Cementless fixation of the tibial component for the ICLH knee[1]

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Summary: The use of polymethylmethacrylate bone cement in joint replacement surgery is not without drawbacks. Certain hazards have been appreciated and the bone cement interface may not be as stable in the long run as was once felt. This paper reports the results in 52 knees which were replaced using the uncemented ICLH (Imperial College/London Hospital) tibial component; the average follow up was two years (range six months to four years). The results were compiled with regard to pain as well as clinical examination and X-ray evaluation. The results were comparable to those achieved in knees replaced using bone cement. Roentgenographic evaluation revealed no evidence of loosening nor sinkage of any of these prostheses. Considerations in the development of a knee prosthesis to be utilized without bone cement and the operative technique employed to implant such a prosthesis are presented. The merits of such a system are discussed.

Introduction

The use of a polymethylmethacrylate (PMMA) interface is in large part responsible for the success of total joint arthroplasty. PMMA may not, however, provide the ultimate answer for implant fixation.

Radiographic lucencies at the bone/cement interface are often present in excess of 50% of cases (Beckenbaugh & Ilstrup 1978, Insall *et al.* 1976, Lord 1982, Skolnick *et al.* 1976*b*, Sloof 1971) and in one series of hip arthroplasty in young patients a lucency rate of 100% was reported (Watts 1980). The benign bone/cement lucent line has been attributed to various factors including cell death from direct thermal effects of polymerizing PMMA, or from the chemical toxicity of methacrylate monomer. Necrosis from preparation techniques (i.e. high speed drills and saws) has also been suggested. Poor implantation techniques – allowing blood or other debris to lie in the interface during implantation – may contribute to the presence of this line (Ahmed *et al.* 1980, Charnley 1970, Danckwardt-Lilliestrom 1969, Dipisa *et al.* 1976, Enis *et al.* 1973, Haas *et al.* 1975, Linder 1977, Meyer 1973, Rhinelander 1972, Semlitsch 1973, Spealman *et al.* 1945, Wiltse *et al.* 1957).

Histologically this interface, even in unfailed implants, contains macrophages and giant cells (Charnley & Crawford 1968, Charnley 1970, 1979, Vernon-Roberts & Freeman 1977, Willert & Semlitsch 1976). Chambers (1980) has recently provided evidence that osteoclasts are essentially the same cell type as macrophages. In light of this information the consistent occurrence of macrophages at the bone/cement interface is especially disconcerting.

Adverse cardiovascular reactions related to the insertion of PMMA have been reported, and the deleterious systemic effects of free methacrylate monomer have been studied (Burgess 1970, Charnley 1970, Cohen & Smith 1971, Enis *et al.* 1973, Frost 1970, Homsey *et al.* 1972, McMaster *et al.* 1974, Meyer 1973, E Morscher 1981, personal communication). Potential toxicity to the surgeon and others in the vicinity of the preparatory field from monomer fumes has also been recognized (Muir 1971).

The mechanical properties of PMMA relative to metallic or polyethylene implants and bone are unfavourable. In comparison to bone and currently used implant materials, PMMA is weak in tension and in shear, and is brittle (Charnley 1970, Haas *et al.* 1975).

Specific to the knee, polyethylene wear was initially a significant problem which has been

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shown to be due partly to the abrasive action of PMMA debris (three-body abrasive wear) (Freeman *et al.* 1978, Weightman 1977). This type of three-body wear can be diminished by the careful removal of all excess PMMA or theoretically it can be eliminated by the use of cementless fixation techniques.

Methods

The first implantation of an uncemented ICLH (Imperial College/London Hospital) tibial component utilizing immediately stable osseo-integration was performed in 1977. Between January 1977 and December 1979 a total of 70 prostheses were implanted without PMMA.

Five patients (6 knees) were lost to follow up because of travel distance or medical disability. Five knees – all in patients with rheumatoid arthritis – became infected. Two patients (2 knees) are excluded because of symptomatic subluxated patella. Five patients (5 knees) died within one year following total knee arthroplasty; the cause of death in these patients was not related to the knee. These 18 knees will not be further considered in this report.

Thus, 52 knees comprise this review. At the time of this review (mid 1981) they had been studied at from six months to four years, the average follow up being two years. The average age at the time of implantation was 60 years (range 24–84 years); there were 11 male and 41 female patients. The diagnosis was rheumatoid arthritis in 27 patients, primary osteoarthrosis in 20 patients, and post-traumatic osteoarthrosis in 4 patients. Diagnosis was indeterminate in one patient.

Previous operations included: meniscectomy (4), high tibial osteotomy (3), combined tibial and femoral (Benjamin) osteotomies (2), and synovectomy (1).

All 52 patients were evaluated subjectively (questions) and objectively (examination) at follow up. Anteroposterior and lateral radiographs were obtained, as well as a skyline view of the patella and a view of the entire extremity taken with the patient standing.

In order to monitor changes at the bone/polyethylene interface, an attempt was made to quantify radiological change in density around the osseo-integration pegs and on the tibial plateau beneath the prosthesis. Various factors, including angle of roentgen beam, exposure technique, and position of the knee affect this determination. However, a close enough approximation can be made to allow reasonable comparison between radiographs. Determination of changes in angle of the prosthesis, indicating settling or collapse, is also affected by roentgen technique; but we felt that any change greater than 3° could be detected (Blaha *et al.* 1982).

Results

The pain of all except one of the 52 patients was improved. A scoring method was used wherein no pain received zero points and severe pain received three points. The average score before knee arthroplasty was 2.0; the average score following arthroplasty was 0.4. These results are shown further in Figure 1. The range of motion was improved or not substantially changed in all except 3 patients. Each of these 3 patients started with a preoperative range of motion greater than 90° and lost an average of 10° total range of motion. Prior to arthroplasty 6 patients had a nearly ankylosed knee with a total range of motion less than 30°; following arthroplasty, 2 of these patients had a range of motion equal to or greater than 90° (Figure 2).

Walking ability was improved in all patients. Before surgery 10 patients were either bed-bound or effectively limited to walking only within the house. Following surgery, all were able to walk but not for longer than 10 minutes. An additional 21 patients who were not walking prior to surgery were able to walk over 10 minutes at follow up. Ability to walk can be grossly assessed by time. Including non-walkers, the average time which patients were able to walk prior to surgery was 12 minutes; following surgery this increased to an average of 37 minutes (Figure 3).

Radiographic evaluation, illustrated in Figures 4 and 5, revealed no evidence of loosening

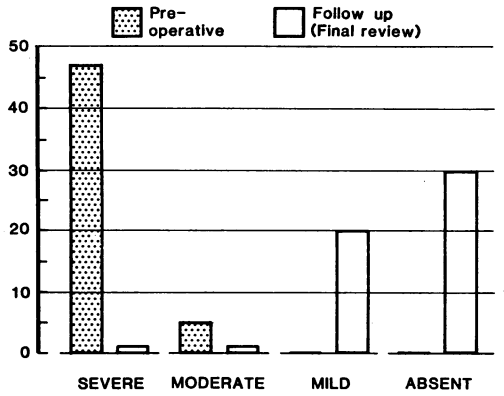

Figure 1. Graph of results with regard to pain

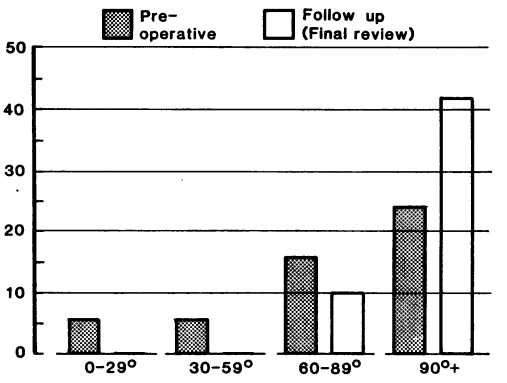

Figure 2. Graph of results with regard to range of motion

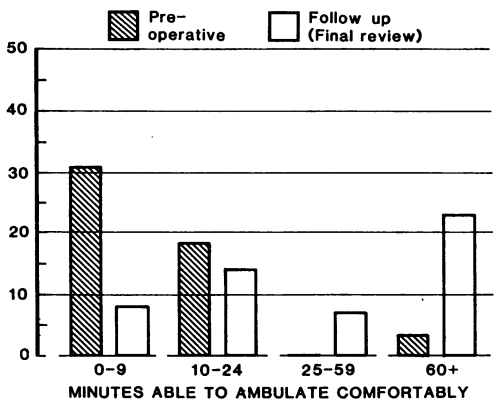

Figure 3. Graph of results with regard to ability to ambulate. The group '0–9 minutes' includes patients who, although able to walk, were housebound. Ability to walk after operation was limited in 27 patients because of rheumatoid arthritis involving joints other than the replaced knee

nor sinkage of any of these prostheses (as limited by considerations described above). No radiolucency was noted at the bone/implant interface in any of these knees. There was an apparent slight increase in the radiodensity of the bone at the interface, either around the pegs or at the tibial plateau, in approximately 40% of the knees; an apparent decrease in radiodensity occurred in approximately 3%; and no change was detectable in the remainder. The change in radiodensity was never significant. Considering the subjective nature of this evaluation, and the fact that the majority of knees fell into the radiologically unchanged group, we felt that the bone/polyethylene interface remained stable over the period of observation.

Discussion

The first implants used for replacement of the surfaces of the knee, the MacIntosh prosthesis for the tibia and the MGH (Massachusetts General Hospital) prosthesis for the femur, did not depend upon the use of PMMA bone cement. The second, and current, generation of implants is secured by the use of acrylic cement. At present several implant types which do not rely on the use of acrylic cement are undergoing development.

A complete review of these is beyond the scope of this paper; but cementless implantation can be considered as one of two types: (1) dependent on bone ingrowth; (2) independent of bone ingrowth, relying on immediate prosthesis/bone interlock. The immediate interlock approach seems to offer several important advantages and therefore the development of cementless fixation for ICLH prostheses has been toward an immediately stable, osseo-integrated implant.

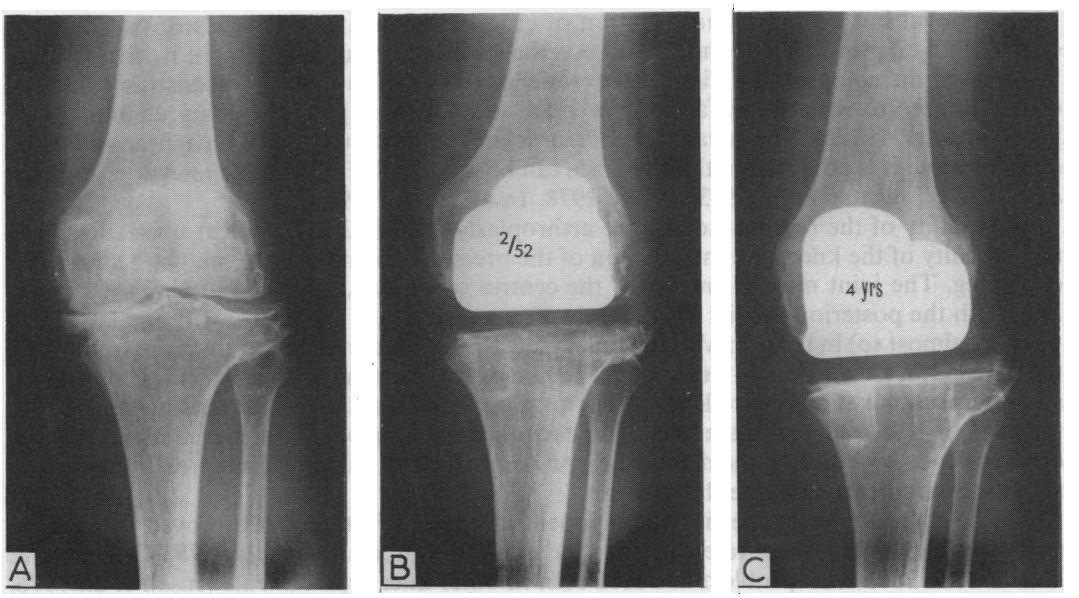

Figure 4. Roentgenograms of a 59-year-old woman with osteoarthrosis whose left knee was replaced in 1977. A, preoperative; the patient has had a previous high tibial osteotomy. B, two weeks postoperative. C, four years postoperative; except for a possible increase in density around the tibial implant, there is no change in the radiographic appearance

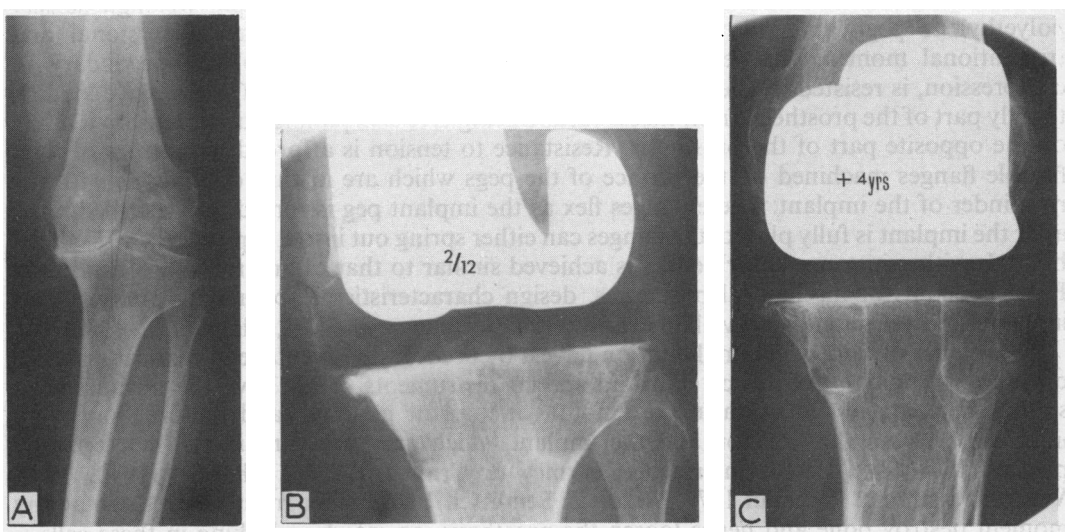

Figure 5. Roentgenograms of a 72-year-old woman with osteoarthrosis who had a left knee replacement in 1977. A, preoperative, demonstrating marked varus deformity. B, two months postoperative macroradiogram of replaced knee. C, four years postoperative; allowing for a difference in roentgen penetration, there is no significant change compared with B

The current version of the ICLH knee is the result of approximately ten years' experience. Instruments requisite for performance of a total knee arthroplasty have evolved along with the implants and are an integral part of the procedure. Results following the use of an earlier version of this implant/instrumentation system have been published (Bargren *et al.* 1976, Freeman *et al.* 1973, 1978).

The ICLH knee prosthesis is an unconstrained, resurfacing device which requires minimal

bone removal but does demand resection of cruciate ligaments. It consists of two or three components, depending on whether or not the patella is resurfaced; there is area contact between all the components. Time and experience have shown that an unconstrained design can be utilized to replace satisfactorily even the severely damaged knee (Bargren *et al.* 1976, Freeman *et al.* 1977*b*). The advantages of a cruciate removing technique have been discussed elsewhere and it is now certain that the knee can be stabilized after cruciate resection (Bargren *et al.* 1976, Freeman *et al.* 1973, 1977*a*, 1978, Insall *et al.* 1979).

The quality of the result of total knee arthroplasty is critically dependent upon alignment and stability of the knee, and the position of the prosthesis relative to the weight-bearing axis of the leg. The joint must aligned with the centres of the hip, knee and ankle in a straight line; with the posterior, medial and lateral soft tissues tight in extension; with the latter two tight (or almost so) in flexion; with the tibial plateau horizontal as viewed from the front; with the patella tracking centrally throughout the range of movement; with tibial external rotation and lateral subluxation controlled; and with the centre of rotation of the prosthesis nearer to the back than to the front of the knee. These requirements can only be achieved reliably in one of two ways: by building them into the prosthesis (i.e. by using a hinge), or by designing suitable instruments to guide the surgeon.

The original design of the tibial component of the ICLH total knee proved to have an unacceptably high failure rate (Bargren *et al.* 1976, Freeman *et al.* 1978, Goldberg & Henderson 1980). This problem has been seen in other knee replacements (Insall *et al.* 1976, Riley & Hungerford 1978, Skolnick *et al.* 1976*a*). By 1975, a redesigned ICLH tibial component having a large surface area was being implanted (Bargren *et al.* 1978). This, like the current prosthesis, obtains full area contact between prosthesis and a flat, cut surface of bone on the proximal tibia.

Osseo-integration between the prothesis and bone is achieved through two high density polyethylene pegs, integral with the prosthesis. The pegs grossly resist torsional and translational moments between prosthesis and bone. Sinkage, or collapse secondary to compression, is resisted by the large flat surface of the prosthesis itself. Compressive loading to only part of the prosthesis from excess varus or valgus causes pulling out, or tension loading on the opposite part of the prosthesis. Resistance to tension is afforded by a series of thin, flexible flanges machined on the surface of the pegs which are in turn continuous with the remainder of the implant. These flanges flex as the implant peg is forced into a drilled hole; after the implant is fully placed, the flanges can either spring out into a gap or lie flexed against bone. In either instance a barb effect is achieved similar to that of an arrow or a fish hook. Further details of mechanical properties, design characteristics, experimental findings and implantation technique are available elsewhere (Freeman *et al.* 1981, Blaha *et al.* 1982).

Techniques of cementless implantation have a theoretical disadvantage of requiring precise operative technique and hence skill and special instruments. They have the advantage of speed, simplicity, a reduction in the amount of implant material, and the creation of an interface between the skeleton and the implant which may not contain the macrophages present at a bone/cement interface (Charnley & Crawford 1968, Charnley 1970, 1979, Vernon-Roberts & Freeman 1977, Willert & Semlitsch 1976). Since macrophages can at any moment destroy bone and hence loosen the prosthesis, an interface lacking in these cells is likely to be more stable biologically, i.e. longer-lasting, than one in which they are present (Chambers 1980). Over the last four years at The London Hospital no uncemented component has loosened nor migrated and no bone loss has been seen radiologically at any uncemented interface: a finding compatible with the prediction of biological stability.

Although no bone loss has been seen, it must also be emphasized that no bone ingrowth has been seen either; whatever may occur in animals, we do not believe that the bone adjacent to elderly osteoarthrosic joints, nor adjacent to porotic rheumatoid joints, will predictably grow into an implant.

Immediate osseo-integration provides several advantages over techniques requiring PMMA or relying on bone ingrowth. For these advantages to be realized, several requirements must be met:

(1) There must be immediate bone/implant interface strength to allow early rehabilitation of the patient, such as in implants stabilized with PMMA.
(2) This immediate strength must not deteriorate with time: the integration system must demonstrate long-term high-fatigue strength and the bone/implant interface must be biologically stable.
(3) Actual intraoperative implantation must not be excessively demanding, yet surface preparation must be precise.
(4) Bone resection requirements must be minimal, and must not exceed those for cemented implants.
(5) The method of integration must be such that, in the event of failure, removing the implant does not destroy a large amount of bone and thus render reimplantation virtually impossible.

The first two requirements, those of implant and interface strength and stability, were explored through laboratory evaluations and animal implantations dating back to 1976. The third and fourth requirements, for 'implantability', were met through the use of appropriate instruments and a specifically designed implant. The final requirement, 'revisability', has been achieved by having an implant made of a material well tolerated by human tissue with a design which does not require a vast area of actual bone interlock.

Our experience substantiates enthusiasm for the immediate interlock technique of non-cemented implant fixation which achieves interdigitation between the living skeleton and the implant. This technique may have a substantial future.

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