were visible over much of the surface. In contrast, only small unworn areas (medially) were visible on the APG inserts.

Wear assessment of metal tibial tray

Macro-assessment was conducted to compare and contrast the damage on the RP and APG tibial trays. The RP tibial trays were characterized by areas of circumferential scratch ‘clouding’ in addition to individual circumferential scratches of varying lengths up to 7 mm, which are thought by the authors to be most probably due to third body particle rolling rather than bearing motion exclusively. Multi-directional scratching was observed on all APG tibial trays, with typical scratches measuring up to 0.5 μm .

Discussion

Characterization of operative wear mechanisms and—even more so—quantification of wear are not insignificant tasks, and even though numerous studies have been published on TKA wear, discrete measurements of wear are uncommon (Table 4). Quantitative studies have included both radio-

graphic in vivo measurements and in vitro measurements from retrieved devices (Argenson and O'Connor 1992, Polyzoides et al. 1999, Benjamin et al. 2001, Lavernia et al. 2001, Hoshino et al. 2002, Gill et al. 2006). Whilst the measurements of Polyzoides et al. (1999) were performed with a CMM technique, Argenson and O'Connor (1992) used single point measurement with a toolmaker's dial gauge. Benjamin et al. (2001) noted that the wear rates measured were much higher than other published data, but represented a group of failed fixed bearing knees. It is suggested, however, by the authors that this study did not control for sterilization method and thus most likely involved bearings that were gamma-irradiated in air. It was also noted in the study of Benjamin et al. that the more conforming inserts (Synatomic; DePuy) had lower wear rates than the flat articular geometry inserts (AMK and PFC; DePuy). The wear rates reported by Plante-Bordeneuve and Freeman (1993) are low; however, increasing the conformity on a fixed-bearing design is known to reduce range of motion and increase stresses at the bone-implant interface, which may lead to implant loosening. We, however, concur with Plante-Bordeneuve and Freeman (1993), Benjamin et al. (2001), and Price et al. (2005) that low wear rates are a function of greater bearing conformance, as is the low incidence of

Table 4. Measurement of wear in total knee arthroplasty

TKA	Bearing	Wear (mm/year)	Reference
Rotaglide	Mobile	0.046	Polyzoides 1999
Oxford Bi-compartmental	Fixed	0.026–0.043	Argenson 1992
AMK, PFC Synatomic	Fixed	0.35	Benjamin 2001
Freeman Samuelson	Fixed	0.025	Plante-Bordeneuve 1993
Porous Coated Anatomic	Fixed	0.13	Lavernia 2001
Interax	Fixed	0.23	Hoshino 2002
Oxford Unicompartmental	Mobile	0.02	Price et al. 2005
AGC	Fixed	0.1	Gill et al. 2006
LCS	Mobile	0.053	Present study

eccentric and asymmetric wear. In this regard, the large surface area and anterior-posterior glide and/or rotation capability of the LCS bearings appear to prevent eccentric and asymmetric wear, and provide an element of self-alignment.

It was not possible in this study to quantitatively subtract the creep component from the penetration rate, thus resulting in the actual wear. This is a common problem in wear studies, and especially in creep-susceptible materials such as polyethylene. Creep was estimated by Rohrl et al. (2005) to account for 0.063 mm of penetration in total hip arthroplasty using radiostereometry, and was assumed to occur within the first 2 months of implantation. Even this most likely underestimates the creep, which may occur to a lessening degree over the life of the bearing, until final failure is imminent. In the case of the LCS bearings, however, the contact mechanics and wear mechanisms are analogous to that of total hip arthroplasty; thus, Rohrl's estimate is probably a good first approximation of the creep contribution.

Determination of the operative wear mechanisms on the superior surface of the LCS inserts revealed several damage modes, burnishing being the most prevalent. Burnishing can be considered to be the least destructive wear mechanism, and is commonly reported in acetabular cups. Yet it may have implications when considering the osteolytic potential of the wear debris (Sychterz et al. 1996, Pierson 2005). It is clear that the increased contact area of both LCS designs has resulted in a dominant wear mechanism akin to that found in total hip arthroplasty. Pitting and scratching were the next most prevalent wear mechanisms, and often

occurred concurrently as a result of third-body debris.

There are many articles which review the fundamental design of the LCS bearing or attribute its clinical success to a large surface contact area and mobility (Schmalzried and Callaghan 1999, McEwen et al. 2001, Kilgus 2002, Kuster and Stachowiak 2002, Stiehl 2002, Buechel 2004). Few studies, however, have demonstrated this from retrieval or post-mortem observations (Collier et al. 1991, Morberg et al. 2002). Qualitatively, Morberg et al. (2002) noted minimal wear with respect to the APG design; however, with retrievals of less than 16 months in situ, little wear was noted and no analysis was undertaken. In the case of Collier et al. (1991), only the meniscal bearings were studied and despite having excellent conformity, they have a much lower total contact area than the LCS design. They were also sterilized in air, and were therefore predisposed to oxidation and delamination.

Fixed-bearing wear assessment has commonly revealed fatigue-initiated delamination due to the combination of high sub-surface stresses and reduced mechanical properties due to oxidation (Hood et al. 1983, Schmalzried and Callaghan 1999). This is confirmed in our own retrieval cohort ($n = 850$), which shows that many of the fixed-bearing inserts exhibited oxidative degradation, indicated by delamination, cracking, and yellowing. Changes in sterilization practices including low-temperature gas plasma, gamma irradiation in an inert atmosphere, and ethylene oxide sterilization have reduced this problem and have been reported to give lower wear rates (Williams et al.

1998). This has also been noted at our institution. The LCS bearings, however, showed no signs of delamination, which was probably due to a combination of modern sterilization methods, conformity, large contact area, and insert mobility.

Backside wear has been recognized as a potential source of polyethylene debris in fixed bearing TKAs and remains contentious in mobile bearings (Furman et al. 1999, Schmalzried and Callaghan 1999, Callaghan 2001, Rao et al. 2002, Akisue et al. 2003, Dennis and Lynch 2004, Conditt 2005). Inferior articulation volumetric rates of 36.4 mm³/year (APG) and 33.4 mm³/year (RP) were estimated for the tibial inserts, which are less than the 138 mm³/year reported by Conditt for 21 posterior-stabilized Insall-Burstein II knees (Conditt et al. 2005). Wear mode assessment of the inferior surface revealed mainly burnishing, although pitting, scratching, and abrasion were also observed. Scratching and abrasion on the inferior surface is most likely due to extraneous particles, which tend to remain in the inferior articulation because there is less relative motion compared to the superior articulation and the planar geometry tends to “capture” the particles. Foreign debris may include bony fragments, extraneous cement, metallic particles, or loose porous coating beads. The most significant difference between the APG and RP designs is the ability of the APG bearing to move in multiple directions compared to the more constrained rotational motion of the RP design. The damage resulting from this principal difference was best observed on the superior surface of the tibial tray. In the case of the RP design, the scratches were concentric and aligned with the principal direction of bearing movement. In contrast, multidirectional scratches were observed on the APG tray and will probably result in higher wear rates due to scratch cross-sectional geometry being potentially orthogonal to the tibial bearing motion. This scenario is likely for all mobile bearing designs with multidirectional inferior motion.

One issue that remains controversial is the size of the wear particles generated and their potential to cause osteolysis. This study has shown that the wear of the mobile bearings is more akin to that observed in the hip, and thus production of fine particle debris is likely. Huang et al. (2002) reported a 47% revision rate due to osteolysis of mobile bear-

ing TKAs; however, both meniscal bearings and rotating platforms were studied and there was no indication as to the proportion of osteolysis associated with each design. In comparison, our retrieval database of tibial inserts (n = 850) has shown an osteolysis rate of 4%, as diagnosed by the surgeon at the time of revision. No osteolysis was reported for the LCS retrievals.

In summary, the linear penetration and volumetric wear measured for the APG and RP mobile bearing designs are similar, and compare more than favorably to reported values for fixed-bearing designs. If the mobile bearings, and in particular the APG design, are confirmed to have a low osteolytic potential then the relatively low wear rates may well result in clinical longevity. It would appear from this study, however, that the APG design may predispose the bearing to increased inferior articulation wear due to multidirectional movement. Thus, use may be driven by clinical considerations rather than the potential for further reduction in wear.

Contributions of authors

Both authors were involved in all aspects of the study, including design, gathering of data, data analysis, and reporting.

No competing interests declared.

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