Review of Kinemax knee arthroplasty performed at the NHS Treatment Centre, Weston-Super-Mare

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As part of the government's initiative to reduce waiting times for major joint surgery in Wales, the Cardiff and Vale NHS Trust sent 224 patients (258 knees) to the NHS Treatment Centre in Weston-Super-Mare for total knee replacement. The Kinemax total knee replacement system was used in all cases. The cumulative survival rate at three years was 79.2% (95% confidence interval (CI) 69.2 to 86.8) using re-operation for any cause as an endpoint and 85.3% (95% CI 75.9 to 91.8) using aseptic revision as an endpoint. This is significantly worse than that recorded in the published literature. These poor results have resulted in a significant impact on our service.

In Wales in 2004 the waiting time for total knee replacement (TKR) was approaching 36 months. In order to reduce this, the Welsh Assembly Government introduced the 'Second Offer Scheme' in April 2004, whereby no patient was to wait more than 18 months for in-patient surgical care, reducing to 12 months in March 2007. In order to be treated within this time patients had to travel for their surgery, with provision shared between the BUPA Hospital Cardiff and the NHS Treatment Centre at Weston-Super-Mare. The Orthopaedic Department at the Weston-Super-Mare General Hospital is separate from the Weston Area Health NHS Treatment Centre. This paper relates only to the work carried out at this latter centre. The two organisations should not be confused.

In June 2006, Rhondda Cynon Taff Local Health Board, in agreement with Weston Area Health NHS Trust, invited the British Orthopaedic Association to carry out an independent review of the surgery performed at the Weston NHS Treatment Centre because the complication rate following surgery was higher than expected (Fig. 1). Their report concluded by making the following recommendations:¹

1. The post-operative radiographs must be available for viewing by the operating surgeon before the patient or the surgeon leave the hospital.
2. There should be close communication between the surgical team and the rehabilitation services so that concerns can be identified and addressed at an early stage.

3. Ideally, one surgeon should oversee the three phases of pre-assessment, operation and follow-up.

4. Surgeons from the original hospital should be informed of problems that might arise.

5. The radiographs of all patients who have undergone joint replacement at the Weston NHS Treatment Centre should be reviewed, and for those found to be suboptimal the patient should be recalled for a further clinical and radiological check.

6. All patients treated at the Weston NHS Treatment Centre should be contacted and offered a clinical review if they have concerns about the outcome of their surgical treatment.

As a result of this report, this paper was written to compare the results of the surgery performed at the NHS Treatment Centre to those already published by other centres. The Kinemax total knee system (Stryker, Howmedica, Rutherford, New Jersey) has proved to be of robust design and has a reported survival at ten years varying between 96% and 97%.^{2,3}

Patients and Methods

Between April 2004 and January 2006, 258 Kinemax TKRs were inserted for osteoarthritis in the Weston-Super-Mare NHS Treatment Centre by a variety of surgeons from Sweden supplied by Scanloc Medical Recruitment (Scanloc, Battle, United Kingdom). All 224 patients were contacted by telephone or letter, and offered clinical and radiological review, which was performed by one of the Cardiff and Vale NHS Trust consul-

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Fig. 1a

Fig. 1b

Anteroposterior radiographs of three knees a) 28 months post-operatively showing 14° of varus of the tibial component and 18° of valgus of the femoral component and b) bilateral varus tibial cuts with matching valgus femoral cuts at 26 months post-operatively.

tant knee surgeons. The radiographs of the patients were reviewed using the IMPAX (AGFA) image software (Agfa Health Care UK Ltd, Brentford, United Kingdom) and the positions of the components were assessed according to the Knee Society Scoring System described by Ewald.⁴ Angles were measured using IMPAX digital templating software (Medi CAD, Altfraunhofen, Germany). Data concerning revision, recommendation for revision and follow-up were taken from the patients' notes.

The radiographs were evaluated for varus malalignment, the degree of posterior slope of the tibial component, valgus malalignment and flexion of the femoral component, oversizing of the components resulting in reduced range of movement, or 'overstuffing' of the patellofemoral joint and overlapping of the tibial tray. The cement-component interface was also evaluated for radiolucent lines and signs of loosening of the components.

For the survival analysis a 'life-table' method was used as described by Armitage and Berry.⁵ This allows the analysis of data from patients with differing durations of follow-up, and also enables joints to enter or be withdrawn from the study at any time. The annual failure rate is calculated, and survival rate is cumulated for each successive year. A variety of endpoints were used, including revision for any cause, aseptic revision and cumulative survival. The 95% confidence intervals were calculated using the Rothman equation.^{6,7}

Results

A total of 258 knees, 115 knees in 101 men and 143 knees in 20 women, had the Kinemax knee implanted. Their mean age was 68 years (36 to 85). Of the 49 patients (52 knees), who were not reviewed, 26 (28 knees) did not ask for an appointment, 20 (21 knees) did not respond or

did not attend their appointment, and three (three knees) had died of unrelated causes. There were 206 knees (80%) left in the study (116 in 98 women and 90 in 77 men); of these, 144 were unilateral single joint arthroplasties and 31 were bilateral (28 staged, three simultaneous). The mean follow-up was for two years (2 to 3). A total of 130 knees (63%) had obtained a satisfactory result, with the patient experiencing no or minimal pain and a range of movement of at least 0° to 90° in a stable knee.

In 76 knees (37%) the result was unsatisfactory. Ongoing pain, for which no cause was found, was present in 14 patients (15 knees) and one patient (one knee) had developed a complex regional pain syndrome. Re-operation had been undertaken in 29 patients (30 knees, 15%) and a further 29 patients (29 knees, 14%) had been recommended to have a revision, but had either declined further surgery at present or were on the waiting list (Fig. 2).

Alignment of the implants. The mean angle of the tibial component was 3.1° of varus (SD 2.4) for the whole group. Of the 206 knees accepting an error of 3° of valgus to 3° of varus as a reasonable margin of accuracy for the horizontal tibial cut, 73 (35%) were found to lie beyond 3° of varus (Fig. 3). There were 80 knees (39%) with more than 8° of valgus of the femoral component (mean 8.20°, SD 2.35). The femoral components were oversized in 75 knees (36%) and the tibial component too large in 80 (39%). Both components were oversized in 37 knees (18%).

Re-operation/revision. Revision operations were carried out in ten knees in ten men and 20 knees in 19 women with mean ages of 70 years (50 to 81) and 67 years (46 to 83) respectively. Revision was required for infection in three patients, two in the first year and another at 24 months. There were eight revisions for malalignment, six for aseptic loosening, one for arthrofibrosis and four for oversized

Fig. 2

Flow diagram showing patients in the study.

Fig. 3

Histogram showing the distribution of varus angulation of the tibial resection in the cohort.

components. In a further eight patients the patella was resurfaced as a secondary procedure (Table I).
Survival analysis. The overall cumulative survival rate with re-operation of any kind as the endpoint was 79.2% at three years (95% confidence interval (CI) 69.2 to 86.8). If aseptic revision was used as the endpoint, including revision for malalignment, oversizing, instability or aseptic

loosening, but not including infection or secondary patellar resurfacing, the cumulative survival rate was 85.3% (95% CI 75.9 to 91.8) at three years. The cumulative survival rate in patients who have been recommended revision but have either declined or were awaiting surgery was 75.9% (80.3%, 95% CI 69.5 to 85.3) at three years (Table II, Fig. 4).

Table I. Reason for revision

Reason for revision	Number of knees	Mean number of months to failure (range)
Septic Infection	3	15.3 (9 to 24)
Aseptic		
Loosening of the tibial component	3	26.7 (14 to 34)
Loosening of the femoral component	1	29
Loosening of both components	2	23.5 (11 to 25)
Malalignment	8	19.5 (11 to 28)
Oversize	4	17.8 (13 to 20)
Arthrofibrosis	1	19
Secondary patellar resurfacing	8	17.8 (1 to 26)

Table II. Life table showing cumulative survival data and 95% confidence interval for overall revision for any cause and aseptic revision

Years since operation	Number at start	Failure	Deaths	Withdrawn	Lost to follow-up	Number at risk	Annual failure rate (%)	Annual success rate (%)	Cumulative survival rate (%)	95% confidence interval
Re-operation any cause										
0 to 1	258	4	1	0	49	231	1.7	98.3	98.3	96.6 to 99.4
1 to 2	204	17	0	43	0	174	9.8	90.2	88.5	82.8 to 92.6
2 to 3	144	8	2	105	0	86	9.3	90.7	79.2	69.2 to 86.8
3 to 4	29	0	1	28	0					
Aseptic revision										
0 to 1	258	1	1	1	49	232	0.4	99.6	99.6	97.2 to 100.0
1 to 2	206	11	0	51	0	175	6.2	93.8	93.4	88.5 to 96.5
2 to 3	144	7	2	107	0	86	8.1	91.9	85.3	75.9 to 91.8
3 to 4	28	0	1	27	0					

Fig. 4

Survival curve for the cohort. Whiskers indicate 95% confidence intervals.

Discussion

In the drive to reduce waiting times it is essential that all patients receive a high quality of treatment in existing NHS hospitals or new facilities. The Weston-Super-Mare NHS

Treatment Centre was an entirely separate facility from the NHS hospital and was staffed by Swedish locums, flown in to perform the operations.

The Kinemax implant has been used widely with good results. Back et al² reported a series of 422 Kinemax TKRs with a cumulative survival of 99.05% at three years, 99% at five years and 96.5% at nine years. Similarly, an American study by Wright et al³ followed 523 knees for ten years; the overall survival with the risk of re-operation for any cause as endpoint was 96.1%, and with the risk of aseptic revision as the endpoint was 97.2%.

The Kinemax knee has been used in Sweden with favourable results. The 2007 report from the Swedish Joint Registry⁸ showed that 2487 Kinemax TKRs were performed in Sweden between 1996 and 2005. This number equates to 4.1% of the total implants used in Sweden. The cumulative revision rate from the Swedish joint registry data is 2.5% at three years.⁸

Malalignment and oversizing of the components are well known to be modes of failure for TKR. Malalignment increases wear, increases the risk of aseptic loosening, increases the need for revision and worsens the outcome.^{9,10} Malalignment of the components by 10° increases the load on the tibial plateau by 34%.¹⁰ Varus angulation of the tibial component of greater than 3° is generally accepted as an error in alignment for the normal

mechanical function of the knee. Many of the arthroplasties performed in Weston-Super-Mare were outside this range.

The results of the Cardiff patients treated at the Weston-Super-Mare Treatment Centre are significantly worse than previously published figures,^{2,3} with a very high revision rate at only three years. This rate continued to rise. There remains a large number of patients disappointed by the outcome of their TKR; many of those who initially refused the offer of revision are now reconsidering their decision. There are also a large number of patients with asymptomatic TKRs with malpositioned or incorrectly-sized components that might still fail. These poor results have resulted in a significant economic impact on our service.

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