
Design: Randomized clinical trial

Study question: When total knee arthroplasty (TKA) is being done, does patellar denervation at the time of the procedure reduce pain and improve patient satisfaction in the postoperative period?

Population/sample size/setting:

- 126 patients (68 women, 58 men, mean age 70) undergoing primary TKA in the orthopedics department of a teaching hospital in the UK
- Eligibility criteria were varus osteoarthritis (OA) with a cruciate retaining knee implant
- Exclusion criteria were valgus deformity, previous trauma or open surgery on the same knee, inflammatory arthropathy affecting the knee, and patellar instability affecting the knee

Interventions:

- All patients were operated on by one of the two senior authors, using a midline incision and a medial parapatellar approach, retaining the cruciate ligament for all implants, and excising osteophytes around the patella
- The surgeons first determined that the patella did not require resurfacing, and then opened a sealed envelope containing a treatment assignment
  - Criteria for patellar resurfacing were abnormal size or shape of the patella, gross patellofemoral mal-tracking, or inflammatory synovitis; these patients were not randomized
  - The distribution of cemented, uncemented, and hybrid implants was the same between the two groups
- Randomization was to either patellar denervation (n=63) or no denervation (n=63)
  - Denervation was done with a monopolar coagulation diathermy set to 50 W
- All patients had the same DVT prophylaxis and postoperative rehab program

Outcomes:

- Outcome measures included patient satisfaction, Oxford Knee Score (OKS), Knee Society Score (KSS), and Knee Society Function Score, patellar score, Activities of Daily Living, (ADL), Visual Analogue Scale, VAS for anterior knee pain, and the UCLA activity scale.
Followup was done at 3 and 12 months for all the outcome measures; Oxford knee scores, VAS, Bartlett patella scores, range of motion, and patient satisfaction were also measured at 24 months.

Patient satisfaction was scored as excellent, good, and poor/fair.
- At 24 months, patient satisfaction in the denervation group was better than for the control group.
  - In the denervation group, 47 were excellent, 9 were good, and 5 were poor/fair.
  - In the control group, 32 were excellent, 15 were good, and 11 were poor/fair.

Flexion at the 24 month followup was greater in the denervation group (103.6°) than in the control group (99.2°).

VAS for anterior knee pain was better in the denervation group at 3 months but not at 12 or 24 months.
- The VAS was 4.5 for the denervation group and 5.1 for the control group.
- The anterior knee pain subscale of the Patellar (Bartlett) score is ranked as severe, moderate, mild or none.
  - For the denervation group at 3 months, 0 were severe, 22 were moderate, 30 were mild, and 11 had no pain.
  - For the control group at 3 months, 0 were severe, 30 were moderate, 31 were mild, and 2 had no pain.
  - For the denervation group at 24 months, 0 were severe, 15 were moderate, 38 were mild, and 8 had no pain.
  - For the control group at 24 months, 0 were severe, 14 were moderate, 37 were mild, and 7 had no pain.

There were no differences in the Oxford score, KSS scores, ADL scores, or UCLA scores during followup.

Authors’ conclusions:

- Patients undergoing primary TKA who did not require patellar resurfacing but who had circumferential denervation of the patella had better relief of anterior knee pain at 3 months than the group with no denervation.
- Although the pain differences were not observed at 12 and 24 months, patient satisfaction at 24 months was greater in the denervation group, and pain relief earlier in the postoperative period could account for that difference.
- Flexion range of motion was also greater in the denervation group at 24 months than in the no denervation group.

Comments:
- The first followup pain scores were recorded at 3 months, but much postoperative pain is likely to be present in the early days and weeks following major surgery.
- The VAS pain score difference at 3 months appears to be small (4.5 for the denervation group and 5.1 for the control group), a difference of 0.6 points, which would usually be considered to be less than the minimal clinically important difference.
- However, the recorded scores at various time points represent current pain, and since the trend over time is toward equalization of pain scores, the three month scores may have been recorded when that equalization was in progress, and data on earlier time points is missing.
- A more informative analysis would have recorded pain scores at numerous times prior to three months, and an analysis could have been carried out comparing the area under the pain curves for the two groups; this would give a representation of the cumulative discomfort during the time when pain is likely to be at its greatest, and the patients’ memories of that early discomfort could affect the satisfaction scores later.
- The analysis is therefore at risk of underestimating the treatment effect of the intervention.
- In other respects, the study design is well-suited to control some threats to internal validity; the fact that randomization was revealed by sealed envelopes in the operating room guarantees concealment of allocation and also eliminates crossovers from assigned treatment to treatment received; the fact that patients and outcome assessors were blinded protects the results from assessment bias; the fact that all procedures involved cruciate retaining implants protects from potential co-intervention bias.
- The study therefore appears to report an unbiased treatment effect which is likely to underestimate the postoperative pain relief from patellar denervation.

Assessment: High quality study supporting good evidence that in patients undergoing primary TKA and who do not have patellar resurfacing, circumferential denervation of the patella during the operation can reduce pain postoperatively and improve patient satisfaction two years later.