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SURVIVORSHIP AND CLINICAL OUTCOME OF THE MINIMALLY INVASIVE UNIGLIDE MEDIAL FIXED BEARING, ALL-POLYETHYLENE TIBIA, UNICOMPARTMENTAL KNEE ARTHROPLASTY AT A MEAN FOLLOW-UP OF 7.3 YEARS

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ABSTRACT

Background: Medial UKA performed in England and Wales represents seven to 11% of all knee arthroplasty procedures, and is most commonly performed using mobile-bearing designs.

Fixed bearing eliminates the risk of bearing dislocation, however some studies have shown higher revision rates for all-polyethylene tibial components compared to those that utilize metal-backed implants. The aim of the study is to analyse survivorship and maximum eight-year clinical outcome of medial fixed bearing, Uniglide unicompartmental knee arthroplasty performed using an all-polyethylene tibial component with a minimal invasive approach.

Methods: Between 2002 and 2009, 270 medial fixed UKAs were performed in our unit. Patients were reviewed pre-operatively, five and eight years post-operatively. Clinical and radiographic reviews

were carried out. Patients' outcome scores (Oxford, WOMAC and American Knee Score) were documented in our database and analysed.

Results: Survival and clinical outcome data of 236 knees with a mean of 7.3 years follow-up are reported. Every patient with less than 4.93 years of follow-up underwent a revision. The patients' average age at the time of surgery was 69.5 years. The American Knee Society Pain and Function scores, the Oxford Knee Score and the WOMAC score all improved significantly. The five-year survival rate was 94.1% with implant revision surgery as an end point. The estimated 10 years of survival rate is 91.3%. Fourteen patients were revised before the five-year follow-up.

Conclusion: Fixed bearing Uniglides UKA with an all-polyethylene tibial component is a valuable tool in the management of a medial compartment osteoarthritis, affording good short-term survivorship.

Level of evidence IV

Keywords

Unicondylar knee arthroplasty; Unicompartamental knee arthroplasty; Survival rate; Revision; All-polyethylene tibial component; Patient reported outcome

1. INTRODUCTION

Total knee arthroplasty (TKA), unicompartamental knee arthroplasty (UKA) and high tibial osteotomy (HTO) are accepted alternative surgical treatments for medial compartment osteoarthritis.

A recent meta-analysis comparing HTO versus UKA indicated that UKA is a more favourable technique for improving clinical outcome and relief of pain up to 10-years following surgery[1]. Survivorship did not differ significantly but there was a trend towards UKA beyond 12 years post-operatively. UKA was also associated with a lower rate of post-operative infection[2,3]. Studies comparing UKA and TKA for treatment of medial joint osteoarthritis (OA) have shown that patients with UKA achieve higher levels of post-operative function[4], range of motion[5,6] and task specific activities such as kneeling[7] up to 10, 15 and two years after surgery respectively. In addition, lower mortality rates, reduced post-operative infection rates and fewer perioperative complications[8] have all been shown with UKA[9,10].

Medial UKA performed in England and Wales represents seven to 11% of all knee arthroplasty procedures, and is most commonly performed using mobile-bearing designs. These may have

advantages in reducing linear polyethylene wear and have been shown, in some studies, to be capable of producing good long term survivorship[11]. However bearing dislocation may occur in one to 5.3% of medial UKAs[12,13]and has been identified as the fourth most frequent mode of failure for mobile-bearing implants[14]. Fixed bearing designs have been shown in several studies to have equivalent clinical and radiographic outcomes compared to mobile-bearing implant designs at mid- and long-term follow-up[15]. A fixed bearing eliminates the risk of bearing dislocation, however some studies have shown higher revision rates for all-polyethylene tibial components compared to those that utilize metal-backed implants[16–18].

The Clear advantage of this implant is its low cost. Also the non-inferior performance of all-poly Total knee replacement (TKR) may support its use[19,20]. Disadvantages of all-polyethylene implant are the lack of modularity, thus care must be taken not to overstuff the joint as one simply cannot downsize the bearing; the lack of potential to change an isolated bearing during future reoperations (e.g. bicompartamental, patellofemoral OA) and the lack of an uncemented option. The aim of this study was to analyse survival and up to eight-year clinical data of fixed bearing all-polyethylene tibia Uniglides UKA and compare to literature data.

2. METHODS

2.1. PATIENTS

Between 2002 and 2009, 270 medial fixed bearing all-polyethylene tibia UKAs (Uniglides, Corin Group PLC, Cirencester, England, UK) were implanted in 236 patients (112 females and 124 males) were performed at our unit.

Patients were offered a UKA if they had typical anteromedial pattern osteoarthritis with radiographic evidence of full thickness loss of articular cartilage confirmed on either an anteroposterior (AP) or Rosenberg weight bearing view. All patients had a minimum of 90° knee flexion, a maximum of 15° of passively correctable varus deformity, a maximum of 10° of fixed flexion deformity and the presence of a functioning anterior cruciate ligament. This was determined by clinical examination. In some cases varus/valgus stress X-rays were performed to confirm cartilage thickness in the lateral compartment, although this was not routinely performed.

Patients with less than 90° of flexion, severe symptomatic patellofemoral arthritis or evidence of lateral tibiofemoral osteoarthritis (more than Ahlbäck grade 1)[21] were not offered a UKA.

Fibrillation or minor circumscribed cartilage lesions of the medial aspect of the lateral femoral condyle or the patellofemoral joint were not seen as contraindications.

2.2. PROSTHESIS DESIGN

The Uniglides (Corin Group PLC, Cirencester, UK) femoral component has a triple-radius femoral geometry and is made of titanium nitride coated cobalt chrome. It is available in cemented or uncemented form. The tibia has both fixed and mobile-bearing options. The ultra-high molecular-weight all-polyethylene tibial fixed bearing component is flat, with a central keel, which is cemented to the prepared surface of the medial tibial plateau. The tibiofemoral articulation formed is unconstrained and non-congruous (Figure 1).



FIGURE 1 THE UNIGLIDES™ FIXED BEARING UNICOMPARTMENTAL KNEE REPLACEMENT

2.3. SURGICAL TECHNIQUE

Depending on individual surgeon preference, the patient was either positioned as for total knee arthroplasty, with a foot rest and lateral side support or, alternatively, using a leg holding device with the lower leg hanging. All medial UKAs were performed using MIS (minimally invasive) technique with a skin incision of approximately eight centimetres and a mini mid-vastus or a subvastus approach. The lateral compartment was inspected for evidence of arthrosis not

determined radiographically. A Langenbeck retractor was placed under the patellar ligament in slight flexion. This gave a limited view, however enough to judge the distal joint surface of the lateral femoral and tibial condyle. An extra-medullary tibial jig was used to set the valgus/varus alignment and the posterior slope of the axial tibial cut. The tibial sagittal cut was made referencing from the tibial jig, aligned with the second metatarsal. A stylus was used to determine the tibial resection depth. Tibial resection was adjusted to allow easy insertion of a seven millimetre spacer feeler gauge, taking into account the thinnest fixed bearing all-polyethylene tibial insert (seven millimetres).

An extra-medullary jig was used to set the femoral component valgus/varus and internal/external rotation. A guide rod was placed through the jig to ensure that flexion/extension of the femoral component was set parallel with the femoral shaft. In the coronal plane, the rod was set to point at a marker dot attached to the patient showing the position of the femoral head midway between the anterior superior iliac spine and pubic symphysis. The posterior femoral cut was made first and then the distal femoral condyle was reamed with the aim to carefully balance the flexion and extension gaps and to ensure that the mechanical axis was not over corrected.

To reduce the risk of cement extrusion posteriorly cement is pressed into tibia with a wet osteotome or gloved finger. Minimal cement is then applied to the all-polyethylene component. During implantation the all-polyethylene tibia is inserted at an angle so that the posterior part of the prosthesis is compressed first allowing excess cement to extrude anteriorly. Any cement that does extrude posteriorly is scraped away prior to implantation of the femur.

2.4. OUTCOME MEASURES

Pre-and post-operative data were collected prospectively. Either a research nurse or physiotherapist carried out a follow-up in a research clinic. Patients underwent physical and radiographic examinations of the knee and completed a questionnaire consisting of the Oxford Knee Score (OKS, 0 worst and 48 best), the American Knee Society Score pain and function domains (AKSS pain, 0 worst and 50 best, AKSS function, 0 worst, 100 best) and Western Ontario and McMaster Universities Arthritis Index (WOMAC, 60 worst and 12 best; pain domain worst 25 and best five; function domain worst 35 and best seven)[22–24] at five and eight years post-operatively. Revision of the prosthesis was used to define survivorship.

2.5. STATISTICAL ANALYSIS

Kaplan–Meier survival analysis was used to determine the survivorship. Only patients with known outcomes were included, thus patients who died (even with unrevised implants) and were lost to follow-up were excluded. Outcome measures were compared using Student's *t*-test for parametric data and the Mann–Whitney *U* test for non-parametric data. Normal distribution was assessed using the Kolgomorov–Smirnov-test. Significance was set at a $p < 0.05$. SPSS version 21 and MedCalc version 14.12.0 were used for statistical analysis.

3. RESULTS

3.1. PATIENT DEMOGRAPHICS

Two hundred thirty-six of the original 270 knees could be followed up. Seven patients (eight knees) could not be contacted and were considered lost to follow-up giving a follow-up rate of 87.4%. Twenty-three patients (26 knees) have since died from unrelated medical conditions. Eleven patients (14 knees) died with the prosthesis in situ. This was verified by contacting the patient's general practitioner or their relatives. In the other deceased patients no data regarding prosthetic revision could be identified (Table 1).

TABLE 1 BREAKDOWN OF EXCLUDED CASES

| Reason for exclusion | Number of knees (number of patients) |
|----------------------------|--------------------------------------|
| Total | 270 (236) |
| Lost to follow-up | 8 (7) |
| Died/died without revision | 26 (23) / 14(11) |
| Included | 236 (230) |

3.1.1. OVERVIEW OF EXCLUDED CASES

The mean follow-up was 7.33 years (SD: 1.94). Every patient with less than 4.93 years FU was revised. The average age at operation and weight at time of surgery was 68.2 standard deviation (SD) 9.9 years (range 41 to 87) and 81.4 ± 17.6 kg (range 51.2 to 161) respectively. Of the 236 knees followed up, 98 were right-sided, 82 were left-sided and 28 were bilateral UKAs. Two hundred thirty-

three knees had a diagnosis of primary medial compartment osteoarthritis, two were post-traumatic, and one suffered from crystal arthropathy.

3.2. SURVIVORSHIP ANALYSIS

Figure 2 shows the survival curve for the 236 medial fixed UKA knees. The survival probability at five years following surgery was 94.1% and at 10-years was 91.3%. Table 2 shows life-table for the 236 implants.

3.3. REVISIONS

Altogether 20 of the 236 knees were revised. The mean time to revision was 3.45 years (SD 1.78). Eighteen knees were revised to TKA, 15 of them to standard primary implants (Genesis II, Smith and Nephew, Memphis, TN, USA; Triathlon, Kalamazoo, MI, USA). The revision cases, with cause and timing of revision and revision prosthesis used are shown in Table 3.

One patient was revised to a TKA at 5.6 years in the private sector and was subsequently lost to follow-up with no data being available as to the reason for revision.

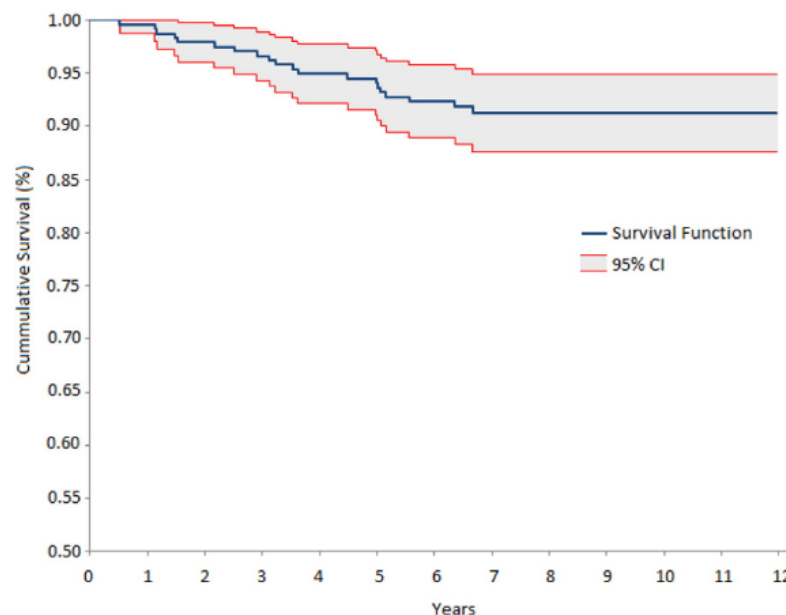


FIGURE 2 KAPLAN-MEIER SURVIVORSHIP CURVE FOR 236 MEDIAL UNIGLIDE KNEES. WITH REVISION AS THE ENDPOINT (RED LINES INDICATE 95% UPPER AND LOWER CONFIDENCE INTERVAL (CI)). MEAN DAYS = 2744.52 (95% CI = 2655.3 TO 2833.7) SD = 695.8.

TABLE 2 LIFE-TABLE OF THE MEDIAL UNIGLIDE PROSTHESIS IN 236 KNEES.

| Year | Number at risk | Revised | Censored | Survivorship | Standard error |
|-------|----------------|---------|----------|--------------|----------------|
| 0-1 | 236 | 1 | 0 | 0.996 | 0.004 |
| 1-2 | 235 | 4 | 0 | 0.979 | 0.009 |
| 2-3 | 231 | 3 | 0 | 0.966 | 0.012 |
| 3-4 | 228 | 4 | 0 | 0.949 | 0.014 |
| 4-5 | 224 | 2 | 3 | 0.941 | 0.015 |
| 5-6 | 219 | 4 | 25 | 0.923 | 0.017 |
| 6-7 | 190 | 2 | 29 | 0.913 | 0.019 |
| 7-8 | 159 | 0 | 49 | 0.913 | 0.019 |
| 8-9 | 110 | 0 | 59 | 0.913 | 0.019 |
| 9-10 | 51 | 0 | 44 | 0.913 | 0.019 |
| 10-11 | 7 | 0 | 3 | 0.913 | 0.019 |
| 11-12 | 4 | 0 | 4 | 0.913 | 0.019 |

3.4. PATIENT REPORTED AND CLINICAL OUTCOME MEASURES

Table 4 shows pre-operative and five-year post-operative OKS, WOMAC and AKSS pain and function scores. Samples were tested for normality by the Kolmogorov–Smirnov test. None of the samples showed normality except for the pre-operative OKS and WOMAC scores. Differences between pre- and post-operative scores were found to be significant for each of the scores calculated by Wilcoxon non-parametric test (pb0.05).

4. DISCUSSION

This study reports the short-term survivorship and outcome of 230 patients with a fixed medial unicompartmental knee arthroplasty.

In our series a survival estimate of 97.9% at two years, 94.1% at five years, and 91.3% at 10-years was calculated following medial fixed bearing UKA. Our follow-up rate of 97.1% is similar to other studies of this nature[25,26]. Recent studies with all-polyethylene tibial components showed worse

or similar survival rates to ours[27,28]. Studies reporting on the survivorship of other fixed bearing implants (Zimmer I and II, Marmor, St Georg, Brigham), showed that 10-year survival rates ranged between 80 and 93.7%[29] . A study on the St. Georg Sled showed 85.9% survival at 18 to 20 years with revision as the end point in patients with a mean age at operation of 67 years[30]. Pennington et al. reported on patients younger than 60 years showing 92% survival at 10 years with Miller-Galante implants[31]. 94% of the same implants done by a single surgeon survived with a mean age at surgery of 66.54 years[32]. 10-year cumulative revision rates of approximately 12 to 13.5% and 11.78% (CI 95% 11.80 to 13.34) were reported for fixed bearing unicompartmental knee replacement (UKR) in the 2014 Swedish Knee Arthroplasty Register (SKAR) and the 11th annual report of the National Joint Registry England and Wales (NJR) respectively.

Medial and lateral UKAs show similar survival rates based on recent studies[26,33,34].

Although several studies have reported similar survival data for UKA and TKA[4,35,36], NJR data show significantly worse survival for UKAs. The lower survivorship of UKA compared with TKA has been a cause for concern for some surgeons leading them to avoid UKA. However of the 20 cases in our study cohort that have been revised, 90% were revised to either a standard primary TKR prosthesis or further UKR. Only two cases required a formal revision prosthesis system (one a Legion and another RT plus (Smith and Nephew, Memphis, TN, USA)).

TABLE 3 SUMMARY OF REVISED UNIGLIDE FIXED BEARING CASES.

| Patient/age (years)/gender | Time to revision/failure (years) | New implant | Cause of revision |
|-------------------------------|--|--|--|
| 1/78/F | 0.5 | Genesis II | Periprosthetic fracture |
| 2/51/F | 1.1 | Triathlon | After 3.5 months revised to one size smaller femoral component for malalignment. At 13.5 months revised to Triathlon due to constant pain |
| 3/63/F | 1.2 | Triathlon | Progression of OA lateral and patellofemoral |
| 4/58/F | 1.5 | Uniglide fixed bearing | Femoral rotational malalignment, pain |
| 5/72/M | 1.5 | Genesis II | Pain, implant in excellent condition |
| 6/67/M | 2.2 | Triathlon | Persistent pain |
| 7/54/F | 2.5 | Triathlon | Aseptic loosening of the tibial component |
| 8/82/M | 2.9 | Triathlon with patella | Progressive OA lateral and patellofemoral and tibial aseptic loosening |
| 9/64/M | 3.1 | Triathlon | Aseptic loosening of both components |
| 10/55/F | 3.2 | Genesis II | Aseptic loosening of both components |
| 11/55/F | 3.5 | Genesis II | Rotational malalignment and pain |
| 12/72/M | 3.6 | Uniglide fixed bearing | At 16 months arthroscopic synovial biopsy, removal of osteophytes/anterior scar tissue and loose body. At 43.5 months revised to fixed bearing Uniglide for synovitis and femoral component wear |
| 13/72/F | 3.6 | Genesis II with Legion stemmed tibial base plate | Progression of OA lateral |
| 14/61/F | 4.5 | Genesis II | Progression of OA patellofemoral |
| 15/53/M | 5.0 | Triathlon | Aseptic loosening of the tibial component |
| 16/66/M | 5.1 | Legion | Aseptic loosening |
| 17/52/M | 5.2 | Triathlon | Progression of OA lateral |
| 18/66/M | 5.6 | Revised to TKR | No data |
| 19/71/F | 6.4 | Genesis II | Progression of OA |
| 20/80/F | 6.7 | RT plus rotating hinge | Progression of OA, incompetent MCL pre-operatively |

TABLE 4 PRE- AND 5 YEAR POST-OPERATIVE PATIENT REPORTED OUTCOME MEASURES DIFFERED SIGNIFICANTLY (ALL $P<0.0001$).

| Mean (CI 95%) | AKSS pain | AKSS function | OKS | WOMAC pain | WOMAC function | WOMAC total |
|---------------------------------------|--------------------|------------------------|------------------------|------------------------|------------------------|--------------------|
| Pre-operative (270 knees) | 8.5 (8.1-9.9) | 55.2 (53.0-57.3) | 19.9 (18.94-20.86) | 15.52 (12.34-18.71) | 21.47 (20.81-22.12) | 37 (36.0-38.0) |
| 5 years post-operative (228 knees) | 40.1 (37.91-42.35) | 76.68 (73.23-80.15) | 37.4 (35.8-39) | 8.19 (7.56-8.82) | 11.96 (11.14-12.87) | 20.2 (18.68-21.62) |
| 8 years post-operative (106 knees) | 42,5 (38.51-46.59) | 70.6 (61.1-80.1) | 34.22 (30.22-38.22) | 9.1 (7.32-10.88) | 14.1 (11.43-16.77) | 23.1 (18.64-27.56) |

The lower survival rates for UKA may relate to surgeons having a lower threshold to offer revision to patients with a problematic UKA. Revisions for unexplained knee pain may be partly responsible for the increased revisions of UKA compared to TKA[37]. Goodfellow et al. investigated the management of patients with poor Oxford Knee Scores following UKA and TKA. In patients with OKS <20 12% of TKAs were revised, whereas 63% of the UKRs with similar scores were revised[38]. The post-operative improvements in patient reported outcomes measured in our study appeared to be consistent with other UKA studies in the literature[39]. In our study, the mean five-year post-operative OKS and improvement compared to the pre-operative level were higher than those reported in the National Joint Registry for England and Wales Eighth Annual Report[37]. Twenty-seven of our cases reported a post-operative OKS <20. Of the 20 patients revised 12 had an OKS of <20. Mean OKS in this cohort was 19.2 (CI 95% 12.3 to 26.1).

The reasons for revision in our study are consistent with published mechanisms of UKA failure[14,25,37,40,41], which include aseptic loosening, arthritis progression and unexplained knee pain. The most frequent reason for revision in our study was progression of OA. This occurred in six cases and most frequently the lateral compartment was affected. Aseptic loosening was the second most common reason for revision in five of the 20 revised cases. This occurred most commonly on the tibial side. One patient was affected by both progression of OA and aseptic loosening of the tibial component. Five patients in our series were revised for knee pain. In our experience the majority of unexplained knee pain following UKA will settle with time. Important causes of pain not related to

the prosthesis should be excluded, such as neuromas of the infra-patellar branch of the saphenous nerve[42]. We apply and propose an oblique minimal invasive skin incision avoiding the course of the infra-patellar branch of the saphenous nerve for this procedure. In some cases Magnetic Resonance Imaging (MRI) can be helpful in exploring the source of pain[43]. Indicating the operation with full thickness cartilage loss has been shown to reduce revision rate[44,45].

It has been suggested that increased strain on the anteromedial tibial cortical bone is a cause of discomfort, which settles with gradual osseous remodelling[46]. The increased tibial strain associated with all-polyethylene tibial designs might be a cause of pain and aseptic loosening [47] and some studies have reported inferior clinical outcome and survival[16–18,48,49]. These findings are also supported by biomechanical studies[47]. Also inferior alignment with these implants has been described compared to metal-backed ones[50]. Yet ever other studies have shown comparable survival rates[51,52]. The results for the Uniglides fixed bearing all-polyethylene tibia, presented in this study are good, suggesting that good results with an all-polyethylene tibia may be design specific.

Older series of fixed bearing UKAs reported polyethylene wear as atypical mode of failure. Linear wear rates have been estimated at 0.15 mm/year for fixed bearing versus 0.04 mm/year in mobile-bearing implants[11,53]. However, recent NJR reports describe similar revision rates for fixed and mobile-bearing UKAs, where the cause for revision was described as polyethylene wear[34]. This may be attributed to the introduction of ultra-high molecular-weight polyethylene and improved sterilization methods and shelf life with improved wear resistance[54] counteracting higher compression and tensile stress in non-congruous fixed bearing designs. Wear rates may be further reduced with improved surface coating of the femoral component. The cobalt chrome femoral component of the Uniglides UKA used in the study has a titanium nitride coating which has been shown to reduce wear of both polyethylene and metal counterparts in vitro[55].

There is some contrast in orthopaedic centres' 10 year survival rate reports and those of joint registry data according to Labek et al.[56]. Registry data for the Uniglides has to be carefully assessed as the Uniglides has both fixed and mobile-bearing options and the registry reports do not generally distinguish between the two designs.

The reasons explaining our superior results may be the somewhat higher mean age, standardized surgical technique in a unit with 20 years experience with fixed bearing UKR including attention not to (over)correct the mechanical axis. The operation was only performed by high volume surgeons in a tertiary referral centre unit.

Another possible explanation is the long learning curve. Surgeons with less than 23 cases per year produce significantly lower survival rates (Swedish Knee Arthroplasty Register 2004)[57]. Rees et al. showed that the average American Knee Society Score of the first 10 cases was significantly lower than that of the subsequent ones[57]. Appropriate patient selection and correct clinical indication for UKA are important factors that could affect survivorship. Pre-operative cartilage thickness in the medial compartment appears to affect survival since re-revision rate was found to be six-fold for knees where there was more than two millimetres of joint space preserved pre-operatively[45]. Limitations of the study are the relatively short follow-up, and the multiple surgeon design, however 89.3% of the cases were performed by the senior author (JHN). To our knowledge this is the first study reporting on survivorship of the all-polyethylene fixed bearing Uniglides UKA prosthesis.

5. CONCLUSION

The Uniglides UKA with all-polyethylene tibial component provides a relatively low cost option for UKA and our results demonstrate satisfactory patient outcomes and survivorship rates comparable to other bearing designs.

Ethics and registration

The procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2000.

The Avon Orthopaedic Centre Knee Database South West Regional Ethics Committee number is 09/H0206/72.

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