A seven-year experience of data collection on the Insall-Burstein II total knee arthroplasty

A PROSPECTIVE STUDY

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We describe a method of audit of a type of total knee replacement, including some details of the organisational difficulties of administering multicentre studies, and draw attention to how this can be done using industrial funding without prejudicing the study. This is a prospective record of 1439 patients who had an Insall-Burstein II (IBII) prosthesis implanted between 1990 and 1994. The data were collected using the American Knee Society scoring system. A method of storing radiographs digitally at low cost is also described.

The results emphasise the need for the long-term collection of data on commonly used devices implanted by a cross-section of surgeons. We conclude that for most patients the IBII cemented, posteriorly stabilised, cruciate-substituting prosthesis will relieve pain and give excellent functional results throughout the patients' remaining years with a very small incidence of revision, except in cases of infection.

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The Insall-Burstein II (IBII) knee prosthesis was introduced as a development of the original design in the 1980s. At that time, the results obtained using the original design were described as good or excellent;¹ longer-term outcomes have been published more recently.^{2,3} As with many innovations, however, only the inventor or a collaborative group with specialist skills and commitment has reported the results. In our study the user group consisted of surgeons from various backgrounds including specialist teaching centres and small-volume users in district general hospitals.

The American Knee Society score⁴ (AKSS), supported by three general categories of disability, depending on whether other joints were involved, was chosen as the principal indicator of outcome. The AKSS is divided into

two components, namely the total knee score and the function score; the higher the score, the better is the performance of the knee (Table I).

Radiological assessment of outcome has proved difficult, both in terms of establishing parameters which may be used to define good technical performance by the surgeon and the implant and, more importantly, in predicting failure. Tibrewal, Grant and Goodfellow⁵ have shown a probable relationship between a medial lucency under the tibial plateau and failure, and surgeons generally accept that residual varus may also lead to failure. Recently, others have shown a close relationship between poor function and malrotation, although methods of assessing rotatory alignment remain unsatisfactory.⁶

In this study we stored anteroposterior standing radiographs and standard lateral views. Some centres could not obtain authorisation for the routine use of long-leg films because of cost, and this has led to a new area of investigation into the storage and the analysis of radiographs, which in a study of this size, pose considerable administrative problems. We devised an inexpensive computer-based system for the digital capture of radiographs and their storage on compact disc.⁷ The ability to provide participating surgeons with this facility proved to be a major factor in maintaining their interest.

Over the period of a long-term study, the principal problems are of maintaining contact with patients and retaining the motivation of all staff involved in the study. Murray, Carr and Bullstrode⁸ have indicated that loss to follow-up is a major problem in many studies. We do not believe, however, that all losses to follow-up should be treated as failures rather than successes. Consultants were motivated to co-operate by regular user meetings, initially at intervals of six months, then annually, thus retaining control of the study without being solely responsible for the collection of data. Validation of data was supported centrally by an audit team and checked regularly by a resident data-processing manager who was also a statistician. The costs of this exercise were recorded.

Patients and Methods

Between October 1990 and November 1994, 1439 patients were entered into the database. They included any patient

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Table I. The American Knee Society Score

Patient category			
A: Unilateral or bilateral (opposite knee successfully replaced)			
B: Unilateral, other knee symptomatic			
C: Multiple arthritis or medical infirmity			
	Points		Points
Pain		Function	
None	50	Walking	
Mild or occasional	45	Unlimited	50
Stairs only	40	>10 blocks	40
Walking and stairs	30	5 to 10 blocks	30
Moderate		< 5 blocks	20
Occasional	20	Housebound	10
Continual	10	Unable	0
Severe	0	Stairs	
Range of motion		Normal up and down	50
5° = 1 point	25	Normal up: down with rail	40
		Up and down with rail	30
Stability		Up with rail: unable down	15
Anteroposterior		Unable	0
<5mm	10	Subtotal	
5 to 10mm	5	Deductions	
>10mm	0	Cane	5
Mediolateral		Two canes	10
<5°	15	Crutches or walker	20
6° to 9°	10	Total deductions	
10° to 14°	5		
≥15°	0	Function score	
Subtotal			
Deductions			
Flexion contracture			
5° to 10°	2	Note >10 blocks = 1 km	
10° to 15°	5	5 to 10 blocks = 1/2 to 1 km	
16° to 20°	10	<5 blocks = <1/2 km	
>20°	15		
Extension lag			
<10°	5		
10° to 20°	10		
>20°	15		
Alignment			
5° to 10°	0		
0° to 4°	3/deg		
11° to 15°	3/deg		
Other	20		
Total deductions			
Knee score			
(If total is a minus number, score is 0)			

between 18 and 75 years of age who required a total knee replacement (TKR) for primary degenerative disease except for those who had received a previous arthroplasty, including unicondylar replacements. Extensive exclusions were avoided to exclude bias. The entire study was incorporated into an agreed, written protocol. The patient was assessed in the larger centres by a physiotherapist or nurse, who was employed by the hospital under the aegis of the University, but sponsored by industry. A standard AKSS score sheet was completed and stored in triplicate; one copy was retained in the notes, one was kept by the consultant's secretary and one was sent to the audit centre. Each patient had a unique identifier allowing only the consultant to retrieve individual data, and all centres were registered under the Data Protection Act. All the information collected was sent in paper form to the audit centre

and processed by experienced data recorders.

The surgeon performed an IBII TKR according to his or her own training, and chose, at the time of operation, whether or not to resurface the patella. He or she filled in a simple report concerning the state of the knee and any intraoperative complications, and was also asked to comment on the soft-tissue balance at the end of the operation. Before discharge, a short form detailing postoperative complications was completed, with details of the range of movement of the knee. The sizes of the prostheses were recorded by attaching the labels from the component packaging to the data sheets.

Surgeons followed their normal postoperative regimen for follow-up of in- and outpatients. Independent observers completed forms for the collection of patient-review data. At time points between one and two years and between five

Fig. 1

The IBII user groups involved in the study.

and seven years AKSS scores were calculated automatically by computer software. These pragmatic time intervals were checked to see if there was any difference within them, but none was detected. Early attempts to collect data at six months and annually were abandoned as being impractical. Revision was defined as an endpoint, and an extra form detailing the adverse events was returned to the audit centre at the time of surgery. Deaths were detected by loss of follow-up, which prompted an enquiry to the office of national statistics, if not confirmed from medical records.

The original radiographs were scanned using an A3 flatbed scanner with a transparency adaptor in full 24-bit colour at a resolution of 150 dots per inch. The images were converted to 8-bit grayscale and saved as uncompressed TIF format files. A predefined naming convention was used to identify and link the images to the relevant patient files. The file size was typically 1.6 to 2 Mb per image and compact discs were used as a cheap and efficient method of archiving; 200 to 300 images can be stored on each disc. Radiographs were stored on compact disc in an encrypted Microsoft Access table, which was linked to the database (Microsoft Access) in such a way that all radiographs and corresponding AKSSs could be retrieved with ease. An additional benefit of compact discs is that they are 'read-only' and this allows examination and processing of a file but protects the original images since they cannot be overwritten. After an initial set-up cost of £10 000 for the purchase of an A3 scanner, computer and CD-writer, a radiograph can be scanned and archived at a cost of £1 to £3.

The surgeons received a paper report every six months in

the first instance, but this was later changed to annually in order to coincide with a one-day meeting at which the results were discussed. The long-term benefits to the study of these meetings cannot be overemphasised.

The details of the IBII network of user groups is shown in Figure 1. A large volume of data was compiled in Belfast, but all information was processed in Dundee.

Results

Patient recruitment and retention. Table II shows the details at follow-up over seven years. All patients were ultimately traced. One died shortly after surgery. We found retention of patients to be difficult initially but later stayed in contact with them annually, and now do so by mail or telephone, which explains the decrease in numbers between the second and fifth years of follow-up. When patients were lost, we checked through medical records and then with the Registry of Births and Deaths annually.

If patients indicated that they did not wish to comply with the study they or their general practitioner were contacted by telephone. This usually revealed general infirmity in the elderly not related to the knee. Patients rarely declined follow-up because they were dissatisfied with their TKR.

Factors related to the initial surgery. Basic demographic and aetiological information, and any previous history of

Table II. Numbers of patients retained over seven years, and compliance by percentage

Status	Preoperative	1 to 2 years	5 to 7 years
Knees	1439	1186	1119
Dead	0	67	162
Missed	0	75	0
Revised	0	10	9
Refused	0	100	82
Compliance	100	87.8	94.0

Table III. Details of patients in the study, by number and percentage

Primary diagnosis	
Osteoarthritis	1144 (79.5)
Rheumatoid	266 (18.5)
Psoriasis	6 (0.4)
Trauma	5 (0.4)
Other	18 (1.3)
AKSS category of disability	
A	419 (29.1)
B	480 (33.3)
C	540 (37.5)
Previous knee surgery	
Meniscectomy	
Open	62 (4.3)
Arthroscopic	64 (4.4)
Osteotomy	77 (5.4)
Synovectomy	54 (3.8)
Patellectomy	15 (1.0)
Arthroscopy	100 (6.9)

knee surgery were recorded. Sixty-five percent of the patients were female and the mean age was 69 (25 to 89). The results are shown in Table III. The figures seem to reflect a general distribution in UK practice.

Medical and postoperative complications. Of the 269 patients with postoperative complications, six had foot drop, 44 thrombosis, 63 haematoma, 53 minor wound breakdown, four major wound breakdown, 12 deep-vein thrombosis, four pulmonary embolism, and 83 unrelated causes. One patient died.

Of the 1439 patients, 1051 had chemical prophylaxis for deep-vein thrombosis or some physical support with pumps, stockings or both. Thus in the early 1990s, about one-quarter of patients received no prophylaxis. The rest of the data on thrombosis and embolism is incomplete and therefore we stopped collecting this information.

The data relating to infection were reliable. Sixty-eight patients had wound discharge but no organism was grown; 61 were clinically infected and of these only 35 had a positive culture. This represents a very low incidence of infection. There was no relationship between initial infection and failure of the implant.

Sixty-four patients required a manipulation under anaesthesia after operation.

The AKSS

Before the operation. The knee scores before operation were low, with a mean AKSS of 27 (0 to 90) and a mean function score of 37 (0 to 100). Patellofemoral pain is not specifically accounted for in this scoring system but we recorded it as present or absent, and it was found as a specific feature in 32% of patients.

Follow-up data from one to two years. At follow-up from one to two years, the AKSS had improved to a mean of 76 (0 to 98), with a mean function score of 67 (0 to 100).

Patellofemoral pain was found in 9%, with a higher incidence in patients who had undergone patellar resurfacing (chi-squared test for independence with continuity correction, $p < 0.05$); the expected number of patients was 27 and the actual number was 39. A similar pattern emerged at five to seven years but was not statistically significant.

A higher proportion of patients with knees of AKSS category C were readmitted than those with knees of categories A and B (chi-squared test for independence, $p < 0.05$); the expected number of patients was 65 and the actual number was 78. There was no relationship between knee category and the need for revision. Ten knees required a revision procedure for infection. Patients with knees of category C had a significantly lower rate of unlimited walking ability than those with categories A and B; the expected number was 143 and the actual number was 121. Patients with knees of category C included a significantly higher proportion of those unable to walk up or down stairs; the expected number was 23 and the actual number was 32.

Follow-up data from five to seven years. At follow-up from five to seven years the mean knee score was the same (77; 6 to 100), as was the mean function score (65; 0 to 100). The incidence of patellar pain decreased to 6% irrespective of whether the patella had been resurfaced or not.

A further nine knees were revised, with some mechanical failures, but most being related to infection. Most mechanical problems arose from the patellofemoral joint.

Table IV. The mean difference in parameters of the AKSS between successful and revised knees at one to two years and at five to ten years. A difference of ten or more points would indicate clinical significance

	Mean difference	95% confidence interval	p value
At one to two years			
Pain	20.64	0.10 to 40.6	<0.05*
Range of movement	4.19	1.97 to 6.41	<0.001*
Stability			
Anteroposterior	0.87	-0.50 to 2.25	0.21
Mediolateral	1.68	-2.15 to 5.53	0.10
Flexion contracture	-1.20	-2.6 to 0.28	0.11
Extensor lag	0.77	0.67 to 0.86	<0.001*
Alignment	-2.72	-7.8 to 2.38	0.26
Walking distance	38.27	29.09 to 47.44	<0.001*
Stairs	11.57	-2.38 to 20.77	0.06
Walking aids	-3.65	-8.77 to 1.46	0.14
At five to ten years			
Pain	11.89	3.0 to 20.96	<0.001*
Range of movement	4.42	-0.60 to 9.45	0.08
Stability			
Anteroposterior	0.54	-0.91 to 1.99	0.46
Mediolateral	2.02	-2.28 to 6.32	0.31
Flexion contracture	-1.4689	-3.02 to 0.01	0.06
Extension lag	1.03	0.91 to 1.16	<0.001*
Alignment	-3.17	-8.86 to 2.52	0.24
Walking distance	12.49	1.48 to 23.49	<0.05*
Stairs	11.85	-2.00 to 25.70	0.06
Walking aids	-3.88	-9.68 to 1.92	0.16

* denotes statistical significance

Table V. Details of costs incurred in the study (£)

	Year 1	Accumulated over 10 years (with 5% inflation)
Co-ordination of participating centres	2551.60	32 092.49
Custom design of database	3402.00	3402.00
Programming for quality control and outcome calculations	1275.75	16 046.25
Manual data quality assurance	1275.75	16 046.25
Data entry	1275.75	16 046.25
Data verification of the transfer from paper to electronic version	1275.75	16 046.25
Generation of monthly reports	1500.00	18 066.84
Scanning by computer	2551.50	32 092.49
Archiving radiographs to hard disc	510.30	6418.50
Preparation and delivery of presentations	5103.00	64 184.99
Statistical analysis	2551.50	32 092.49
National statistics flagging	0.00	2500.00
Subtotal	23 272.80	255 834.79
Equipment	15 000.00	15 000.00
Consumables	1500.00	18 866.84
Travel	7500.00	94 334.19
Total	47 273.00	384 035.82
Total per patient		261.43

Revised knees. One of the aims was to attempt to identify specific information which would indicate early failure, but with only 19 revisions out of 1439 arthroplasties, such criteria were not available. The only differences in the AKSS scores between successful and revised knees related to pain and walking distance (Table IV).

Radiological analysis. There were only two mechanical failures at seven years with all earlier revisions following infection. The small numbers do not allow analysis. There were increases in radiolucent lines in the radiographs taken shortly before revision, but no early radiological indicators of impending failure.

We retain a radiographic library which is easily cross-referenced to the clinical-score database and will allow further analysis as we continue to follow these patients.

Cost analysis of the trial. Costs were largely related to staff salaries, with a modest initial set-up. Those outlined do not include local data collection. In some centres staff were employed, and in others consultants undertook the task or delegated it to junior and secretarial staff, while retaining control. Clearly, the costs of their time should be taken into account in any detailed analysis. Table V simply indicates the costs for the first year including set-up, and the projected ten-year accumulated costs allowing for inflation. The figures represent the co-ordination of 15 centres, and the provision of support, quality assurance and feedback and digital storage of the radiographs. The ultimate accumulated cost per patient of collecting data over ten years is £261, which seems a modest amount.

Discussion

This is a report of the medium-term results of a substantial cohort of unselected patients undergoing IBII TKR in a number of hospitals. The operation was performed by

surgeons of varying experience, but all were at senior level. Follow-up has been unusually good. We were able to account for all our patients and most were followed up for seven years.

The IBII TKR has been shown to give predictable and reliable results in patients with degenerative disease of the knee. Most of the patients treated were elderly which reflects general orthopaedic practice. This particular prosthesis is a cruciate-substituting device which allows the surgeon some latitude when carrying out the critical soft-tissue element of the operation, especially in the presence of flexion and varus deformities.

The overall knee scores fall into the good or excellent category as described in previous studies. The pre- and postoperative AKSS scores, however, are lower. Most patients were assessed independently by nurses and physiotherapists whose main concern was the accuracy and completeness of the data rather than the clinical outcome.

The study also emphasises the need to quantify the results according to levels of disability as comorbidities play a major part in the long-term outcome. In this typical population, a straightforward knee replacement gives satisfactory results in most patients throughout life. When seeking to justify modifications of design, we should accept that most patients will do well with the relatively simple posteriorly-stabilised, cruciate-substituting device, which is highly reliable.

Insall himself coined the term 'generic knee arthroplasty' to imply exactly this conclusion. The clear implication is that we need to separate the advantages of a well-tried and tested device available to the elderly from the need to assess the dependable longevity in younger and more demanding patients. This is the reason often given for justifying continued development of increasing complex and technically demanding devices such as rotating-bearing

arthroplasties. Our study demonstrates the advantages of long-term concerted collection of data and shows that the IBII type of design comprehensively addresses the pain and function of arthritis of the knee in most patients.

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