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A comparison of short term radiological alignment outcomes of the patient specific and standard instrumentation for primary total knee arthroplasty: A systematic review and meta-analysis

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ABSTRACT

Objective: The aim of this study was to review the radiological alignment outcomes of patient Specific (PS) cutting blocks and Standard Instrumentation in Primary Total Knee Arthroplasty.
Methods: We hypothesized that the use of PS techniques would significantly improve sagittal, coronal and rotational alignment of the prosthesis on short term. We performed a systematic review and a meta-analysis including all the randomised controlled trials (RCT) using PS and standard (ST) total knee arthroplasty to date.
Results: A total of 538 PS TKA and 549 ST TKA were included in the study. Statistical analysis of the outliers for femoral component sagittal, coronal and rotational positioning, tibial component sagittal and coronal positioning and the overall mechanical axis were assessed. We found that there was no significant benefit from using PS instrumentation in primary knee arthroplasty to aid in the positioning of either the tibial or femoral components. Furthermore sagittal plane tibial component positioning was worse in the PS than the traditional ST group.
Conclusion: Our results suggest that at present PS instrumentation is not superior to ST instrumentation in primary total knee arthroplasty.
Level of evidence: Level 1, Systematic review of therapeutic studies.

Introduction

Component alignment is an important aspect of arthroplasty surgery. The correct placement of the implants improves the longevity of the joint.[1] Malalignment of more than 3° in coronal plane after total knee arthroplasty has been found to be associated with increased revision rates and inferior functional scores.[2,3] Patient specific instrumentation is relatively new technique used in total knee arthroplasty. Proponents of this technique suggest that there is lower risk of implant malpositioning and suggest that it a more reliable for accurate component positioning than the standard anatomical referencing techniques. They also suggest this associated with no increase in operative complications.[4–6]

In our study, we hypothesized that there are significant benefits regarding the short term radiological alignment of the both femoral and tibial components using the patient specific instrumentation as opposed to the standard instrumentation. The hypothesis was tested using a meta-analysis of randomised controlled trials comparing the above two techniques for primary TKA.

Materials and methods

A systematic review and meta-analysis was conducted according to guidelines described in the Cochrane handbook for systematic reviews of interventions and PRISMA statement.[7,8]

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Study selection criteria

Types of studies

Only the randomised controlled trials were included in this study.

Types of participants

The participants were adult patients who underwent primary TKA using either a PS or ST instrumentation regardless of the type prosthesis.

Types of interventions

The interventions were PS and ST instrumentations.

Types of outcome measures

The outcome measures were number of mechanical axis, tibial and femoral component outliers in post-operative radiographs or CT scans. Outliers defined as more than 3° deviation from neutral alignment on the sagittal and coronal planes. Furthermore; rotational outliers of the femoral components were also used as an outcome measure.

Exclusion criteria

Studies without randomisation, quazi-randomised studies, animal studies, studies where the above mentioned outcomes were not evaluated and where minimally invasive techniques are utilised are excluded to attempt on reducing the heterogeneity between studies and improve the quality of the meta-analysis.

Search methods for identification of studies

Finding existing systematic reviews and meta-analyses

The following databases were searched in March 2016 to establish whether there has been any previous systematic reviews or meta-analyses comparing PS and ST instrumentation in TKA: Cochrane Database of Systematic Reviews (CDRS), Database of Abstracts of Reviews of Effects (DARE), and Medline (1950 to March 2016).

Finding published and unpublished primary studies

The search terms were used patient specific* and knee replacement, patient specific* and knee arthroplasty, custom fit* and knee arthroplasty, custom fit* and knee replacement, customised* and knee, customized and knee. A MEDLINE search was then refined to find clinical trials and randomised controlled trials (RCTs) in adult humans. The search was extended to other databases, namely EMBASE, the Cochrane Controlled Trials Register, AMED and CINAHL instrumentation and total knee replacement published in any language from 1966 to March 2016. The bibliographies of retrieved trials and other relevant publications were examined for additional articles. The following websites were searched to identify unpublished and ongoing studies: Current Controlled Trials (www.controlled-trials.com); Centre Watch (www.centerwatch.com); Trials Central (www.trialscentral.org); System for Information on Grey Literature in Europe (www.opengrey.eu); The UK National Research Register (www.nihr.ac.uk/Pages/NRRArchive.aspx).

Data collection and analysis

Selection of the studies

Two authors (IA, and AS) applied the search strategy independently and all relevant study abstracts were hand searched by them after which potentially suitable studies were reviewed in full paper format by each of the authors independently. Disagreement was discussed and resolved with the other authors.

Assessment of methodological quality of included studies

The review authors used a modification of the generic evaluation tool used by the Cochrane Bone, Joint and Muscle Trauma Group (Table 1).[9] Two authors (MB and RC) assessed the methodological quality of each study. Disagreement was resolved by discussion with the senior authors. Although the total quality assessment scores (QAS) was reported for each study, it was not used to weight the studies in the meta-analysis.

Data extraction and management

A data extraction form was designed and agreed by the authors. Initially, two authors (MB and RC) extracted the data independently which was later on reviewed jointly to produce agreed accurate data.

Table 1
Quality assessment items and possible scores.

A. Was the assigned treatment adequately concealed prior to allocation?
2 = method did not allow disclosure of assignment
1 = small but possible chance of disclosure of assignment or unclear
0 = quasi-randomised or open list/tables
B. Were the outcomes of participants who withdrew described and included in the analysis (intention to treat)?
2 = withdrawals well described and accounted for in analysis
1 = withdrawals described and analysis not possible
0 = no mention, inadequate mention, or obvious differences and no adjustment
C. Were the outcome assessors blinded to treatment status?
2 = effective action taken to blind assessors
1 = small or moderate chance of unblinding of assessors
0 = not mentioned or not possible
D. Were the treatment and control group comparable at entry? (Likely confounders may be age, partial or total rupture, activity level, acute or chronic injury)
2 = good comparability of groups, or confounding adjusted for in analysis
1 = confounding small; mentioned but not adjusted for
0 = large potential for confounding, or not discussed
E. Were the participants blind to assignment status after allocation?
2 = effective action taken to blind participants
1 = small or moderate chance of unblinding of participants
0 = not possible, or not mentioned (unless double-blind), or possible but not done
F. Were the treatment providers blind to assignment status?
2 = effective action taken to blind treatment providers
1 = small or moderate chance of unblinding of treatment providers
0 = not possible, or not mentioned (unless double-blind), or possible but not done
G. Were care programmes, other than the trial options, identical?
2 = care programmes clearly identical
1 = clear but trivial differences
0 = not mentioned or clear and important differences in care programmes
H. Were the inclusion and exclusion criteria clearly defined?
2 = clearly defined
1 = inadequately defined
0 = not defined
I. Were the interventions clearly defined?
2 = clearly defined interventions are applied with a standardised protocol
1 = clearly defined interventions are applied but the application protocol is not standardised
0 = intervention and/or application protocol are poorly or not defined
J. Were the outcome measures used clearly defined? (by outcome)
2 = clearly defined
1 = inadequately defined
0 = not defined
K. Were diagnostic tests used in outcome assessment clinically useful? (by outcome)
2 = optimal
1 = adequate
0 = not defined, not adequate
L. Was the surveillance active, and of clinically appropriate duration?
2 = active surveillance and appropriate duration
1 = active surveillance, but inadequate duration
0 = surveillance not active or not defined

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