Acta Orthop. Belg., 2013, **79**, 307-311

ORIGINAL STUDY

Patient-matched Total Knee Arthroplasty : Does it offer any clinical advantages ?

Samuel BARKE, Ed MUSANHU, Constant BUSCH, Giles STAFFORD, Richard FIELD

From the South West London Elective Orthopaedic Centre, Dorking Road, Epsom, Surrey

This study aimed to assess if patient-matched cutting blocks reduce operating time, blood loss and length of stay on top of improving implant alignment and offer operational or economic benefits, as claimed by manufacturers.

We retrospectively reviewed patients undergoing TKA using patient matched technology and compared them with patients undergoing TKA using standard instrumentation ; all were operated on between September 2010 and June 2012. All procedures were performed by a single surgeon at a single centre using the same implants. We collected data on operating time, length of stay and blood loss and also measured component alignment.

Thirty-nine patients underwent TKA using patient-matched technology during the study period. Data was compared with that from 50 patients undergoing TKA using standard instrumentation during the same period. We found no significant difference in operating time, length of stay or blood loss between the two groups. There was also no difference in femoral or tibial component alignment although we did observe that the femorotibial angle of TKAs using patient-matched technology was 0.9º more valgus (183.5º versus 182.6º, p = 0.035).

In this study, patient-matched technology did not appear to give any clinical advantages over standard techniques although, equally, it did not appear to show any disadvantages. Further studies are needed to evaluate whether operational or economic benefits may be achieved by adoption of patient matched instrumentation.

No benefits or funds were received in support of this study. The authors report no conflict of interests.

Keywords : total knee arthroplasty ; patient-matched cutting blocks ; results.

INTRODUCTION

Total Knee Arthroplasty (TKA) has long been recognised as the gold standard treatment for advanced osteoarthritis of the knee. With the annual number of TKAs performed continuing to rise (*7*) alongside an increasing economic burden, there is still much impetus to improve clinical efficiency

■ Samuel Barke, MBBS, Surgical Research Fellow.
■ Ed Musanhu, MBChB MSc MRCS, Clinical Teaching Fellow.
■ Constant Busch, MBBS BSc (Hons) FRCS (Eng) FRCS (Tr and Ortho), Consultant Orthopaedic Surgeon, Ashford & St Peter's Hospitals NHS Foundation Trust.
■ Giles Stafford, MBBS BSc (Hons) FRCS, Consultant Orthopaedic Surgeon & Deputy Director of Research.
■ Richard Field, PhD FRCS FRCS (Orth), Consultant Orthopaedic Surgeon & Director of Research.
South West London Elective Orthopaedic Centre, Dorking Road, Epsom, Surrey.
Correspondence : Samuel Barke, MBBS, Research & Education, South West London Elective Orthopaedic Centre, Dorking Road, Epsom, Surrey, KT18 7EG, UK.
E-mail : sambarke1@doctors.org.uk

while maintaining patient satisfaction and long term results. Patient-matched technology is one such method that industry has developed to achieve this goal.

Patient-matched technology utilises pre-operative imaging to create a 3-dimensional model of the affected knee. This model is used to generate custom instrumentation to guide resection of the distal femur and proximal tibia (*5*). The suggested benefit of this method is improved accuracy of component placement as well as increased efficiency through reduced operating time, equipment use and patient length of stay (*8*). To date, the only published prospective, randomised study did show statistically significant reductions in hospital stay and operative time as well as better post-operative mechanical alignment compared to the control group. However, this was with a small cohort (*8*) and a number of other studies have failed to fully replicate these results (*1,3,9*).

We have audited the first cohort of patients undergoing patient-matched TKA at our centre, by a single surgeon. We have compared the operating time, blood loss, length of hospital stay and component alignment of these cases with a cohort of the same surgeon's TKAs undertaken with standard instrumentation. We have analysed the results to determine whether there were any differences in these metrics between the two groups.

MATERIALS AND METHODS

We retrospectively reviewed all patients undergoing TKA between September 2010 and June 2012 by a single surgeon (CB) at a single centre (The South West London Elective Orthopaedic Centre (the EOC)). During this period 39 patients underwent TKA using the Visionaire® patient-matched extramedullary instrumentation (Smith & Nephew Inc., Memphis, USA) and 50 patients underwent TKA using standard instrumentation (femoral intramedullary and tibia extramedullary). All patients received the Genesis II® implant (Smith & Nephew, Memphis, USA). We recorded operating time, blood loss, length of stay and measured component for all cases. We also compared the operating time of the first five cases undertaken using patient-matched instrumentation with the last five to investigate whether learning curve had a significant impact.

All patients in the patient–matched group underwent pre-operative imaging as per the Smith & Nephew guidelines. This involved magnetic resonance imaging (MRI) of the knee and a full-length weight-bearing radiograph. These images were sent to Smith & Nephew for analysis and subsequent production of femoral and tibial cutting blocks.

We classified operating time as time between knife-to-skin and skin closure. This information is collected routinely in our centre by nursing staff as part of normal theatre documentation. We used percentage fall in haemoglobin (Hb) and haematocrit (HCT) to demonstrate blood loss. All patients had a pre-operative full blood count (FBC) check and a routine check on the second post-operative day. If a patient received a blood transfusion before this time his/her pre-transfusion Hb/HCT was used.

Post-operative AP knee radiographs were used to measure component alignment. This was done using TraumaCad x-ray analysis software. Femoral alignment angle was measured between a line parallel to the femoral condyles and a line along the femoral shaft axis. Tibial alignment angle was measured between a line parallel to the baseplate of the component and a line along the tibial shaft axis. Femorotibial angle is the total of the femoral and tibial alignment angles, with results > 180° indicating valgus alignment.

The unpaired Student's t-test was used to compare all the data between the 2 groups. Variance was compared using the two sampled F-test.

RESULTS

In the patient-matched group there were 20 men and 19 women. The standard group contained 25 men and 25 women. The patients in the patient-matched group were significantly younger than those in the standard group ($p = 0.0001$). There was no significant difference in BMI (Table I).

There were no significant differences in length of stay, operating time or percentage fall in Hb between the two groups ($p > 0.05$). The difference in both tibial and femoral component alignment between the groups was also statistically non-significant. There was, however, a significant 0.9° difference in femoro-tibial angle between the two groups ($p = 0.035$) (Table II). We found the variance of femoral component alignment to be significantly greater in the patient-matched group (Table III).

Table I. — Demographics

	Standard group (n = 50)	Patient-matched group (n = 39)	p value
Age (mean, SD, range)	72.7 ± 8.56 (48-86)	64.0 ± 9.0 (45-88)	0.0001
BMI (mean, SD, range)	30.4 ± 5.3 (22-46)	30.3 ± 5.9 (23-44)	0.93
Sex (male/female)	25/25	20/19	–

Table II. — Outcomes

Variable	Standard group (n = 50)	Patient-matched group (n = 39)	p value
Operating time (min) (mean, SD, range)	75.34 ± 12.86 (56-123)	74.38 ± 11.07 (51-108)	0.712
Length of Stay (days) (mean, SD, range)	6.72 ± 4.11 (2-24)	5.74 ± 3.81 (3-19)	0.254
% Hb fall (mean, SD, range)	31.6 ± 6.3 (20.3-45.7)	29.3 ± 7.1 (12.8-43.4)	0.112
% HCT fall (mean, SD, range)	31.8 ± 5.4 (19.7-40.1)	29.5 ± 7.9 (11.4-44.2)	0.112
Femoral component alignment (mean, SD, range)	94.7 ± 1.26 (92-98)	95.0 ± 1.74 (91-98)	0.253
Tibial component alignment (mean, SD, range)	87.9 ± 2.10 (84-93)	88.5 ± 2.02 (85-94)	0.223
Femoro-tibial angle (mean, SD, range)	182.6 ± 2.1 (178-188)	183.5 ± 1.82 (180-188)	0.035

DISCUSSION

We found no significant improvement in measures of clinical efficiency (operating time and length of stay) between the two groups although there was a non-significant mean reduction in length of stay of nearly one day in the patient-matched group. However, this could be explained by the significantly lower mean age of this group. Indeed, at our centre the median length of stay following TKA is 4 days for the age range 60-69, compared to a median of 5 days for those aged 70-79.

Equally there was no significant difference in the percentage fall in Hb or HCT from pre-operative to post-operative measurements. It is sometimes claimed that use of patient-matched instrumentation will reduce blood loss because the intramedullary canal is not violated (*4*). The operating surgeon routinely uses extramedullary instrumentation for tibial alignment. Although major bleeds are often seen from the femur, rather than the tibia, it is likely that, as the tibial canal is not violated when using standard instrumentation, we would not see as significant a difference in blood loss between the two cohorts. Mean alignment of both the tibial and femoral components was similar in both groups. However, the variance in femoral alignment using standard instrumentation was significantly less than that using patient-matched ($p = 0.038$). This suggests that aligning the femoral component using an intramedullary guide gives more reproducible results than with a patient-matched cutting block. There were no significant differences in the variance of tibial component alignment.

There was a statistically significant difference between the post-operative anatomical alignment of the groups, with the patient-matched being in 0.9° more valgus with a mean of 183.5°. The clinical significance of this is unclear. It is generally accepted that restoring a neutral mechanical axis is the gold standard of TKA. This is accomplished by achieving approximately 5° to 7° valgus femoro-tibial

Table III. — Component angle – Variance

	F statistic	p value
Femoral component	0.531	0.038
Tibial component	1.097	0.774

alignment and is based on the long-held belief that a mechanical axis ≥ ±3° from neutral is associated with increased rate of component failure. However a number of studies in recent years have challenged this view, showing that malalignment (≥ ±3° from neutral) showed no significant disadvantage in terms of clinical outcome (*6,10*). While we can not comment as to whether the difference in anatomical alignment would put the patient-matched or the standard group closer to neutral mechanical axis it is likely that a difference of 0.9° would not result in a significant difference in clinical outcome.

There are a number of limitations to this audit. This is a retrospective, non-randomised review and as such patient opinion will have influenced which group they went into. This could, in part, explain why the patient-matched group were significantly younger than the standard group as they may have had better access to tools for self-research, such as the internet. Secondly, component alignment was measured from AP knee radiographs which are taken as part of our standard post-operative assessment. This limitation applies to both groups, and although there is some evidence to show that alignment measured from long leg radiographs is comparable to that from AP knee radiographs (*2*), the lack of a weight-bearing long leg radiograph means we cannot comment on post-operative mechanical alignment. Finally, the surgeon and theatre staff were new to the patient-matched procedure which may have skewed the surgical time. Indeed, the operating surgeon is sure that using the patient-matched instrumentation saved time. However, there was no significant difference in mean operating time between the first and last five patient-matched TKAs (79.8 versus 76.8 minutes, $p = 0.718$) and there was only a small trend toward a reduction in length of operation over time (Fig. 1). As there was no demonstrable learning curve we did not see it necessary to exclude the first cases from the study.

There were two cases (case 4 and 24 in figure 1) where operating time was considerably lengthened. In both of these cases it became clear at the time of operation that the cuts made with the patient-matched block were incorrect. It took some time to appreciate how to rectify this error and to undertake subsequent soft tissue balancing. Both cases had satisfactory alignment on post-operative radiographs.

These findings go against those of Noble *et al* (*8*) who, in the first randomised prospective study on patient-matched instrumentation, found statistically significant reduction in length of stay and operating time as well as improved alignment in the patient-matched cohort. Both Boonen *et al* (*1*) and Nunley *et al* (*9*) also found operating time to be significantly less in that cohort. Our findings do, however, confirm those of others (*1,3,9*) who have shown that patient-matched instrumentation does not appear to improve component alignment.

An extra factor to consider is the number of instrument trays used. Although not measured in this study it has been reported that using a patient-matched system reduces the number of instrument trays used to a mean of 4.3 compared with a mean of 7.5 when standard instrumentation is used (*8*). This may well have an impact on set-up and clear-up times as well as cost of sterilisation and re-packing.

The senior author reports that there have been some issues with the patient-matched tibial cutting blocks. There have been at least three cases where the suggested cut was off by a large margin. As such we encourage the surgeon to check the cuts, which can be done with a specially available insert and alignment rod. The reason for these errors is unclear but it is thought that they may have resulted from the 3D MRI reconstruction and long leg radiographs being incorrectly processed, leading to rotational maladjustment. We have found that, with time, far more MRIs are being rejected by the manufacturer because of artefact. It has also been suggested that having larger paddles on the small tibial cutting block would make it easier to position correctly.

Overall, this study did not show any clinical advantages over standard techniques although, equally, it did not appear to show any disadvantages.

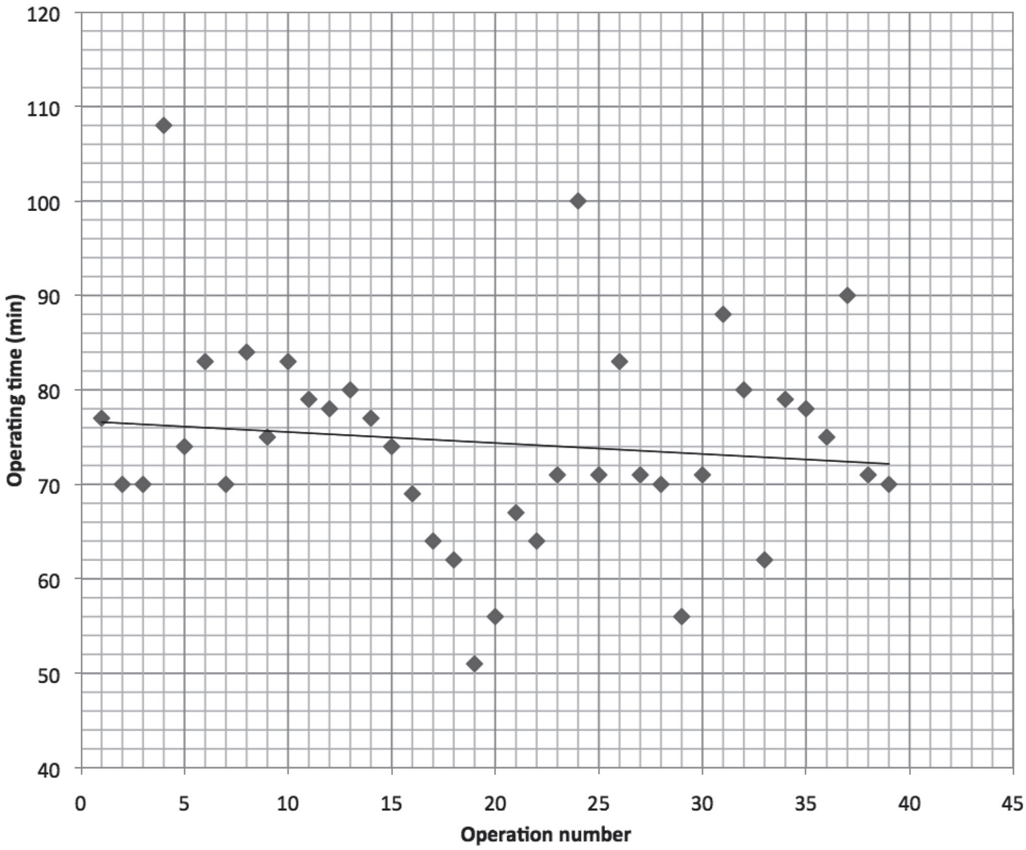

Fig. 1. — Learning curve : operating time with respect to operation number

Further studies are needed to evaluate whether operational or economic benefits may be achieved by adoption of patient matched instrumentation.

REFERENCES

1. **Boonen B, Schotanus MGM, Kort NP.** Preliminary experience with the patient-specific templating total knee arthroplasty. *Acta Orthop* 2012 ; 83 : 387-393.
2. **Colebatch AN, Hart DJ, Zhai G *et al.*** Effective measurement of knee alignment using AP knee radiographs. *Knee* 2009 ; 16 : 42-45.
3. **Conteduca F, Iorio R, Mazza D *et al.*** Are MRI-based, patient matched cutting jigs as accurate as the tibial guides ? *Int Orthop* 2012 ; 36 : 1589-1593.
4. **Kandel L, Vasili C, Kirsh G.** Extramedullary femoral alignment instrumentation reduces blood loss after uncemented total knee arthroplasty. *J Knee Surg* 2006 ; 19 : 256-258.
5. **Lombardi AV Jr, Berend KR, Adams JB.** Patient-specific approach in total knee arthroplasty. *Orthopedics* 2008 ; 31 : 927-930.
6. **Matziolis G, Adam J, Perka C.** Varus malalignment has no influence on clinical outcomes in midterm follow-up after total knee replacement. *Arch Orthop Trauma Surg* 2010 ; 130 : 1487-1491.
7. **National Joint Registry** 8th Annual Report 2011. Surgical data to 31st December 2010. Available from : www.njrcentre.org.uk/NjrCentre/Portals/0/Documents/NJR%208th%20Annual%20Report%202011.pdf.
8. **Noble JW, Moore CA, Liu N.** The value of patient-matched instrumentation in total knee arthroplasty. *J Arthroplasty* 2012 ; 27 : 153-155.
9. **Nunley RM, Ellison BS, Ruh EL *et al.*** Are patient-specific cutting blocks cost-effective for total knee arthroplasty ? *Clin Orthop Relat Res* 2012 ; 470 : 889-894.
10. **Parratte S, Pagnano MW, Trousdale RT, Berry DJ.** Effect of postoperative mechanical axis alignment on the fifteen-year survival of modern, cemented total knee replacements. *J Bone Joint Surg* 2010 ; 92-A : 2143-2149.