
M. A. R. FREEMAN, R. C. TODD, P. BAMERT, W. H. DAY

From The London Hospital, London

The essentially satisfactory results from the ICLH implant as used until 1975 were marred by examples of loosening and sinking of the tibial implant, by patellar pain of varying severity, by wear of the tibial implant caused by fragments of cement and by failure consistently to control the alignment of the leg. This report describes the methods now being used to overcome these complications and gives an account of the success so far achieved.

Work on the design of an implant—which replaced only the surfaces of the affected bones and lacked, as do the natural articular surfaces, any direct mechanical link between the components—began at Imperial College in 1968. It was at first known as the Freeman–Swanson prosthesis but is now known as the ICLH (Imperial College–London Hospital) prosthesis. The first prosthesis was inserted at the London Hospital in 1970. In 1972 preliminary results were reported to the British Orthopaedic Association (Freeman and Swanson 1972) after which a multi-centre trial, which continues today, was instituted at the London Hospital, several other hospitals in the United Kingdom and one in Sweden. From this trial we have learned that the functional state of the replaced knee can remain essentially unchanged for four years (Bargren et al. 1976) and five years (Freeman 1977) after replacement but does not necessarily do so; that the severely damaged knee can be successfully replaced using this technique (Freeman, Sculco and Todd 1977); and that with the possible exception of the varus osteoarthritic knee the results are better than those achieved by osteotomy (Freeman, Bargren and Miller 1977). Broadly speaking the procedure as practised up to 1975 was capable of relieving pain in the arthritic knee whilst controlling instability, correcting severe deformity and increasing the range of movement, but a study of the complications and failures showed that this outcome could not be achieved reliably. In particular it was found that the tibial component tended to sink and to loosen; that patellar pain persisted in many knees after the operation and sometimes required treatment by patellectomy; that the polyethylene surface of the tibial component in knees coming to revision nearly always showed surface damage which could be attributed to polymethylmethacrylate cement inadvertently left in the posterior compartment of the knee (Revel, Weightman and Freeman 1978); and that alignment of the knee and the control of instability could not be achieved accurately and reliably by eye (Freeman, Sculco and Todd 1977).

These defects have been encountered throughout the period of development of this implant and the procedure for its insertion. The appropriate modifications have been introduced one by one rather than in groups so that the effect of modifying any one variable could be observed: as a consequence progress towards a full solution has been slower than it might have been, but solutions for each of these defects can now be described. Modifications to the implant and to the instruments were initially carried out (with one exception) at Imperial College and changes in the surgical procedure were made at the London Hospital but there have been considerable and variable delays between the introduction of a modification at the London Hospital and its use elsewhere: some surgeons may still be using the version of the prosthesis described in 1972 (Swanson and Freeman 1972) (a version which resembles the present prosthesis only with respect to the profile of part of its articular surfaces) and it is certainly the case that the instruments and techniques used today (December 1977) at the London Hospital are not in use elsewhere.

The clinical results obtained in the knees operated upon up to 1975 have already been described in the publications mentioned above, and we therefore now describe the solutions which have been devised for the defects in the procedure listed above, the extent to which these have been successful and, in the briefest summary, the current prosthesis and procedure and the clinical results to be obtained with them.

R. C. Todd, F.R.C.S., Essex County Hospital, Lexton Road, Colchester, Essex, England.
P. Bamert, M.D., Anker Strasse 28, CH 3006 Bern, Switzerland.
Requests for reprints should be sent to Mr M. A. R. Freeman.
MATERIALS AND METHODS

Loosening and sinkage of the tibial component. The first version of the tibial component was made small enough (6.4 x 4.1 centimetres) to be implanted into all knees—even the smallest—so that only one size of implant had to be manufactured. As a consequence, in most knees the prosthesis rested upon only part of the cross-section of the tibia and on the cortex only posteriorly. Bargren et al. (1978) showed that the compressive strength of the tibia replaced in this way provided little if any margin of safety against fatigue failure. On the other hand, if the prosthesis used was large enough to cover the whole of the top of the tibia including its cortices, the compressive strength was increased approximately twofold. Thus since early 1975 a tibial component measuring 7.7 x 4.7 centimetres has always been employed. A specially designed power-driven instrument with which any excess polyethylene can be trimmed at operation ensures that the component does not overhang the tibia.

The results using this prosthesis have been assessed by reference to the incidence of tibial sinkage and loosening in 200 knees replaced with the small-area tibial component before April 1975, as compared with 160 knees replaced with a tibial component covering the whole of the cut surface of the bone after April 1975.

Patellar pain. There seems no reason why tibiofemoral replacement should abolish patellofemoral pain. In 1970 a patellectomy was done as part of the first ten replacements; the result was a disastrous series of failures in wound healing. Accordingly the patella was retained but it then had to travel over both the distal femur and the short anterior flange of the prosthesis. In 1973 a version of the prosthesis with an anterior flange high enough to cover the whole of the patellar surface of the femur was introduced and in 1974 three knees were replaced with this version of the prosthesis combined with resurfacing of the patella with an implant of ultra-high molecular weight polyethylene. Delays in manufacture prevented the regular use of this femoral component until December 1976; between 1975 and that date the posterior surface of the patella was resected (with or without subsequent covering with soft tissue) and as smooth as possible a surface was fashioned from the femur itself and the short anterior flange of the prosthesis. In 1977 resection (without replacement) of the posterior surface of the patella continued but the femoral surface of the patellofemoral joint was regularly replaced with the high anterior flanged femoral component. The question then remained: would this combination sufficiently reduce patellar symptoms to outweigh the possible complications, such as loosening and fracture associated with patellar replacement?

We have examined the efficacy of replacement of the femoral surface of the patellofemoral joint and resection of the articular surface of the patella by seeking patellar symptoms in fifty randomly selected knees replaced with a prosthesis having a short anterior femoral flange, as compared with the first seventeen knees replaced with a high anterior flange and having at least a six-month follow-up. (We have as yet too few patients whose patellae have been replaced to compare them with these two groups.)

Cement inadvertently left at the back of the joint. In the original operative technique a monocondylar femoral prosthesis was inserted first, and any cement expressed posteriorly was removed. More cement was then placed on the top of the tibia and the tibial component was inserted into the gap between the femoral component and the tibia in the flexed knee. This last step was difficult and frequently resulted in cement being carried behind the tibia where it was out of sight and therefore not removed. The resulting “cementophyte” was often milled through the prosthesis and damaged the polyethylene.

The initial solution to this problem was suggested in 1975 by Insall. He implanted the tibial component first, after which any posterior cement could be seen and removed. A bicondylar femoral component was then inserted, the cement being placed on the prosthesis, not on the bone. Since the cruciate ligaments had been removed, residual cement could now be seen and removed through the “empty” intercondylar notch. Although in theory foolproof, this procedure still occasionally left cement behind the tibia and we have therefore developed a method by which the tibial component can be fixed to the tibia without cement at all (Fig. 1). This technique has been in use at the London Hospital since early 1977.

We have examined the efficacy of the first modification to the original procedure by seeking acrylic cement radiologically in fifty randomly selected knees replaced with a monocondylar femoral prosthesis inserted first, as compared with fifty randomly selected knees replaced with a bicondylar femoral prosthesis inserted second. We also now report the early symptomatic and radiological results obtained after cementless fixation of the tibial component.
contracted soft tissues. This left the tissues on the originally convex side of the deformity overlong and as a consequence the knee was likely to be unstable (Freeman, Sculco and Todd 1977). In 1975 it was realised that the contracted soft tissues could be released surgically in a controlled fashion so as to realign the knee, stability being achieved by "blocking the joint open" with the prosthesis.

**Fig. 3**
A routine radiograph to show that the knee has been correctly aligned. The bar is slightly lateral to the hip which is acceptable; a corresponding error in a valgus direction is not acceptable.

To do this and to ensure accurate alignment of the hip, knee and ankle, a new instrument was designed and used at the London Hospital in 1975. With this instrument, the Tenser (Fig. 2), the medial and lateral compartments of the knee can be distracted separately thus "turning" the tibia into varus, valgus or neutral alignment and tensing the medial and lateral soft tissues. The correct alignment is confirmed by a straight bar running through the instrument and extending proximally to the hip and distally to the ankle (Fig. 3). We have also found that to prevent lateral translocation of one component on the other the prosthesis must be placed so as to be precisely horizontal when the patient stands, and the patellofemoral joint must be so managed surgically that the patella always runs in the midline of the knee when the joint is flexed. Surgical instruments and a technique to achieve these objectives reliably have been developed.

We have estimated the efficacy of the techniques of soft tissue release regulated by the Tenser by comparing the postoperative stability and alignment of fifty randomly selected knees replaced before the introduction of this technique with fifty randomly selected knees replaced after its introduction. The realignment of the patellofemoral joint is outside the scope of this paper.

**RESULTS**

**Loosening and sinkage of the tibial component.** On review, in September 1977, of 200 consecutive knees replaced at the London Hospital between 1972 and 1975 the incidence of aseptic loosening and sinkage (Fig. 4) was 12.5 per cent. Precise assessment of the moment of onset was not always possible but we regard these complications as having developed in the first year after operation in 1 per cent, in the second year in 3.5 per cent, in the third year in 2.5 per cent and in the fourth year in 5.5 per cent, showing a gradually increasing incidence of these complications as the years went by. We would particularly draw attention to the fact that the incidence after the first two years was 4.5 per cent. In contrast, we have so far observed no case of loosening nor of sinkage in 160 knees replaced between April 1975 and June 1977 using a tibial component large enough to cover the whole of the top of the tibia.

**Patellar pain.** It is difficult to prove that pain in a replaced knee is certainly patellar in origin. Very few knees treated in this series had pain sufficiently severe to merit patellectomy and we have had to rely upon the clinical and radiological features in making a diagnosis. These features are: that the pain is felt in the front of the knee, that the patella is tender, that the pain is felt more severely on the stairs, that radiographs show impingement by the patella against the short anterior flange of the femoral prosthesis (Fig. 4) and that a lateral bone scan shows increased uptake of radionuclide in the patella. Since not all our patients have been investigated in these various ways, we have based our estimates for this report simply upon the presence or absence of pain in the front of the knee.

**Fig. 4**
A radiograph of a right knee showing tibial sinkage anteriorly combined with loosening, patellar impingement on the prominence of the short anterior flange causing patellar pain, and excessive cement at the back of the joint.

In fifty randomly selected knees operated upon using the short anterior flange prosthesis between January 1974 and January 1975 the incidence of such pain six months after replacement was 42 per cent. We have only seventeen knees replaced with the high anterior flange version of the femoral component combined with posterior resection of the patella which can be evaluated six months after operation. Two of
these patients have mild anterior pain in the knee and in one of these the patella was not accurately realigned.

We thus have an incidence of anterior pain in the knee of 42 per cent using the short anterior flange version of the prosthesis as against 12 per cent using the high anterior flange, or 6 per cent if the knee in which the patella was misaligned be excluded. It must be emphasised that the pain in the latter group was mild and did not result in any subjective disability.

Cement at the back of the joint. In fifty randomly selected knees replaced in which the monocondylar version of the femoral prosthesis had been inserted before the tibial component, significant quantities of cement were radiologically visible behind the tibial component in thirty (60 per cent). In many it was obvious that the cement overlapped the top of the tibial component to enter the joint (Fig. 4) and experience has shown that cement entering the joint in this way may not always be visible radiologically. In contrast, in fifty randomly selected knees operated upon using the bicondylar femoral component inserted after the tibial component, cement was present posterolateral to the tibial component in three and posterior to the tibial component in one (a total of 8 per cent). Radiographs of these knees showed no intra-articular cement.

No excess cement could be present in any knee with a tibial component fixed without cement (Fig. 5).

**The alignment and stabilisation of the tibiofemoral joint.** In fifty randomly selected knees operated upon by various surgeons at the London Hospital in the period before October 1974, when soft tissue release and the Tenser were first used, 32 per cent were either imperfectly aligned or unstable when stressed six months later (Fig. 6). Twelve of these knees (24 per cent of the total) were either unchanged or had deteriorated after the operation. It is of particular significance that of eighteen knees whose alignment and stability were normal before operation, only ten had remained so six months after it.

The results in the fifty randomly selected knees after the regular use of the Tenser and soft tissue release at the London Hospital are set out in Figure 7. It will be seen that 94 per cent of knees were finally stable and in an acceptable alignment (0–10 degrees valgus). In particular all those knees which were normally aligned and stable before operation remained so when assessed at six months. Of the remaining 6 per cent (three knees) the alignment and stability was improved in two and remained unchanged in one. In no case was there a final malalignment greater than 5 degrees beyond the acceptable range.

**DISCUSSION**

It will be seen that the modifications to the prosthesis and to the operative technique introduced between January 1973 and December 1976 have been successful in remedying the earlier defects. Thus we have not so far encountered an example of loosening nor of sinkage of the larger tibial component; the incidence of patellar pain has been reduced from 42 per cent to 12 per cent (or 6 per cent if patellar subluxation be excluded); the presence of acrylic cement behind the tibial component has now been eliminated altogether with the use of the cementless version; and the problem of postoperative malalignment and instability of the tibiofemoral joint has been virtually eliminated by the use of the Tenser and soft tissue release procedures.

Certain qualifications must be entered with respect to this satisfactory outcome. The incidence of tibial loosening and sinkage of the small-area component continued to be a major problem in the third and fourth years after operation. As yet we have no results for the large tibial component three and four years after operation and the incidence of loosening may rise. Nevertheless the contrast in the first two years is sufficiently striking to suggest that the results cannot but be substantially better than before.

Patellar pain has not been entirely eliminated by the use of a femoral component with a higher anterior flange combined with resection of the posterior surface of the patella. Nevertheless its incidence had been greatly reduced and in one of the two knees in which the symptom persists it can be attributed to malalignment. In the other, although anterior pain is present it is trivial in severity. We do not have a sufficient number of knees in which the patella has been replaced to permit a comparison to be made between this method of managing the patellofemoral joint and the methods here evaluated. Nevertheless it is our impression that
Figures 6 and 7—Tibiofemoral alignment before and after operation in fifty randomly selected knees treated without soft tissue release procedures nor the use of a Tenser (Fig. 6) as compared with fifty randomly selected knees treated with the use of soft tissue release procedures and a Tenser (Fig. 7).
replacement of the patella virtually eliminates anterior pain and that there is also a difficult-to-define improvement in the quality of function of the knee. Against these advantages would have to be set the as yet theoretical disadvantage of a somewhat increased incidence of late complications such as loosening of the prosthesis and fracture of the patella. Only time will tell where the balance of advantage is to be struck.

The technique for the elimination of the residual acrylic cement in the posterior compartment of the knee suggested to us by Insall (1975) has proved very successful. Nevertheless we have on several occasions still left some cement behind the tibia, especially posterolaterally, but it is possible to ensure that no cement is left upon the articular surface. It may well be that cement behind the tibial component is of no long-term significance provided it does not enter the joint and thus the use of this technique alone may well represent a complete solution to the problem. On the other hand, if a tibial component that does not require acrylic cement for its fixation is employed the problem no longer exists. We have employed such a component since January 1977 and the clinical results are indistinguishable from those obtained in knees in which cement has been used.

The use of the Tenser combined with soft tissue release procedures has enabled the tibiofemoral joint to be aligned and stabilised regardless of the initial severity of fixed malalignment or of instability. The instrument is simple to use but of course must be employed with a proper understanding of the surgical technique.

Ninety per cent of the patients whose knees were replaced in 1976 at the London Hospital required no analgesia six months after operation although a number had mild anterior pain. All were walking for various distances out of doors, had a range of movement from full extension to 90 degrees of flexion or more and had a normally aligned and stable tibiofemoral joint. These results have been improved upon with respect to the incidence of anterior pain in the knee by the introduction of the high anterior flange version of the femoral component in 1977. Symptomatically the results have not been affected by the use of a tibial component fixed without the use of cement.

REFERENCES


