Premature failure of Kinemax Plus total knee replacements

We describe a cohort of patients with a high rate of mid-term failure following Kinemax Plus total knee replacement inserted between 1998 and 2001. This implant has been recorded as having a survival rate of 96% at ten years. However, in our series the survival rate was 75% at nine years. This was also significantly lower than that of subsequent consecutive series of PFC Sigma knee replacements performed by the same surgeon. No differences were found in the clinical and radiological parameters between the two groups. At revision the most striking finding was polyethylene wear. An independent analysis of the polyethylene components was therefore undertaken. Scanning electron microscopy revealed type 2 fusion defects in the ultra-high molecular weight polyethylene (UHMWPE), which indicated incomplete boundary fusion. Other abnormalities consistent with weak UHMWPE particle interface strength were present in both the explanted inserts and in unused inserts from the same period.

We consider that these type 2 fusion defects are the cause of the early failure of the Kinemax implants. This may represent a manufacturing defect resulting in a form of programmed polyethylene failure.

Regular surveillance is essential to identify the early failure of any joint replacement. The history of early pain, swelling and loss of function of a replacement may lead to revision. The quality of life of the patient following revision has been shown to be lower than that following primary joint replacement.1 We have observed the early failure of a group of Kinemax Plus implants and postulate that the cause of the failure was severe polyethylene wear. We are not aware of a similar group of patients who have experienced early failure of this implant due to polyethylene failure. The Kinemax Plus total knee replacement (Stryker Howmedica Osteonics, Allendale, New Jersey) has been found previously to have a nine-year survival rate of 96%.2,3 We used a combination of clinical, radiological and material analysis to compare our Kinemax Plus group of patients to a similar group who received a PFC Sigma total knee replacement (Johnson and Johnson Professional Inc, Raynham, Massachusetts). Both groups received implants at a similar age and both prostheses were sterilised in similar conditions. All circumstances that might have contributed to failure of the Kinemax Plus were assessed, including patient demographics and operator error. After removal, inserts were examined at an independent reference centre for evidence of possible modes of accelerated polyethylene wear.

Materials and Methods
Between January 1998 and June 1999 a consecutive series of 71 Kinemax Plus total knee replacements (TKRs) were carried out on a total of 63 patients. The subsequent change to the PFC knee replacement was instigated by a perceived problem with the Kinemax Plus locking mechanism of the insert on to the base-plate. Over the following 18 months 63 PFC Sigma TKRs were performed on 58 patients. All procedures were carried out by the senior author (JH) or one of his team under supervision using the same surgical technique for both prostheses. A medial parapatellar approach was employed through an anterior midline skin incision. Intramedullary femoral alignment and extramedullary tibial alignment jigs were used. Palacos cement was used in all cases, and early mobilisation was encouraged after operation. Patellar resurfacing was not routinely carried out. All patients were entered into the Freeman Hospital Arthroplasty Register and followed up by the arthroplasty nurse practitioner team. Routine follow-up was carried out at six weeks, three months, one year, two years, five years and ten years. The complete records were available for 57 of the Kinemax Plus patients and 49 of the PFC patients and were used to assess the demo-
graphic data, pre- and post-operative range of movement, sizes and batch numbers of the prosthesis components, the time to revision and the reason for revision. The remaining patients had incomplete follow-up data because they had moved away from the region or died. The demographics of the two cohorts are shown in Table I. The post-operative radiographs were evaluated for evidence of malalignment of the components using the method described by Bankes et al.4 (Fig. 1). Those analysed for evidence of malalignment were the short leg films taken after three months. In cases which were revised, all of the radiographs were analysed for signs of polyethylene wear.

We defined failure as the need for revision in patients presenting with pain, swelling and loss of function of the knee replacement. This excluded patients requiring revision for anterior knee pain.

Analysis of the explants and unused implants. All failed prostheses were analysed independently at the Centre for Biomedical Engineering (CBME), School of Engineering, at Durham University. An unused Kinemax Plus implant from the same period was also available for similar analysis. The CBME had performed the initial wear characterisation of the Kinemax and Kinematic prostheses using the Durham Knee Simulator and had shown that the rates of wear in the Kinemax were slightly higher than those in the Kinematic, but this difference was not statistically significant.5 The pattern of polyethylene wear between the two prostheses was also different, with the Kinemax insert wearing in a teardrop fashion and more posterolaterally when internal-external rotation was added to the simulator. The Kinematic prosthesis showed wear at a similar rate but with a rectangular area.

The analysis of each retrieved ultra-high molecular weight polyethylene (UHMWPE) insert from the Kinemax Plus patients involved examination of both the surface and subsurface for signs of failure. Each insert underwent topographical mapping and macroscopic analysis,6 followed by

**Table I. Patient demographics**

<table>
<thead>
<tr>
<th>Kinemax Plus knee replacements (n = 71)</th>
<th>PFC knee replacements (n = 63)</th>
<th>Statistical analysis (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>63</td>
<td>58</td>
</tr>
<tr>
<td>Number of deaths</td>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>Age at time of surgery (yrs) (SD)</td>
<td>69.85 (8.32)</td>
<td>70.21 (9.99)</td>
</tr>
<tr>
<td>F:M</td>
<td>37:26</td>
<td>35:23</td>
</tr>
<tr>
<td>Mass (SD)</td>
<td>77.57 (8)</td>
<td>75.24 (10)</td>
</tr>
<tr>
<td>Duration of follow-up (mths)</td>
<td>76</td>
<td>72</td>
</tr>
<tr>
<td>Underlying pathology (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>56 (79)</td>
<td>43 (68)</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>5 (7)</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Not recorded</td>
<td>10 (14)</td>
<td>17 (27)</td>
</tr>
</tbody>
</table>

![Fig. 1a](image1.png)  
![Fig. 1b](image2.png)

Post-operative weight-bearing radiographs showing a) coronal and b) sagittal alignment analysis as used by Bankes et al.4 This method assesses alignment by calculating the coronal alignment indirectly as the sum of cTCA-90 and cFCA-90 (the angle between the anatomical axis of the femur and tibia) to give a value representing the valgus alignment of the knee corrected for any persistent ligamentous imbalance; 7° is considered optimal.
an in-depth analysis using low-voltage environmental scanning electron microscopy (ESEM) as well as optical microscopy in order to assess the wear properties. The degree of macroscopic wear of the inserts was described using the point system devised by Hood et al.\(^6\) 0 points (no wear), 1 point (<10% wear), 2 points (10% to 50% wear) and 3 points (>50% wear). The results of the analysis are shown in Table II.

### Preparation of Surface and Subsurface Samples

In order to analyse the UHMWPE of the retrieved implants further, cylindrical cores were taken perpendicular to the articulating surface and then carefully sectioned into 500 µm thick disc-shaped specimens using a diamond cutter.\(^7\) The prepared samples were examined directly using FEI XL30 low-voltage ESEM. The samples were imaged under an ESEM mode and were uncoated in order to avoid potential artefacts caused by surface coating. The samples from the unused tibial insert were prepared in 35 µm thin sections using a microtome. These were then mounted on glass and examined to reveal the morphology of the subsurface structure using a Zeiss Axiovert 200M optical microscope in a bright field.

### Data Analysis

The data were analysed using the Prism 4.0 for Microsoft Word statistical program. A Kaplan-Meier survival analysis was undertaken and further subgroup analysis was performed using two-sided \(t\)-tests for parametric data, with non-parametric variables assessed using the Mann-Whitney U test.

### Results

Between 1998 and 2008, none of the PFC replacements required revision. Seven revisions were undertaken in the Kinemax group, with another four patients with five knee replacements offered revision for failed prostheses. The radiographs from one of the Kinemax Plus patients requiring revision are shown in Figure 2. For the purposes of survival analysis, the endpoint defining failure was the date at which the decision to revise was made. The Kaplan-Meier survival analysis (Fig. 3) shows that the survival rates for both prostheses remained comparable up to five years, after which that of the Kinemax Plus declined significantly, with a 76% survival at nine years. Discernible problems with patellar tracking were not encountered in either group. A breakdown of the characteristics of the patients offered or undergoing revision is presented in Table III. At least 80% of the operations in each cohort were performed by the consultant. The median length of time to revision or decision to revise in the Kinemax was 86.5 months (54 to 109). At revision, those patients who had significant polyethylene wear as seen on pre-operative radiographs were found to have significant osteolysis, debris and synovitis.

### Possible Causes for Failure

We assessed all factors associated with failure in both groups. A number of possible patient-related aetiological factors have been cited in the early failure of knee replacements, including weight, the pre-operative range of movement and pre-operative valgus malalignment.\(^8\) No statistically significant difference was found in these factors between the Kinemax and PFC patients (Table IV).

We examined the post-operative radiographs for evidence of malalignment in the coronal and sagittal planes\(^9\) (Fig. 1), but found no statistically significant difference in alignment between the Kinemax Plus and PFC cohorts \((p > 0.05)\) and no statistically significant difference between the revised and non-revised Kinemax Plus groups \((p > 0.05)\) (Table V).

#### The UHMWPE Inserts

The retrieved UHMWPE inserts were sent for analysis. At revision, on inspection it was noted that the majority of the wear was found postero-medially on the UHMWPE insert (Fig. 4), and in some cases the insert was completely extruded.

All of the polyethylene implants had a shelf-life of less than four years, as required by the Department of Health guidelines regarding sterility. Thus, we presume that the polyethylene was manufactured between 1994 and 1998 during which period the standard technique of sterilisation was by gamma irradiation in a vacuum. The batch numbers of the revised implants were collected, and no correlation was found between batch number and failure. The manufacturing technique used for the Kinemax Plus UHMWPE was bulk extrusion followed by machining.

Increased wear of the polyethylene insert has been observed when the liners are 8 mm or less in thickness.\(^10\) In our patients the majority of the failed polyethylene inserts were 10 mm or less, and there was no difference between the thickness of the inserts in those which did or did not fail. Analyses of the inserts identified that the predominant macroscopic wear pattern was severe delamination. Surface embrittlement was also observed, and was often associated with surface and subsurface cracks. Analysis by scanning electron microscopy (SEM) of horizontal and vertical sections taken from the non-weight-bearing surfaces of each insert revealed areas of incomplete inter- and intra-particle boundary diffusion at a molecular level within the UHMWPE. These persistent memories of boundary lines indicated that UHMWPE particles may have been weakly bonded. These weak bonds are associated with subsurface cracks and fissures.

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**Table II. Wear of explanted Kinemax Plus polyethylene liners**

<table>
<thead>
<tr>
<th>Case</th>
<th>Duration in vivo (mths)</th>
<th>Average wear score</th>
<th>Front</th>
<th>Back</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>93</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>92</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>92</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>81</td>
<td>3</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>101</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>6</td>
<td>109</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

- Grade 2 indicates wear of 10% to 50% of the surface of the tibia insert\(^6\)
- Grade 3 indicates >50% of wear\(^6\)
Analysis of the unused Kinemax Plus insert from the same period was found to show similar defects due to incomplete boundary diffusion. Typical features at the bearing surface and on subsurface analysis shown by SEM are shown in Figures 5 and 6. As a control, an unused Kinemax Plus implant from the same period was also analysed, which showed clear machine marks and occasional defects with evidence of inhomogeneity and poorly bonded regions, as shown in Figure 7.

Discussion
We have observed premature mid-term failure in a cohort of patients who required revision of their Kinemax Plus TKRs secondary to polyethylene failure. We have attempted to explain the reasons for such accelerated and catastrophic polyethylene wear by clinical and radiological analysis of the implant in each patient, followed by material analysis of the explanted inserts, which showed similar patterns of wear both clinically and macroscopically. At revision, the majority of the wear was observed at the posteromedial corner of the polyethylene. This caused extrusion of the polyethylene in two cases, with significant surrounding osteolysis seen at re-operation.
The need for analysis of the explants became clear when no other reason could be found to explain our failures. There was no radiological evidence of significant malalignment of the implants, which only started to fail after five years, differing from the recent analysis of Kinemax Plus failures performed by Davis, Davies and Newman.\textsuperscript{11}

Material analysis of the Kinemax Plus inserts supports the hypothesis that there was a failure of fusion of the molecular components of the polyethylene at the time of manufacture. Previous large series described cumulative survival rates of the Kinemax Plus of 96.5% at nine years, with no specific mention of premature polyethylene wear.\textsuperscript{12}

In the Norwegian Arthroplasty Register a cumulative survival at five years of 91.9% was found in bicompartmental Kinemax Plus replacements, which improved to 100% when patellar resurfacing was excluded from the causes of failure.\textsuperscript{2} Ewald’s\textsuperscript{13} series of 521 consecutive Kinemax knee replacements and the review by Back et al\textsuperscript{12} of 421 Kinemax knees showed that the majority of failures occurred secondary to infection. In neither series were there failures due to polyethylene wear.

Our two groups of patients were well matched for age, pre-morbid condition, weight, alignment of the components, pre- and post-operative range of movement, Amer-

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**Table III. Patients with a Kinemax knee undergoing or offered revision**

<table>
<thead>
<tr>
<th>Patient identifier</th>
<th>Age (yrs)</th>
<th>Gender</th>
<th>Weight (kg)</th>
<th>Underlying pathology</th>
<th>Size of UHMWPE\textsuperscript{†} insert (mm)</th>
<th>Side</th>
<th>Time to revision (mths)</th>
<th>Type of revision</th>
<th>Radiographic abnormalities (time)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>63</td>
<td>M</td>
<td>8</td>
<td>OA</td>
<td>10</td>
<td>R</td>
<td>93</td>
<td>Insert only</td>
<td>UHMWPE wear</td>
</tr>
<tr>
<td>2</td>
<td>69</td>
<td>M</td>
<td>72</td>
<td>OA</td>
<td>10</td>
<td>R</td>
<td>92</td>
<td>Insert only</td>
<td>UHMWPE wear</td>
</tr>
<tr>
<td>3</td>
<td>69</td>
<td>F</td>
<td>60</td>
<td>OA</td>
<td>10</td>
<td>R</td>
<td>92</td>
<td>Total - TC3</td>
<td>UHMWPE wear</td>
</tr>
<tr>
<td>4</td>
<td>74</td>
<td>F</td>
<td>75</td>
<td>OA</td>
<td>10</td>
<td>L</td>
<td>81</td>
<td>Total - TC3</td>
<td>UHMWPE wear, medial tibial lucency and progressive loosening</td>
</tr>
<tr>
<td>5</td>
<td>62</td>
<td>F</td>
<td>10</td>
<td>OA</td>
<td>R</td>
<td>101</td>
<td>Total - TC3</td>
<td>UHMWPE wear</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>63</td>
<td>M</td>
<td>8</td>
<td>OA</td>
<td>R</td>
<td>109</td>
<td>Total - TC3</td>
<td>UHMWPE wear</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>60</td>
<td>F</td>
<td>8</td>
<td>OA</td>
<td>R</td>
<td>77</td>
<td>Offered revision</td>
<td>UHMWPE wear</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>64</td>
<td>F</td>
<td>85</td>
<td>RA</td>
<td>8</td>
<td>L</td>
<td>54</td>
<td>Total - TC3</td>
<td>Progression of lucencies</td>
</tr>
<tr>
<td>9</td>
<td>80</td>
<td>F</td>
<td>8</td>
<td>OA</td>
<td>8</td>
<td>R</td>
<td>80</td>
<td>Offered revision</td>
<td>UHMWPE wear, medial tibial lucency</td>
</tr>
<tr>
<td>10</td>
<td>65</td>
<td>F</td>
<td>93</td>
<td>OA</td>
<td>8</td>
<td>R</td>
<td>75</td>
<td>Offered revision</td>
<td>No</td>
</tr>
<tr>
<td>11</td>
<td>65</td>
<td>F</td>
<td>10</td>
<td>OA</td>
<td>R</td>
<td>95</td>
<td>Offered revision</td>
<td>UHMWPE wear, medial and posterior tibial lucencies</td>
<td></td>
</tr>
</tbody>
</table>

* OA, osteoarthritis; RA, rheumatoid arthritis
† UHMWPE, ultra-high molecular weight polyethylene

**Table IV. Comparison of patient-related causes for implant failure between the Kinemax and PFC knees**

<table>
<thead>
<tr>
<th>Kinemax</th>
<th>PFC</th>
<th>Failed Kinemax</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mass (kg)</td>
<td>77</td>
<td>75</td>
</tr>
<tr>
<td>Medial pre-operative range of movement (° of flexion) (range)</td>
<td>105 (90 to 140)</td>
<td>95 (80 to 110)</td>
</tr>
<tr>
<td>Pre-operative valgus deformity (number of patients)</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

**Table V. Component alignment of Kinemax group compared to failed Kinemax group**

| Coronal tibial component angle (cTCA;β) | 89 | 90 | 84 to 96 | 82 to 92 |
| Coronal femoral component angle (cFCA;α) | 97 | 96 | 96 to 100 | 96 to 98 |
| Coronal alignment of the knee (CAK) | 6.5 | 6 | 0 to 13 | 3 to 9 |
| Sagittal femoral component angle (sFCA;γ) | 4 | 1 | 0 to 8 | -1 to 4 |
| Sagittal tibial component angle (sTCA) | 84 | 79 | 79 to 94 | 75 to 89 |

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**Fig. 4**

Photograph showing characteristic posterior and lateral macroscopic wear of explanted insert.
ican Society of Anaesthesiologists grade and gender. No statistically significant difference between the two groups was identified as a possible contributor to the high rate of failure. All operations were carried out either by or under the direct supervision of the senior author, which minimises surgical technique as a bias.

Malalignment is recognised as an important cause for early failure of any TKR, and we were able to exclude this. Previous analysis of failure of Kinemax Plus TKRs inserted between 1992 and 2001 was performed by Davis et al\textsuperscript{11} in 2007. They suggested that failure could have been due to ‘bad batch’ polyethylene, but concluded that operator error was the main cause of the excessive polyethylene wear in their cohort. We assessed each failed prosthesis for signs of operator error, but failed to identify any evidence for this, and indeed similar methods of alignment were used during operation for the two different knee systems. The difference between the Davies group and our own related to the period of follow-up. In their series the implants all failed in the first five years whereas our prostheses failed at a median of seven years.

Bankes et al\textsuperscript{4} found that with the Kinemax Plus system no adverse clinical or radiological effects were detected in the subgroup of knees with less favourable alignment at
Our cohort was due to material failure of the UHMWPE, probably at the time of manufacture, exacerbated by post-
manufacturing oxidation. The effect of gamma irradiation in air of UHMWPE and the accelerated effects this has on
manufacturing oxidation. The effect of gamma irradiation, which has been shown to weaken UHMWPE.14
Sutula et al14 found subsurface oxidation and zones of sign-
ificantly reduced strength and ductility after three years following gamma irradiation. These authors also raised
concerns over dissociation between the tibial baseplate and the polyethylene component. During our analysis of the
implants there was no specific evidence of this. Lack of backside wear in all the implants studied supported our
view that the inserts had not become mobile.15

Incomplete boundary diffusion with retained UHMWPE powder particle memory has been found to predispose
UHMWPE to crack initiation and then propagation.16 Incomplete boundary diffusion, or type-2 diffusion defects,
can theoretically act as stress risers within the UHMWPE,17
and their effect may be exacerbated by methods of sterilisa-
tion and repeated in vivo wear. These findings support our
hypothesis that the cause for failure within our cohort of
patients was due to UHMWPE material factors.

We consider that the failure of the Kinemax implants in
our cohort was due to material failure of the UHMWPE,
probably at the time of manufacture, exacerbated by post-
manufacturing oxidation. The effect of gamma irradiation
in air of UHMWPE and the accelerated effects this has on
wear is well described,14 and may be a contributing factor.
We are undertaking further analysis of the implants, look-
ing specifically at levels of oxidation.18

No benefits in any form have been received or will be received from a commer-
cial party related directly or indirectly to the subject of this article.

Fig. 6

Scanning electron microscopy of subsurface (ca 2 mm below articulat-
ing surface) showing weakly bonded ultra-high molecular weight poly-
ethylene at approximately micrometre scale.

Fig. 7

Scanning electron microscopy showing weakly bonded ultra-high
molecular weight polyethylene and crack propagation in unused
implant. Incomplete fusion defects were found on both the used and
unused Kinemax inserts as shown by the arrows on the opposite SEM
image. This further supports the hypothesis of UHMWPE failure at the
material manufacturing stage.

6.5 years. Our findings agree with this. There was no statis-
tically significant difference demonstrated between the
radiological findings of the knees that failed and those that
did not, and between the Kinemax and the PFC cohorts.

Other factors implicated in the failure of polyethylene
are the method of sterilisation, the thickness of the poly-
ethylene bearing surface and the age of the implant. The
maximum age of the polyethylene implants was four years
in all cases, and there was no statistically significant differ-
ence in the maximum thickness of the implants in the failed
as opposed to the satisfactory Kinemax implants. Poly-
ethylene wear appeared to be the causative factor in the
failure of the Kinemax Plus knee replacements in our

patients. Numerous factors are thought to effect the longev-
ity of UHMWPE, and much of our knowledge comes from
the analysis of failed prostheses. Kinemax Plus knee
replacements in 1998 and 1999 were sterilised with gamma
irradiation, which has been shown to weaken UHMWPE.14

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