Berstock, J., Murray, J., Whitehouse, M., Blom, A., & Beswick, A. (2018). Medial subvastus versus the medial parapatellar approach for total knee replacement: A systematic review and meta-analysis of randomized controlled trials. *EFORT Open Reviews, 3*(3), 78-84. [170030]. https://doi.org/10.1302/2058-5241.3.170030

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Twenty randomized controlled trials comprising 1893 primary total knee replacements were included in this review.

The subvastus approach conferred superior results for mean difference (MD) in time to regain an active straight leg raise (1.7 days, 95% confidence interval [CI] 1.0 to 2.3), visual analogue score for pain on day one (0.8 points on a scale out of 10, 95% CI 0.2 to 1.4) and total range of knee movement at one week (7°, 95% CI 3.2 to 10.7). The subvastus approach also resulted in fewer lateral releases (odds ratio 0.4, 95% CI 0.2 to 0.7) and less peri-operative blood loss (MD 57 mL, 95% CI 10.5 to 106.4) but prolonged surgical times (MD 9.7 min, 95% CI 3.9 to 15.6).

There was no difference in Knee Society Score at six weeks or one year, or the rate of adverse events including superficial or deep infection, deep vein thrombosis or knee stiffness requiring manipulation under anaesthesia.

This review demonstrates evidence of early post-operative benefits following the subvastus approach with equivalence between approaches thereafter.

Keywords: arthroplasty; surgical approach; knee; meta-analysis; review; replacement

Introduction

Although several surgical approaches to the knee exist, the medial parapatellar approach has been used in 93% of primary total knee replacements (TKRs) performed in England and Wales between 2004 and 2014. This approach requires an incision through the quadriceps tendon, which may impair the extensor mechanism of the knee post-operatively. The subvastus approach was described by Erkes in 1929 and popularized by Hoffman in 1991. It has the theoretical advantage of preserving the quadriceps mechanism with reports suggesting improved post-operative quadriceps muscle strength, conservation of the patellar blood supply, improved patellar tracking, expedited rehabilitation and reduced post-operative pain resulting in shorter hospital stays. The subvastus approach was used in 1% of TKRs in England and Wales between 2004 and 2014.

Randomized controlled trials (RCTs) comparing these two approaches include small numbers of participants and largely fail to demonstrate clinically relevant differences. Previous reviews of this topic have compared the medial parapatellar approach with a combination of the quadriceps sparing approaches (midvastus, mini-midvastus and subvastus together). The aim of this study was to use meta-analytical methods to pool functional outcomes and adverse events from trials of the subvastus and medial parapatellar approaches to TKR exclusively.

Methods

We conducted the systematic review and meta-analysis using methods described in the Cochrane Handbook for Systematic Reviews of Interventions and in accordance with the Preferred Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines. The protocol for this
systematic review is registered and available on the PROSPERO database CRD42014007261.

Search strategy

Electronic searches of MEDLINE, Embase, Scopus, AMED, CAB Abstracts, as well as The Cochrane Library and clinicaltrials.gov trials registry, using the term ‘subvastus’, were conducted on 30 January 2017. The full search strategy as applied in MEDLINE is detailed in Supplementary Table 1. Searches of the reference lists of relevant studies and the Web of Science citation tracking facility were used to identify further studies. Relevant non-English articles were included and translated.

Study selection, data extraction and assessment of risk of bias

All RCTs of adult participants (age > 18 years) undergoing primary TKR surgery, largely for the treatment of osteoarthritis, and comparing the medial parapatellar or the subvastus approach were included. The primary outcome measure was the Knee Society Clinical Rating System (KSS) at six weeks and one year. Secondary outcome measures were duration of surgery, tourniquet time, peri-operative blood loss, post-operative pain, days to regain an active straight leg raise and range of movement (ROM) at one week and one year. In addition, data regarding complications such as the incidence of lateral release, knee stiffness requiring manipulation under anaesthesia, post-operative infection and deep vein thrombosis were also analysed. The following additional information was recorded: study setting; population; participant demographics; follow-up rates and study period (see Supplementary Table 2); study methodology; recruitment; implant type; and rehabilitation protocols (see Supplementary Table 3).

Two authors independently reviewed all the titles and abstracts of studies identified from the literature searches. Full texts of any potentially useful studies were obtained and reviewed in detail. Data regarding the primary and secondary outcomes of interest to this meta-analysis were extracted in duplicate by two authors, using a standardized form.

We contacted the authors of studies to provide additional data including means and standard deviations when these were lacking. We also requested information on outcomes not reported in the publications. The risk of bias for each study was assessed using the Cochrane risk of bias tool (see Supplementary Table 4).15

Meta-analysis

Meta-analysis was performed using RevMan version 5 software if five or more studies reported a particular outcome. We calculated overall summary estimates and 95% confidence intervals (CI) with inverse variance weighted random effects models due to significant heterogeneity with mean differences for continuous variables and Mantel-Haenszel method odds ratios (ORs) for dichotomous and adverse event data. If standard deviations could not be obtained from the authors, they were calculated from p-values or inputted using a mean of the other standard deviations in the meta-analysis. This technique has been validated as an accurate approximation.17 Where only data ranges were reported, the method of Walter and Yao was used to estimate standard deviations.18 Where data were presented graphically, means and standard deviations were estimated from the graph and included. Statistical heterogeneity was characterized with the I² statistic.19

Results

Characteristics of included studies

After screening in duplicate, 20 RCTs published between 1991 and 2016 involving 1893 knee replacements in 1694 patients were included in this review.20-39 The progress of articles through this review is summarized as a flow diagram in Figure 1. The number of study participants ranged from 2022,36 to 231.29 Full details of study characteristics are recorded in Supplementary Table 2, and a summary of the number of participants and length of follow-up in each study is provided in Supplementary Table 5, with the results of meta-analysis summarized in Supplementary Table 6.

Excluded studies

The study by Lai et al,40 which is similar to that of Pan et al,26 has been retracted. Weinrauch et al describe a significant bias in the use of navigation between the groups in their study and therefore it has been excluded.41

Quality assessment and risk of bias

Methodological considerations including standardization of both groups (e.g. with regard to rehabilitation, post-operative analgesia and implant design) are summarized in Supplementary Table 3. The risk of bias within each study has been assessed according to the Cochrane risk of bias tool and is summarized in Supplementary Table 4. Overall, the risk of bias is low; however, several studies used quasi-randomization techniques (e.g. alternate allocation), which introduces bias of indeterminate clinical significance. Random sequence generation was adequately described contributing to a low risk of bias in 11/20 studies. Masking of patients from their treatment allocation was adequate in 9/20, unclear in 8/20 and inadequate in 3/20 studies. Outcome assessors were adequately masked in 12/20, unclear in 7/20 and inadequate in 1/20 studies.

Analysis of heterogeneity

Heterogeneity (I²) was in the range of 0% to 97% for the outcomes reported in this meta-analysis. Examining the
forest plots for highly heterogeneous outcomes (tourniquet time, ROM and days to straight leg raise), there is generally agreement on the direction, but not the size of the effect. We therefore hypothesize that the heterogeneity is most likely due to differences in surgical practices and patient demographics (clinical heterogeneity) rather than statistical heterogeneity.

Analysis of publication bias
Funnel plots were inspected for the primary outcome measure KSS (Fig. 2) and there was no evidence of significant publication bias.

Meta-analysis results
The results of all meta-analyses are summarized in Supplementary Table 6. Eleven studies reported the KSS at six weeks following 1109 TKRs. No significant difference in score between the approaches was observed (mean difference 5.7 points better following subvastus, 95% CI -0.06 to 11.51; p = 0.05) (Fig. 3). At one year post-operatively, six studies report KSS following 740 TKRs and the mean superiority of the subvastus approach was 1.76 points, which was not statistically significant (Fig. 4).

The number of days to regain an active straight leg raise was recorded in nine studies following 811 TKRs. Straight leg raising was regained 1.7 days earlier following the subvastus approach (95% CI 1.04 to 2.33; p < 0.00001) (Fig. 5).

Visual analogue scores for pain on day 1 were recorded in six studies following 512 TKRs. The subvastus approach was associated with a 0.8-point benefit over the medial
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Parapatellar approach on a scale of 0 to 10 (95% CI 0.22 to 1.35; p = 0.006) (Fig. 6).

ROM was 7° better following the subvastus approach at one week in four studies (95% CI 3.21 to 10.73; p < 0.0005) (Supplementary Fig. A), but this difference did not persist at one year (Supplementary Fig. B).

Peri-operative blood loss was reported in 12 studies including 1046 TKRs. The subvastus approach was associated with a statistically significant reduction in peri-operative blood loss by 58 mL (95% CI 10.5 to 106.4; p = 0.02) (Supplementary Fig. C).

Operative times and tourniquet times were both approximately 10 minutes longer following the subvastus approach (Supplementary Figs D and E, respectively); however, only the difference for total operative time reached statistical significance (95% CI 3.88 to 15.57; p = 0.001). These meta-analyses demonstrate significant heterogeneity (I² = 88 and 97%, respectively).
The OR of performing a lateral release was significantly lower following the subvastus approach (OR 0.36; 95% CI 0.19 to 0.68; p = 0.001) (Supplementary Fig. F). No differences in the rates of manipulation under anaesthesia for stiffness, superficial or deep wound infection, or deep vein thrombosis were identified (see Supplementary Figs G, H, I, J).

**Sensitivity and subgroup analysis**

Post hoc sensitivity analyses were performed to attempt to identify sources of bias, reduce or explain heterogeneity, and test the robustness of our findings. A post hoc subgroup analysis, with the removal of trials with a high or unclear risk of sequence generation bias (quasi-randomized studies) did not alter the primary outcome, KSS.

Restricting the meta-analysis for operative time to the four studies, which report previous surgeon experience with the subvastus approach, did not alter the results (MD 10.6 minutes, 95% CI 5.6 to 15.6).

**Discussion**

This systematic review and meta-analysis demonstrates earlier return of straight leg raise, lower visual analogue pain scores on day 1 and improved ROM at seven days following the subvastus approach. Although the 5.7-point benefit in KSS at six weeks following the subvastus approach was not statistically significant (p = 0.05), the minimally important clinical difference for KSS is approximately 11 points.42 No differences between approaches were observed at one year post-operatively and no differences in adverse events were observed.

Compelling evidence for a benefit in time to regain an active straight leg raise following the subvastus approach has emerged. Each of the nine studies reporting time to regain an active straight leg raise suggest a benefit in favour of the subvastus approach. The difference in return of straight leg raise was greater than a day and a half, which we consider clinically significant. Earlier straight leg raising may result in expedited rehabilitation and shorter stays in hospital. The obvious explanation for this is that the quadriceps tendon has been left intact and uninjured; however, some authors also suggest that everting the patella may be detrimental to the quadriceps mechanism. Patella eversion occurs during the medial parapatellar, but not the subvastus approach. Furthermore, fewer lateral releases were required following the subvastus approach, suggesting that leaving vastus medialis obliquus in continuity led to subjectively improved patellar tracking.

Similarly, each of the six studies reporting visual analogue pain score on day 1 suggest a benefit following the subvastus approach. Pain is frequently reported following TKR, and this may be a distressing symptom in the immediate post-operative period, necessitating multimodal anaesthesia and potentially delaying rehabilitation. The improvement in subjective pain scores after TKR has been shown to correlate with patient satisfaction,43 but comparative data on long-term pain scores are not available.

The KSS is a surgeon- and patient-reported outcome measure which relies on an assessment of ROM which contributes to the overall score. Where blinding of the outcome assessor to the treatment allocation did not occur, the use of surgeon-reported outcome measures introduces risk of bias, and therefore interpretation of the pooling of KSS data in these studies must be performed cautiously. In any case, the differences observed were not clinically relevant, therefore equivalence should be assumed.

Operative times were found to be longer with the subvastus approach. The heterogeneity between studies was I² = 88%, suggesting significant variation exists. To investigate the potential effect of a learning curve, we repeated the meta-analysis with the exclusion of studies which did not report prior surgical experience with the subvastus approach. This made no difference to the result of the meta-analysis, strengthening the robustness in the conclusion that the subvastus approach does take longer to perform. It is traditionally considered more challenging to perform and some authors have described technical difficulties everting the patella, limiting exposure of the joint.3 Obesity, which makes surgery more challenging, has been cited as a potential contraindication to performing the
subvastus approach.\textsuperscript{44,45} As a result, the midvastus approach, which may afford easier exposure, is used more commonly than the subvastus in both the UK\textsuperscript{1} and the USA.\textsuperscript{46} However, series of the subvastus approach exist in all scenarios, including morbidly obese patients with body mass index (BMI) > 40 kg/m\textsuperscript{2},\textsuperscript{4,45} patients with significantly valgus knees\textsuperscript{47} and patients with fixed flexion deformities and stiff knees.\textsuperscript{48} Only 7/20 studies in this review excluded patients based on raised BMI. The midvastus approach does not completely spare the quadriceps, negating the theoretical advantage of the subvastus approach.

Our meta-analysis supports the findings of Teng et al from 2012.\textsuperscript{13} We have included 11 additional RCTs and used imputation techniques to estimate variances, making additional data available for analysis. This additional data increases the robustness of our findings. Other meta-analyses have compared the medial parapatellar approach with a combination of quadriceps sparing approaches (midvastus, subvastus and mini-midvastus approaches).\textsuperscript{9,12} The advantage of our review is that we have confined the comparison to that of the subvastus and medial parapatellar approaches alone, facilitating clearer surgical decision-making.

We acknowledge the relatively short-term follow-up presented in the studies included within this meta-analysis. Only 9/20 studies report follow-up data at or beyond one year. Half of the studies (10/20) present follow-up at three months or less. While any early advantages of a particular approach are interesting, those which persist over the longer term are obviously more important. Our meta-analysis includes 1893 TKRs and does not identify a difference in approaches beyond the early post-operative period.

Conclusions

Early post-operative advantages following the subvastus approach (earlier return of active SLR, reduced pain on day 1, reduced blood loss and lower frequency of lateral release) need to be balanced with longer operative times (10 minutes) and the lack of evidence of medium or long-term differences between approaches. The incidence of adverse events between the approaches appears similar. The subvastus and medial parapatellar approaches are both safe alternatives for TKR.

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**ICMJE CONFLICT OF INTEREST STATEMENT**

M. Whitehouse declares grants/grants pending from Healthcare Quality Improvement Partnership; payment for development of educational presentations from Depuy, activities outside the submitted work. A. Blom declares grants/grants pending from Stryker, activity outside the submitted work.

**FUNDING STATEMENT**

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

**LICENCE**

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