Extramedullary or intramedullary tibial alignment guides: a randomised, prospective trial of radiological alignment

M. R. Reed, W. Bliss, J. L. Sher, K. P. Emmerson, S. M. G. Jones, P. F. Partington

From Wansbeck General Hospital, Ashington, England

We undertook a prospective, randomised study of 135 total knee arthroplasties to determine the most accurate and reliable technique for alignment of the tibial prosthesis. Tibial resection was guided by either intramedullary or extramedullary alignment jigs.

Of the 135 knees, standardised postoperative radiographs suitable for assessment were available in 100. Correct tibial alignment was found in 85% of the intramedullary group compared with 65% of the extramedullary group (p = 0.019).

We conclude that intramedullary guides are superior to extramedullary instruments for alignment of the tibial prosthesis.

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Patients and Methods

Between March 1999 and August 2000 we performed 135 cemented AGC total knee replacements (Biomet Merck Limited, Bridgend, UK) using a standard surgical technique with a tourniquet in 126 patients in a single unit under the care of four surgeons. The local research Ethical Committee approved the trial. Knees which were suitable only for one of the two methods of instrumentation were excluded at the stage of preoperative planning. Intramedullary alignment was used for the preparation of the distal femur and patients were randomised by cards at the time of operation to have either intramedullary or extramedullary guides for the preparation of the proximal tibia. The cards were prepared in identical thick envelopes by one author (MR) who was not present at any of the surgical procedures. In only one case was the operating surgeon unhappy with the overall alignment of the knee and an adjustment was made to the tibial cut. This patient was excluded.

Both intramedullary and extramedullary techniques were carried out in accordance with the manufacturer’s instructions. The entry point of the intramedullary device was determined by the preoperative plan for the centre of the tibial axis. This was usually just anterior to the tibial attachment of the anterior cruciate ligament. The guide, which was 8 mm in diameter was passed to the level of the distal physeal scar although this was not confirmed radiologically. For the extramedullary device the central shaft of the resector was aligned parallel to the axis of the tibia and centred on the midpoint of the talus, 3 mm medial to the centre of the ankle. A tibial slope of zero degrees was used in all cases to reduce the likelihood of malrotation of a posteriorly sloped cut which would influence varus/valgus alignment.

Three months after operation standing long-leg anteroposterior radiographs were taken which were acceptable for analysis provided that the knee was in maximum extension, with the patella pointing forwards and both hips and ankles were visible on the film. Of the 135 knees recruited into this study, acceptable films were available for only 100 with 54 knees (51 patients) in the intramedullary group and 46 knees (44 patients) in the extramedullary group. The radiographs were assessed for the alignment of the tibial component (Fig. 1) by a surgeon who was unaware of the
method used (WB). The angle of the tibial component (TCA) is that between the mechanical axis of the tibia and the transverse axis of the component. It was calculated by marking the film and then measuring using a goniometer with a precision of 1°. Although alignment of the limb can be accurately measured manually, there are no data available to support its use in defining the alignment of components. Other comparable studies, however, have used similar techniques. 4-10

Valgus angles were designated as those less than 90° and varus angles as those greater than 90°. The proportion of tibial prostheses aligned within two degrees of 90° was the endpoint of the study. 5,7,11,12 Before we began the study we undertook a power calculation which found that in order to detect a difference of 15% in correct alignment 48 patients were needed per group (80% power, alpha = 0.05, two-sided comparison of two independent proportions). The statistical analysis was performed with Microsoft Excel (Microsoft, Redmond, Washington).

Results
The baseline patient characteristics are shown in Table I and the results in Table II. Correct tibial alignment was found in 85% of the intramedullary group and in 65% of the extramedullary group (p = 0.019). The distribution of the alignment angles of the tibial component is shown in Figure 2. Varus malalignment was more common with both systems of instrumentation.

Discussion
Bono et al 6 performed a cadaver study to assess the intramedullary device and found that passage of the rod to the distal epiphysial scar significantly improved alignment. Severe bowing has been found to preclude this 8,9 and such patients were not included in our study.

The centre of the mechanical axis of the tibia runs through the mid-point of the talus and not the mid-point of the talus.
the ankle. Dennis et al.\textsuperscript{11} had excellent results from extramedullary alignment and recommended that the device be centred 3 mm medial to the mid-point of the ankle. Our study included this refinement but excluded tibiae unsuitable for the extramedullary jig because of abnormal anatomy or excess soft tissue.

Opinion is divided as to which alignment guide is superior for positioning of the tibial component. A recent survey of British orthopaedic surgeons\textsuperscript{13} found that 75.6\% prefer extramedullary and 20.3\% prefer intramedullary, with the remainder using both or neither technique. Our study is the first randomised trial which has assessed which system to use and the refinements of each technique were included in the protocol. A review of the unrandomised literature has shown that two studies were in favour of the intramedullary technique\textsuperscript{5,14} with others being equivocal.\textsuperscript{7,8,10} Dennis et al.\textsuperscript{11} disagree with these findings, but crucially do not state how far the intramedullary alignment guide rod was passed and concede that the two groups had different surgeons.

A limitation of our study is the fact that we have addressed only alignment in the frontal plane since that is known to be associated with a poor outcome.

One proposed disadvantage of intramedullary systems is the risk of venous embolism. Parmet et al.\textsuperscript{15} have addressed this issue and concluded that the incidence of a large venous embolism does not differ with the alignment technique and that release of the tourniquet is the key event. We had no cases of thromboembolism in our study.

Our findings have shown that in tibiae suitable for the technique, intramedullary tibial alignment guides passed to the distal epiphyseal scar are more likely to provide correct alignment of tibial prostheses than extramedullary devices.

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References