PROXIMALLY CEMENTED VERSUS UNCEMENTED FREEMAN-SAMUELSON KNEE ARTHROPLASTY

A PROSPECTIVE RANDOMISED STUDY

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We studied the effect of a layer of cement placed under the tibial component of Freeman-Samuelson total knee prostheses with a metal back and an 80 mm intramedullary stem, using roentgen stereophotogrammetry to measure the migration of the tibial component during one year in 13 uncemented and 16 cemented knees.

The addition of cement produced a significant reduction in migration at one year, from a mean of 1.5 mm to one of 0.5 mm ($p < 0.01$), including a significant reduction in pure subsidence. One year postoperatively the clinical results were similar between the groups, but, at three years, one uncemented knee had required revision.

Loosening of the tibial component is still a major cause of failure in knee arthroplasty (Bryan and Rand 1982; Cameron and Hunter 1982; Insall and Dethmers 1982; Thornhill, Dalziel and Sledge 1982; Freeman, Samuelson and Bertin 1985; Moreland 1988). Among the important factors affecting fixation are design, operative technique, and alignment (Vince, Insall and Kelly 1989; Walker, Hsu and Zimmerman 1990). The use of cement has now become the subject of controversy.

During the decade, 1970 to 1980, most knee arthroplasties were cemented but several long-term studies from that period revealed an unacceptably high revision rate due to mechanical loosening. Tew and Waugh (1982) reported a nine-year cumulative survival rate of 56%, defining survival as the prosthesis remaining

in situ. In contrast, Insall and others have reported excellent long-term results using the cemented total condylar knee (Ranawat and Boachie-Adjei 1987; Scuderi et al 1989; Vince, Insall and Kelly 1989).

During the following decade, 1980 to 1990, several non-cemented designs were used with good short-term results (Freeman et al 1982, 1985; Hungerford and Kenna 1983; Hungerford and Krackow 1985; Landon, Galante and Maley 1986). The long-term results have yet to reveal whether the use of cementless prostheses, introduced to avoid the drawbacks of polymethylmethacrylate cement (PMMA), has in fact created more problems than it has solved.

Many of the published papers comparing uncemented with cemented fixation do not report matched randomised groups (Laskin 1988; Rorabeck, Bourne and Nott 1988; Lindstrand, Stenström and Egund 1988; Ebert et al 1989; Rosenberg, Barden and Galante 1990). In some of these studies age, bone quality and type of prosthesis differed between the groups, and results were evaluated only in the traditional way, by clinical and standard radiographic examination. Dodd, Hungerford and Krackow (1990) found no differences between 18 matched pairs of PCA knee arthroplasties, using uncemented and cemented fixation on opposite sides in the same patient. The question is unresolved.

In Gothenburg, we used the Freeman-Samuelson prosthesis since 1982 as a three-compartment arthroplasty, in most cases without cement. We have recently shown that the addition of a metal back with a 110 mm stem to the tibial component significantly reduces early migration and tilt (Albrektsson et al 1990). We now report a prospective and randomised study undertaken

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to determine whether PMMA used proximally on the tibia would further decrease the migration of an 80 mm stemmed, metal-backed, tibial component. In addition we sought to establish a guideline for tibial component fixation with respect to age, weight, diagnosis, sex and bone quality, using a randomising method taking these factors into account. Roentgen stereophotogrammetric analysis (RSA) was used for the assessment of fixation (Selvik 1989).

METHODS

The indications for surgery were osteoarthritis in stages IV or V (Ahlbäck 1968), or rheumatoid arthritis with complete destruction of the cartilage in one or more compartments. The patients were randomised using the minimisation method (Pocock 1983) into groups for cemented or cementless fixation. The factors used in the randomisation were: hospital, diagnosis, weight, sex, age and bone quality according to the Singh index (Singh, Nagrath and Maini 1970). For each of the factors we had two alternatives: the hospital was either the London Hospital or one of the Gothenburg hospitals; the diagnosis was rheumatoid arthritis (RA) or osteoarthritis (OA); weight was above or below 80 kg; age, 70 years and less or above 70 years. The Singh index has six grades, we used grades 1 to 3 as indicators of poor bone quality and grades 4 to 6 as showing good bone quality.

The operations were performed in a standardised manner by one of four surgeons who were familiar with the procedure, using the Freeman-Samuelson total knee prosthesis (Protek AG, Berne, Switzerland) with a metal tray and a tibial intramedullary stem of 80 mm in every case (Fig. 1). A minimal amount of the tibial surface was resected, and a tensor used in order to obtain correct alignment. If the knee was selected for cemented fixation, Simplex cement (Howmedica, London, England) in a doughy state was pressed into the tibial cancellous bone, care being taken to avoid placing any cement into the stem hole.

The patients were examined clinically and radiographically before and after operation and at three, six and 12 months. Additionally, all knees were examined by RSA at one week and at three, six and 12 months postoperatively (Ryd 1986; Selvik 1989), only the migration of the tibial component was studied.

RSA is a precise radiographic method with an accuracy of about 0.2 mm (Ryd 1986). The polyethylene tibial component was marked with six steel balls by the manufacturer, and tantalum markers were inserted into the tibial metaphysis during the operation. Thereafter, simultaneous anteroposterior and lateral radiographs were taken with the knee inside a calibration cage with precisely placed markers in its walls. Two-dimensional measurements of the radiographs were made on a precision digitising table with an accuracy of 10 µm (Hasselblad Engineering, Gothenburg, Sweden). Three-

dimensional co-ordinates of the markers in the prosthesis and in the bone were determined using the program X-RAY. This allowed us to use the program KINEMA to measure any movement of the tibial component relative to the bone after the postoperative reference examination. Migration was expressed as the maximal total point of motion (MTPM) of the markers in the prosthesis relative to the bone. MTPM is a three-dimensional vector, representing the magnitude of the migration in any direction; it should not be interpreted as pure subsidence.

Patients

A Freeman-Samuelson knee arthroplasty was performed on 37 knees in 36 patients. There were 29 women and seven men, one woman having both knees replaced. The mean age was 66 years (range 39 to 84). The diagnosis was osteoarthritis in 17 and rheumatoid arthritis in 20 cases. Only one patient weighed more than 80 kg. The Singh index was less than 3, showing poor bone quality, in 22 patients, mostly those with rheumatoid arthritis. Many of the patients had severe joint destruction with fixed deformities: ten patients had a valgus deformity exceeding 10°, 11 a varus deformity of more than 10°, and 15 a flexion contracture of more than 10°. Among these there were seven patients with varus or valgus deformities exceeding 20° and two patients with flexion contractures of more than 30°. In several of these knees the loss of bone stock was considerable.

The indication for the arthroplasty was moderate to severe pain when walking and evidence of joint destruction on the radiographs. All operations were performed in ultra-clean air laminar flow, and intravenous dicloxacillin was given eight-hourly for 48 hours. Dextran or heparin was used as anti-thrombotic prophylaxis for the first five days.

After operation, the knee was placed in a Robert Jones bandage and put on a continuous passive motion

Fig. 1

The tibial element of the Freeman-Samuelson prosthesis.

machine starting with an excursion of 0° to 30°. The patients were kept in bed until the third day. Walking was with crutches, partial weight-bearing for the first six weeks. Full weight-bearing without crutches was allowed after three months.

All knees were followed by RSA for one year. No patient was lost to follow-up but, due to inadequate marking of the bone or insufficient stereo exposures, eight knees were subsequently excluded (Table I). The clinical follow-up and annual radiography has been for three years. Pain level, flexion range and walking ability were recorded at one year (Table II). At three years, note was taken of major complications such as clinical failure, and obvious radiographic loosening and revision surgery were recorded.

For comparison between the two groups Mann Whitney's two-sided test and Fisher's exact test were used.

RESULTS

There were no postoperative infections or other serious complications. All except two patients were pain free at one year, the other two having mild pain or discomfort for the first few steps. Flexion range was between 60° and 120° (mean 103° ± 12°), only one patient had flexion of less than 90° for unknown reasons. Thirteen patients walked unlimited distances, 11 could walk for 30 to 60 minutes and two for ten to 30 minutes. Three patients could walk for less than ten minutes; one of these (case 29) suffered a stroke three months after the operation, and the other two were disabled by rheumatoid arthritis. At one year after operation the cemented and the uncemented groups were clinically similar (Table II).

The mean MTPM value at one year for the cemented group was 0.5 mm (± 0.3) and for the uncemented group

Table I. Randomisation of the series by number of knees. Number at start and finally evaluated

	Entered trial		Assessed at one year	
	Cemented	Uncemented	Cemented	Uncemented
Diagnosis				
RA	10	10	7	8
OA	8	9	6	8
Sex				
Female	14	16	10	13
Male	4	3	3	3
Weight (kg)				
+80	0	1	0	1
-80	18	18	13	15
Singh index				
1 to 3	11	11	8	9
4 to 6	7	8	5	7
Age (yr)				
+70	10	7	7	7
-70	8	12	6	9
Hospital*				
L	2	2	2	2
S/Ö	16	17	11	14
Total	18	19	13	16

*L London; S Sahlgrens', Ö Östra

1.5 mm (± 1.1; $p < 0.01$, Mann Whitney's U test, Fig. 2). Three uncemented knees (cases 3, 6 and 8) migrated more than 2 mm and two of these migrated continuously throughout the year. Even if these three knees were to be excluded the difference between the two groups would still be significant ($p < 0.01$). In general, most migration occurred during the first months and thereafter the majority of the prostheses became stable. This pattern was particularly evident in the cemented group. Analysing the direction of the migration, we found that the uncemented knees subsided a mean of 0.7 mm (± 1) compared with a mean of 0.02 mm (± 0.3) for the cemented knees ($p < 0.01$). No other specific pattern of migration was apparent in either group.

No significant differences in MTPM at one year were observed with respect to age, sex, diagnosis, weight or Singh index (Fisher's exact text).

DISCUSSION

Good clinical results for cemented knees have been reported in some studies, with success rates of more than 90% after ten years (Ranawat and Boachie-Adjei 1987; Vince et al 1989). However, radiolucencies around the prostheses have been reported after three to seven years in 65% (Ecker et al 1987) and this may indicate impending failure.

RSA has already been used to study the migration of a number of cemented and uncemented prostheses (Ryd 1986, 1991; Albrektsson et al 1990; Ryd et al 1990). However, the same component has been evaluated with and without cement in only one series and even then the

Fig. 2

Migration (MTPM) during one year for uncemented and cemented Freeman-Samuelson tibial components. Mean values and standard error of the mean.

Table II. Clinical data and RSA values for 29 knees

Case	Hospital*	Sex/Age†	Diagnosis	Singh index‡	At 1 year				MTPM (mm)		
					Flexion	Walking¶	Pain	Fixation	3 mth	6 mth	12 mth
1	O	F-	RA	-	105°	2	None	U	0.3	-	0.3
2	O	F+	OA	+	95°	1	None	U	0.5	0.6	1.2
3	O	M+	OA‡	+	90°	2	None	U	1.4	3.0	4.5
4	O	F-	RA	-	100°	1	None	U	0.5	0.4	0.5
5	O	F-	OA	+	100°	1	None	U	0.6	-	0.4
6	O	F+	OA	+	105°	1	None	U	2.3	-	3.0
7	S	F+	OA	+	115°	2	None	U	2.0	0.9	1.7
8	S	M+	RA	-	110°	3	None	U	2.2	2.4	2.3
9	S	F-	RA	-	95°	2	None	U	-	0.4	0.4
10	S	F+	RA	-	100°	1	None	U	-	0.9	0.9
11	S	M+	OA	+	100°	2	None	U	0.6	1.5	1.7
12	S	F-	RA	-	100°	2	None	U	0.7	-	1.4
13	S	F-	RA	-	110°	1	None	U	1.2	1.3	1.1
14	S	F-	RA	-	105°	4	None	U	-	0.7	0.9
15	L	F-	OA	-	60°	3	Mild	U	-	-	1.4
16	L	F-	OA	+	105°	1	None	U	-	1.1	2.0
17	O	F+	RA	-	120°	2	None	C	0	-	0.2
18	S	F-	RA	-	110°	2	None	C	0.3	0.3	0.3
19	S	F+	OA	+	100°	2	None	C	0	-	0.5
20	S	F-	RA	-	110°	1	None	C	-	0.5	0.6
21	S	F-	OA	+	120°	1	None	C	1.7	1.2	1.2
22	S	M-	RA	-	100°	2	None	C	0.2	0.8	0.6
23	S	F-	RA	-	105°	1	None	C	0.6	1.1	0.6
24	S	F+	OA	+	115°	1	None	C	0.4	0.3	0.8
25	S	F+	OA	+	95°	1	None	C	0	0	0.3
26	S	F+	RA	-	95°	4	None	C	-	-	0.7
27	S	M-	RA	-	115°	1	None	C	0.2	-	0.2
28	L	M+	OA	-	120°	2	None	C	-	0	0.4
29	L	F+	OA	+	95°	4	Mild	C	-	0.4	0.3

* Östra; S Sahlgrens'; L London

† Age: - 70 or under; + over 70

‡ Over 80 kg; all others under 80 kg

§ Singh index: + grades 4, 5 and 6; - grades 1, 2 and 3

¶ Walking: 1 = unlimited; 2 = 31 to 60 minutes; 3 = 11 to 30 minutes; 4 = 2 to 10 minutes

|| Fixation: U uncemented; C cemented

two groups of knees were not prospectively randomised with respect to other variables including age and diagnosis (Ryd et al 1990). Although open to these criticisms, the published results suggest that cement improves initial fixation. Thus, Ryd et al (1990) studying the PCA prosthesis showed that the addition of cement reduced the migration rate at one year from a mean MTPM of 1.9 mm to 0.8 mm, which is approximately the same as for other cemented prostheses (Ryd 1986).

Our results tend to confirm this impression. Using an identical prosthesis in each of two groups of knees matched with respect to age, diagnosis, osteoporosis, body-weight and sex, we have shown that the addition of cement produces a statistically significant reduction in migration at one year, from a mean MTPM of 1.5 mm to one of 0.5 mm ($p < 0.01$). However, MTPM describes the three-dimensional movement of the prosthesis. It should not be interpreted simply as subsidence because a prosthesis can migrate without sinking. When analysing the direction of migration we found that the cemented knees subsided only occasionally (mean 0.02 mm) while the uncemented knees did so consistently (mean 0.7 mm). The cemented interface seems to be more secure than the uncemented: very little progression of migration was seen after six months. The difference between other uncemented systems and prostheses fixed with cement is

totally accounted for during the first six months (Ryd et al 1990).

In our material, three knees, all in the uncemented group, had a migration exceeding 2 mm at one year. One of them (case 3) was overweight at 105 kg. Another, case 8, had severe RA with poor bone quality and severe deformities and was technically suboptimal. The third, case 6, was technically satisfactory and we have found no reason for the considerable migration.

In our small number of cases, we were unable to detect differences within the criteria of age, sex, diagnosis, weight or bone quality. Half of the results were from patients with rheumatoid arthritis who present a huge variation in activity level, loading of prosthetic components and bone quality. Any of these might explain the lack of significance of other factors. Only one patient had a body-weight exceeding 80 kg. In our series of both RA and OA knees there was, with two exceptions, a perfect match between diagnosis and bone quality. Since the mean migration was much the same for the two groups, it seems that the influence of poor bone quality was compensated for by the lower activity and loading in the patients with rheumatoid arthritis.

In our uncemented cases, the initial stability of the press-fit prosthesis relied upon its general shape (Albrektsson et al 1990) and on the initial interlock with

flanged polyethylene pegs (Day et al 1979; Blaha et al 1982). Thus, any improved fixation which might have been achieved by biological events about a porous-coated or hydroxyapatite-covered prosthesis was excluded. Nevertheless, the mean MTPM recorded at one year (1.5 mm) was similar to that recorded by Ryd (1986) for a porous-coated, unstemmed prosthesis (1.9 mm).

Therefore our findings for a press-fit component might perhaps be relevant to porous-coated implants in which bone ingrowth has not been achieved. Even an uncemented stem contributes some stability, a finding in keeping with our own RSA studies (Albrektsson et al 1990) and with cadaver studies (Volz et al 1988; Walker et al 1990). The addition of an uncemented stem to a proximally cemented component is an attractive method of fixation since it is associated with the least migration so far reported (0.5 mm at one year) whilst the absence of cement round the stem makes the implant relatively non-invasive and easy to remove in the event of failure.

Finally, the question must be posed: do studies of early migration such as these form a basis for predicting the long-term behaviour of a prosthesis, in particular its ten-year revision rate? This question has been addressed in other studies (Snorrasson 1990; Rimmer, Grewal and Freeman, personal communication 1991). An implant that migrates initially may later become stable, but this is not always so (Ryd 1991). Some may continue to migrate for one or more years; these can be identified

early since they seem to migrate more during the first year (Ryd 1986). It would seem that continuous migration of this sort must eventually end in clinical failure. Of the three uncemented prostheses in our study which had migrated more than 2.0 mm (cases 3, 6 and 8) one (case 8), required revision at three years; indeed, all prostheses eventually revised for loosening after other RSA studies have shown continuous migration (Ryd 1991).

We conclude that a proximally placed layer of PMMA under the tibial component enhances its security, presumably by increasing the contact area and increasing the shear and tensile strengths of the interface as compared with a press-fit. An uncemented stem further increases the security of such an implant without greatly increasing its invasiveness. Finally, existing data strongly suggest that early progressive migration may predict late clinical failure (Ryd 1991); if this is so, our findings would suggest that proximal cement should be used under the tibial trays of stemmed tibial prostheses, particularly in elderly patients and in those with poor bone quality.

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