The reliability and accuracy of digital templating in total knee replacement

We aimed to determine the reliability, accuracy and the clinical role of digital templating in the pre-operative work-up for total knee replacement.

Initially a sample of ten pre-operative digital radiographs were templated by four independent observers to determine the inter- and intra-observer reliability of the process. Digital templating was then performed on the radiographs of 40 consecutive patients undergoing total knee replacement by a consultant surgeon not involved with the operation, who was blinded to the size of the implant inserted. The Press Fit Condylar Sigma Knee system was used in all the patients. The size of the implant as judged by templating was then compared to that of the size used.

Good inter- and intra-observer agreement was demonstrated for both femoral and tibial templating. However, the correct size of the implant was predicted in only 48% of the femoral and 55% of the tibial components. Albeit reproducible, digital templating does not currently predict the correct size of component often enough to be of clinical benefit.

The correct sizing of implants is a key determinant in the long-term success and function of knee arthroplasty surgery. Oversizing of the femoral component can lead to ‘overstuffing’ of the patellofemoral joint and a reduction in the post-operative range of knee flexion. Conversely, undersizing of the component can lead to a flexion-extension mismatch, with instability in flexion. Overhanging of the tibial tray may produce post-operative pain, especially on the medial side of the joint. An undersized tray may be poorly supported by the tibial cortex and lead to sinkage of the component.

Pre-operative planning with templates aims to assess the size and orientation of the implants to be used at operation, thereby ensuring that components of the correct size are available. Hence, the method of templating must be accurate and reproducible. The analogue methods that were used previously were generally flawed because of variations in the magnification factor of the radiographs. Analogue scaling and routine pre-operative CT scans have been suggested as potential but imperfect solutions to this problem.

Recently, with the widespread use of digital imaging software, the Picture Archiving and Communication System (PACS), conventional radiographs are becoming increasingly rare. Methods have been developed using PACS to enable pre-operative planning and templating for hip and knee replacements. These systems provide a permanent record of the templating and permit scaling of the radiographs with reference to a scaling ball of fixed size.

The aim of this study was to assess the inter- and intra-observer reproducibility and the accuracy of digital templating, and to evaluate its role in pre-operative planning using the Press Fit Condylar Sigma (PFCΣ) Knee System (DePuy, Leeds, UK).

Patients and Methods

Between 1 April and 31 September 2007, standard pre-operative radiographs of the knees of 40 consecutive patients were taken by appropriately trained radiographers using a 30 mm spherical scaling ball placed adjacent to the joint line on both the anteroposterior (AP) and lateral views. Four observers independently digitally templated the first ten radiographs, using mediCAD (version 2.04 HecTec GmbH, Erlenweg, Germany) (Figs 1 to 3). Each had received identical training in the use of the templating software. The same ten radiographs were then templated again after an interval of two weeks, without reference to the previous results. Intrar- and inter-observer agreement was then assessed using the linear weighted kappa (κ) coefficient of Cohen. Table I interprets κ as a level of agreement.
The patients subsequently underwent total knee replacement (TKR) using the fixed-bearing posterior cruciate retaining version of the PFCΣ Knee System. The operations were performed by one of the senior authors (MCF and AR) using specialist jigs and the sizes which were implanted were recorded. Digital templating was carried out on the preoperative images by the senior author who had not carried out the operation, and who was blinded to the sizes which were implanted. The results were collected and analysed independently of the operating and templating surgeons.

**Results**

**Reliability.** The linear weighted κ intra-observer coefficients for the four observers are shown in Table II. Both femoral and tibial templating demonstrated good or moderate agreement for all observers. The weighted κ inter-observer coefficient is shown in Table III. The mean values of κ were calculated for all observers and demonstrate a good level of agreement for both femoral and tibial templating.
Accuracy. Of the 40 patients the templated size of the femoral component was correct in 19 (48%). When allowing for a difference of ± 1 size the templated size was correct in 39 patients (98%). The tibial templating correctly predicted the size of the implant used in 22 patients (55%), and in all 40 when allowing for a difference of ± 1 size. Five patients were analysed in a separate subgroup following review of the post-operative radiographs. All were deemed to have a femoral component one size too large. Four of the five had been correctly templated for the size of the femoral component compared to the size implanted. The fifth had been templated two sizes too large compared to the size implanted, which was a large discrepancy. Taking into account the exclusions, the femoral component was sized correctly in 15 patients (43%) and in all 35 patients for ± 1 of the correct size. The tibial component was correctly sized in 19 patients (54%) and in all 40 for ± 1 of the appropriate size.

Discussion
Manufacturers of implants recommend that templating should be part of the assessment for all patients before operation. Digital templating systems allow this to take place and facilitate the creation of a permanent record of the templating.

Templating must be shown to be an accurate predictor of the anatomical measurements found at operation. It must be reliable and reproducible, with different observers producing consistent results. This study has shown that the process may be performed with good correlation between observers. It does not, however, predict the correct size often enough to be of clinical benefit.

The prediction of the size of the component was only correct in approximately half of the patients. However, when allowing for a discrepancy of ± 1 in sizes, the accuracy rose to more than 95%. The poor accuracy of the process and the discrepancy between templated and implanted sizes may be accounted for by the variety of sizes of component available. The PFC Σ TKR comes in nine sizes (1, 1.5, 2, 2.5, 3, 4, 5, 6, 7) for both femoral and tibial components. The whole sizes differ by between 4 mm and 5 mm in both the AP and mediolateral directions. Consequently, there is likely to be a compromise in the sizing of the implants, both during templating before operation and at the time of surgery. In systems with a smaller choice of sizes, there is necessarily a greater difference between adjacent sizes. This will result in a greater compromise in perfection of fit, and increase the likelihood that the templated and implanted sizes will correspond. This needs to be considered when comparing the digital templating data from this study with the analogue data published by previous authors using the PFC and other knee arthroplasty systems.8

Analysis following the exclusions showed no significant change in the accuracy of templating. The excluded patients were all female and on review of the post-operative radiographs were deemed to have had an oversized component implanted. We included these patients because they may represent a subgroup of women with an altered ratio between the AP and mediolateral distances of the distal femur, being broader in AP for a given mediolateral measurement.9,10

### Table II. Weighted κ intra-observer coefficients

<table>
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<tr>
<th>Observer</th>
<th>κ</th>
<th>95% CI*</th>
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<tbody>
<tr>
<td>Femur</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>0.84</td>
<td>0.67 to 1.00</td>
</tr>
<tr>
<td>B</td>
<td>0.56</td>
<td>0.24 to 0.88</td>
</tr>
<tr>
<td>C</td>
<td>0.55</td>
<td>0.19 to 0.90</td>
</tr>
<tr>
<td>D</td>
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<td>0.52 to 1.00</td>
</tr>
<tr>
<td>Mean</td>
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<td>0.41 to 0.95</td>
</tr>
<tr>
<td>Tibia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>0.66</td>
<td>0.36 to 0.95</td>
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<tr>
<td>B</td>
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<td>0.44 to 0.97</td>
</tr>
<tr>
<td>C</td>
<td>0.66</td>
<td>0.37 to 0.94</td>
</tr>
<tr>
<td>D</td>
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<td>0.65 to 1.00</td>
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<tr>
<td>Mean</td>
<td>0.72</td>
<td>0.46 to 0.96</td>
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</table>

* 95% CI, 95% confidence interval

### Table III. Weighted κ inter-observer coefficients

<table>
<thead>
<tr>
<th></th>
<th>κ</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Femur</td>
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<td>0.66</td>
</tr>
<tr>
<td>Tibia</td>
<td>Mean</td>
<td>0.65</td>
</tr>
</tbody>
</table>

* 95% CI, 95% confidence interval

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Fig. 4
Immediate post-operative anteroposterior and lateral radiographs.
these patients, the standard PFC\(\Sigma\) components do not provide a perfect fit in the mediolateral plane when the correct AP size is used. If the correct mediolateral sizing were used the femur would be notched, or if the component was moved anteriorly to compensate, the flexion gap would be lax. No bias effect on the accuracy of the templating software was identified in this subgroup, with four of the five excluded patients being correctly templated.

The femoral components were consistently templated less accurately than the tibial implants. A potential reason for this is the forward projection of the femoral condyles on the lateral radiograph of the knee. The lateral femoral condyle has a larger distal radius which is more prominent anteriorly and less prominent distally than the medial femoral condyle.\(^2\) This increases the difficulty of identifying the osseous landmarks while templating the femoral component.

Previous problems associated with analogue templating, particularly with fixed flexion deformities and the effects of magnification,\(^5\) should be overcome by the accurate scaling of the digital radiographs. However, the accuracy of the method used depends solely upon the appropriate placement of the scaling ball at the time of imaging.\(^11\) If the ball is placed at a point too far from the joint line, errors in the digital correction of magnification can occur. Numerous scaling techniques for digital radiography have been suggested using anatomical measurements, coins or fixed-diameter scaling balls.\(^12,13\) The variability seen due to errors in magnification applies principally to the hip joint because of the difficulty in identifying the joint line, which is relatively easy in the knee.

Digital templating is a useful aid in the pre-operative assessment of patients undergoing TKR, allowing the surgeon to plan his approach and consider the size of the implant to be used. It is currently insufficiently accurate to allow the ordering of implants for individual cases, but it does predict the use of extreme or unusual sizes of implants, allowing the surgeon to ensure that these are available at operation. It also provides a permanent record of pre-operative planning process,\(^14\) which may be important for medicolegal purposes.

A number of useful functions are available on the software package which can be used to assess bone loss, patellar orientation or the presence of unusual anatomical variations. With the increasing use of computer-guided surgery, digital templating may become an intra-operative process.\(^15,16\)

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References