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Patella Denervation in Primary Total Knee Arthroplasty – A Randomized Controlled Trial with 2 Years of Follow-Up

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ABSTRACT

We randomized 126 consecutive patients undergoing primary total knee arthroplasty into group 1: patella denervation (n = 63) and group 2: no patella denervation (n = 63). Assessment was performed preoperatively and at 3, 12 and 24 months post-operatively. Average follow-up of patients was 26.5 months for denervation group and 26.3 months for no denervation group ($P = 0.84$). Pain scores for anterior knee pain were significantly better in the denervation group at 3 months but not at 12 and 24 months. Patient satisfaction was higher in the denervation group. Flexion range was higher in the denervation group at 3, 12 and 24 months review ($P < 0.01$). There were, however, no statistically significant differences with other validated knee scores.

Knee arthroplasty for primary osteoarthritis has been proven to provide excellent pain relief and improved postoperative function. However, not all primary knee arthroplasty operations are judged as successful by the patient with up to 20% not being satisfied with the outcome following surgery [1,2]. Residual pain in the replaced knee, especially anterior knee pain, has been well known to both patients and surgeons alike, but the reasons for this are not always apparent. The optimal treatment of the patella during primary total knee arthroplasty (TKA) is not clear. Resurfacing of patella has been extensively studied with numerous studies showing conflicting results [3–6]. Furthermore, it is associated with complications such as wear of the patellar polyethylene, loosening of the patellar component, patellar fracture, and rupture of the patellar tendon that lead to difficulty in revision operations at a later stage.

The patella is innervated by multiple superficial sensory nerves, including the medial cutaneous nerve of the thigh, the lateral femoral cutaneous nerve, the medial and lateral retinacular nerves, and the anterior femoral cutaneous nerve [7,8]. The presence of substance-P fibers, Ruffini and Pacinian corpuscles is documented, although their exact role is uncertain; it may include pain/pressure reception, and possibly proprioception. This provides an argument for patellar retention.

Surgeons across the world differ in their practice, with some surgeons performing denervation of patella routinely in all cases of knee arthroplasty and others performing the procedure when the patellofemoral joint is found to be worn at the time of operation. There is yet another group of surgeons who do not believe in this procedure and hence never carry out denervation of patella during knee arthroplasty.

Between April 2009 and June 2010, we conducted a randomized control trial at our institution with an aim to provide level I evidence of the effect of concomitant circumpatellar denervation during primary knee arthroplasties for primary osteoarthritis. We designed this as a randomized non-inferiority study with a null hypothesis that there is no difference in the outcome between two groups.

Material and Methods

We sought statistical advice regarding the design and sample size needed for the study.

The criterion for the sample size was its adequacy to estimate parameters for a subsequent hypothesis-testing trial. We used the Oxford knee score for sample calculation and we estimated that with n = 55 per group, a two-sided 95% confidence interval for the difference between treatments would extend +/− 1.5 U from the observed mean if the standard deviation was 4.0.

All patients provided informed consent, and all the information was kept confidential. The study was approved by regional ethical committee.

We randomized 126 patients undergoing primary TKA for primary osteoarthrosis under the care of two senior authors (VVR, GJM) into two groups: Group 1 – denervation group (n = 63), Group 2 – no denervation group (n = 63). All patients had varus osteoarthrosis and had a cruciate retaining implant. Patients with valgus deformity,

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previous trauma or open surgery on the same knee, inflammatory arthropathy affecting the knee, patellar instability affecting the knee were excluded from the study. During surgery, randomization using sealed envelopes was carried out once the surgeon was satisfied that the patella did not require resurfacing. Our criteria for patellar resurfacing included: abnormal size or shape of patella, gross patello-femoral mal-tracking, crystalline or inflammatory synovitis noted during operation. The randomization was done using computer generated numbers, which were then enclosed in sealed envelopes. All the operations were performed by two senior authors (VVR and GJM) or under their direct supervision. Patients and assessors were blinded with regards to denervation status for the duration of study. Assessment was performed preoperatively, 3, 12 and 24 months postoperatively by three independent experienced practitioners by means of questionnaires and physical assessment. Outcome measures included patient satisfaction, Oxford Knee Score, OKS [9], Knee Society Score, KSS, and Knee Society Function Score [10], patellar score [11], Activities of Daily Living, ADL score [12], Visual Analogue Scale, VAS [13], for anterior knee pain and University of California and Los Angeles, UCLA [14], activity scale. Routine demographic data including age, gender, side of surgery, duration of symptoms prior to surgery and body mass index (BMI) were recorded preoperatively. The demographics of the study patients have been provided in the Table 1. The implants used were NexGen cruciate retaining in all cases of which 86 (68%) implants were cemented, 37 (29%) were uncemented, 3 (2.4%) were hybrid (Fig. 1).

The surgical technique was standardized in all cases with a midline incision and medial parapatellar approach. Cruciate retaining implants were used in all cases. Patellar tracking was then checked with 'no thumb test' both on trial implants as well as after seating of definitive implants. Once the definitive femoral and tibial components were seated in with appropriate polyethylene insert, excision of osteophytes around the patella was carried out. The denervation of the patella using a monopolar coagulation diathermy set to 50 W was carried out in the denervation group (Valleylab Inc., Boulder, CO). Prophylaxis for deep vein thrombosis (DVT) included low molecular weight heparin injection until the patients were fully mobile and discharged from ward. All patients had the same postoperative physiotherapy protocol. One non-weight bearing radiograph of knee, anteroposterior (AP) and lateral, was carried out before discharge and further radiographs were performed at 3 months and 1 year post op. Study follow-up with clinical and radiological assessment using VAS pain scores, Oxford scores, Knee Society Score (KSS) and Knee Society Function score, patellar score, Activities of Daily Living score (ADL) and The University of California and Los Angeles (UCLA) score was carried out by one of the three independent trained arthroplasty nurse practitioners. This was carried out preoperatively, 3 and 12 months postoperatively for the all the outcome measures. Oxford knee score, VAS pain score, Bartlett patella score, flexion range and patient satisfaction were assessed at 24 months of follow-up. We carried out sensitivity analyses taking into account the base line, preoperative values. Even though this is not necessarily a better analysis, we felt that it is vital to check the limits of the 95% confidence intervals for the unadjusted (t-tests) and adjusted (analysis of variance) analyses to see whether they contain any clinically important values. Therefore both analyses were carried out i.e., t-tests and also analysis of covariance adjusting for the baseline values of the outcome of interest.

Table 1
Patient characteristics and follow-up.

Profile	Group 1 Denervation n = 63 Mean (SD, SE)	Group 2 No Denervation n = 63 Mean (SD, SE)	*P* value
Age in years	69.9 (8.6, 1.1)	69.8 (8.1, 1.0)	0.96
Female:male	32:31	36:27	0.29
Body mass index (BMI)	29.1 (4.3, 0.55)	29.3 (3.5, 0.44)	0.80
Mean preop duration of symptoms (months)	19.1 (12.48, 1.6)	17.8 (11.7, 1.5)	0.56
Mean duration of follow-up (months)	26.49 (4.09, 0.52)	26.33 (4.83, 0.61)	0.84

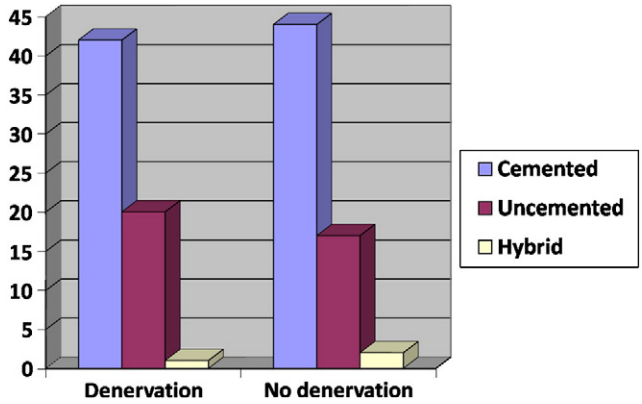

Fig. 1. Implants used (Nex Gen, cruciate retaining, Zimmer corporation). chi-Square test $P = 0.72$.

Results

The demographics and preoperative scores were analyzed and there were no statistically significant differences between groups. The average follow-up of patients was 26.5 months for denervation group and 26.3 months for no denervation group ($P = 0.84$) (Table 1). One patient in the no denervation group was unwilling to continue in the study after 3 months of follow-up for personal reasons. One patient in the denervation group and two patients in the no denervation group died during the second year of follow-up due to reasons unrelated to knee arthroplasty. Two patients in the no denervation group underwent revision of femoral implants for early aseptic loosening. One patient in the denervation group was revised for periprosthetic fracture of the tibia following an injury. All the revisions were carried out during the second year of follow-up. The number of patients assessed at 24 months was therefore 61 in the denervation group and 58 in the no denervation group.

Patient satisfaction was measured as excellent, good, fair or poor. The patient satisfaction was higher with more number of patients rating the procedure as excellent in the denervation group (chi square 8.1, $P < 0.05$), Fig. 2. Flexion at the latest follow-up was higher in the denervation group (t-test, $P = 0.01$), Table 2. The anterior knee pain

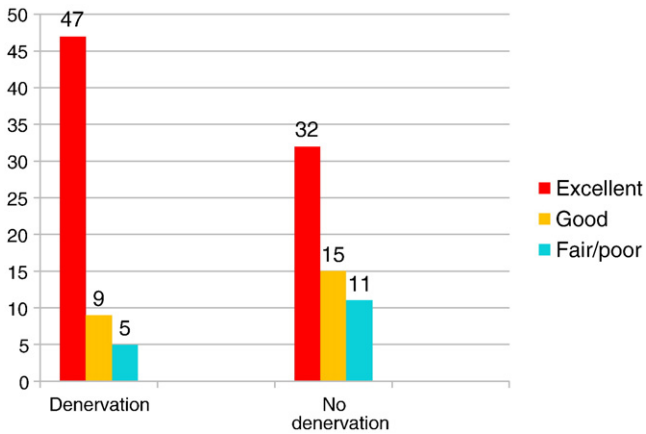

Fig. 2. Patient satisfaction at 24 months post op (chi-Square test 8.1, $P < 0.05$).