A Randomized Controlled Trial Evaluating Functional and Clinical Outcomes and Pain Scores Following Patellar Denervation in Total Knee Replacement Surgery

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Abstract

B*ackground:* Total Knee Replacement is the treatment of choice of end-stage knee osteoarthritis. Anterior knee pain (AKP) after TKR could negatively affect patient satisfaction and knee function. AKP has been reported in 4% to 49% of patients undergoing primary TKR with no patellar resurfacing, so this study aimed to evaluate the functional and clinical outcomes and pain scores after patellar denervation in total knee replacement surgery. *Aim:* is to evaluate the functional and clinical outcomes and pain scores after patellar denervation in total knee replacement surgery at the department of Orthopedic Surgery and Trauma, Suez Canal University Hospital, Ismailia, Egypt. *Subjects/Materials:* this study included 24 patients divided into 2 groups (PD group and NPD group) who met specific inclusion criteria and data collection involved preoperative assessment, operative measures, post operative care and follow up. Methods: The study was Prospective Randomized controlled study which evaluated functional and clinical outcomes and pain scores following patellar denervation in total knee replacement surgery. *Results:* The PD group consistently has higher OKS scores compared to the non-PD group at all follow-ups. The PD group also showed significantly better outcomes in WOMAC scores at all follow-ups compared to the non-PD group.
The PD group exhibited significantly higher Patellar Scores (PS) compared to the non-PD group at 3 months follow-up. *Conclusion:* Patellar denervation appears to be a valuable adjunct to total knee replacement, providing better functional and clinical outcomes and less pain compared to non-denervation approaches.

Keywords: Total knee arthroplasty, patellar denervation, WOMAC, OKS.

Introduction:

Significant efforts have been undertaken to minimize anterior knee pain after total knee replacement surgery, leading to the development of methods such as circumferential patellar denervation using electrocautery (PD), patellar resurfacing, and excision of the infrapatellar fat pad. PD is a commonly employed technique in both patellar resurfacing and non-resurfacing total knee replacements. [1]

In theory, patellar denervation with electrocautery may help decrease the occurrence of anterior knee pain by interrupting superficial sensory nerves surrounding the patella, potentially enhancing knee movement and thereby alleviating pain in the anterior knee region. Nevertheless, the precise impact of PD on the frequency and intensity of anterior knee pain following total knee arthroplasty remains a topic of discussion. [2]

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Several randomized controlled trials (RCTs) have been conducted on the impact of patellar denervation (PD), yielding mixed findings. Therefore, the main goal of this study is to assess the functional and clinical outcomes, as well as pain levels following patellar denervation in total knee replacement surgery.[3]

By analyzing the postoperative results of both groups, we intend to evaluate the effectiveness of this technique and its possible benefits compared to the control group.

Patients and Methods:

The study was conducted as Prospective Randomized controlled study level III at the department of Orthopedic Surgery and Trauma, Suez Canal University Hospital (SCUH) after approval from the institutional research board (approval #5355).

The study was conducted on 26 patients with severe knee osteoarthritis presented to Orthopedic surgery outpatient clinic and were prepared for total knee replacement surgery.

Patients were divided into two groups and there was one case dropped out from each group leaving 12 patients per group. All of them met the criteria of inclusion.; patients with severe primary knee osteoarthritis scheduled to undergo total knee replacement surgery of Age above 45 years old. The exclusion criteria included patients with prior major surgery on the same knee, peripheral neuropathy, patellar instability and history of patellar fracture or dislocation without operation.

The sample size was calculated and after adding 10% to compensate for non-responders, n= 13 patients per group.[3]

Data collection:

The data collected in this study involved a comprehensive assessment of patients having TKR. The study followed ethical standards and obtained informed consent from all participants before any procedures were performed. The data collection process included pre-operative assessment, patient preparation, operative measures, postoperative care, and follow-up evaluations.

Pre-operative Assessment:

All patients included in the study were evaluated through: Complete history taking including: personal history, history of chronic diseases, history of previous operations, medications.

General examination, local knee examination, limb length discrepancy and limb deformities.

Assessment of knee scores including: (OKS, WOMAC index, VAS, ROM and FPS).

Imaging included Bilateral knee x-rays (anteroposterior standing and lateral views) and Whole length both lower limbs x-ray was conducted as a part of the investigations.

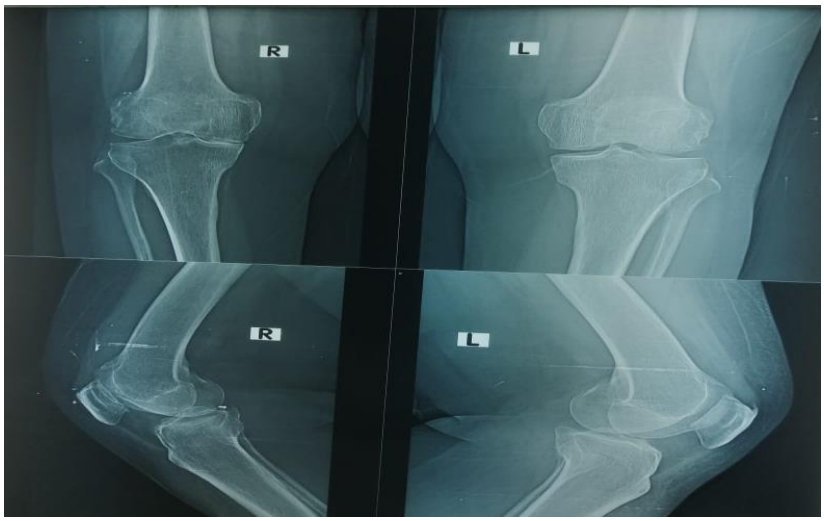

Figure 1: preoperative x-rays of both knees (anteroposterior in standing position and lateral views).

Operative measures:

Type of implant:

Zimmer Nex gen cemented prosthesis either standard or long stem

Surgical Technique:

Patients were placed supine on the operative table; a general or spinal anesthetic was administered with the use of tourniquet above the knee.

A standard midline incision with a medial parapatellar approach was used.

The infrapatellar fat pad , medial and lateral meniscus, as well as ACL, were excised.

Patellar denervation in semi-circumferential manner was performed by electrocautry to a depth of 2 to 3 mm around the patella after removal of all patellar osteophytes at the end of the procedure according to the group.

Steps:

The femoral cuts were performed in 5 to 7 degrees of valgus with approximately 9 to 10mm of bony resection distally.

The tibial cuts were then performed perpendicular to the tibial axis

Proximal tibial cut was performed, and structures were released until a neutral alignment, and symmetric extension gap was achieved, then the femoral component was inserted followed by the tibial component.

The same steps were then performed with the knee at 90 degrees flexion. A rectangular flexion gap equal to the extension gap is desired. then posterior femoral condyle cuts were performed.

Patellar denervation was done at the end of the procedure according to the group then wound closure

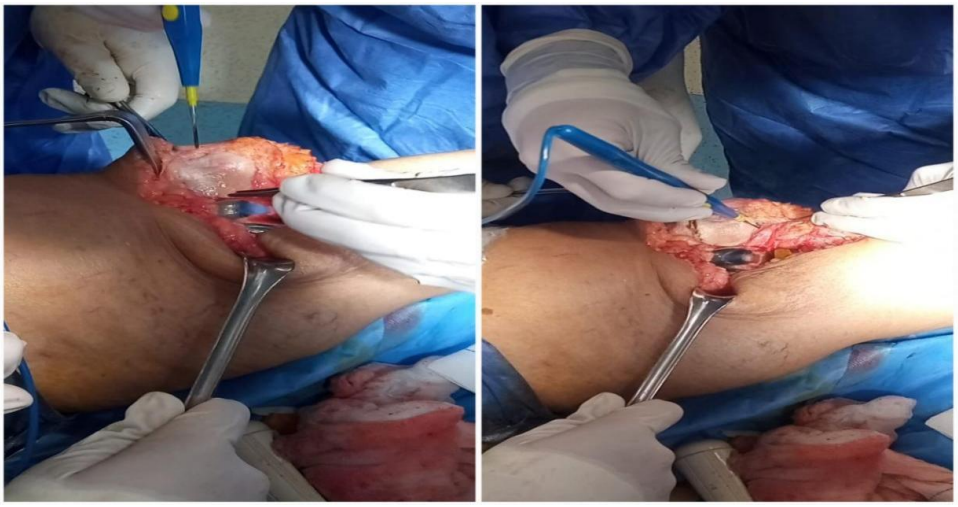

Figure 2: patellar denervation electrocautary procedure.

Post-operative care and follow up:

All patients received the same post-operative medical treatment with antithrombotic prophylaxis for five weeks with oral anticoagulant (Rivaroxaban 10 mg) according to an integrated pathway protocol and began weight bearing post operative using 4 wheeled walker.

Patients were discharged from hospital when their drains showed no or minimal blood collection.

Patients were then followed up postoperatively at 2 weeks, 6 weeks, 3 months then at 6 months with reassessment of knee scores, pain scores and range of motion throughout all follow up intervals.

Statistical analysis

Data was fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM

Corp) Qualitative data were described using number and percentage. The Kolmogorov-Smirnov test // Shapiro-Wilk test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation, median and interquartile range (IQR). The significance of the obtained results was judged at the 5% level.

Results:

Demographic data

The mean age for the NPD group was 62.17 ± 7.35 years, while the mean age for the PD group was slightly lower (59.42 ± 7.83 years). The p-value of 0.385 indicates that the difference in age between the two groups is not statistically significant, suggesting that age was relatively similar across both groups.

In the NPD group, 41.7% were males and 58.3% were females. In contrast, the PD group had a lower percentage of males (16.7%) and a higher percentage of females (83.3%).

About 33.3% of the non-PD group and 58.3% of the PD group had HTN. 8.3% of the non-PD group and 16.7% of the PD group had DM. 8.3% of the PD group (one case) had familial mediterranean fever (FMF) and 8.3% of the PD group had chronic liver disease (CLD). 8.3% of the PD group had lupus erythematosus (SLE) (one case) and 26.5% of the PD group had rheumatoid arthritis RA (Table 1)

Table (1): Comparison between the two studied groups regarding demographic data

	Non - PD (n = 12)	PD (n = 12)
Age (years)	62.17 ± 7.35	59.42 ± 7.83
Sex		
Male	5 (41.7%)	2 (16.7%)
Female	7 (58.3%)	10 (83.3%)
Chronic illness		
HTN	4	7
DM	1	2
FMF	0	1
CLD	0	1
SLE	0	1
RA	0	3

HTN: Hypertension, FMF: Familial Mediterranean fever, DM: Diabetes Mellitus, CLD: Chronic Liver Disease, RA: Rheumatoid Arthritis, SLE: systemic lupus erythematosus

The oxford knee score (OKS) among the two studied groups

Pre-operatively, the PD group had a higher mean OKS (11.50) compared to the non-PD group (10.50), with a significant difference (p = 0.013*). This suggests that the PD group reported better knee function.

Six weeks post operatively, the mean OKS for the PD group (26.42) was higher than that for the non-PD group (24.33), but the difference was not statistically significant (p = 0.085).

Three months post operatively; the PD group had a significantly higher mean OKS (34.42) compared to the non-PD

group (29.67) with a p-value of 0.008*. This indicates a meaningful improvement in knee function for the PD group.

Six months post operatively, the PD group continued to show significantly better knee function with a higher mean OKS (39.50) compared to the non-PD group (33.08), with a p-value of <0.001*. This highlights a substantial and statistically significant difference in knee function.

The PD group consistently has higher OKS scores compared to the non-PD group at all follow-up points. Significant differences are observed in 3-month, and 6-month follow-up periods, suggesting better knee function outcomes for the PD group over time. (Figure 3)

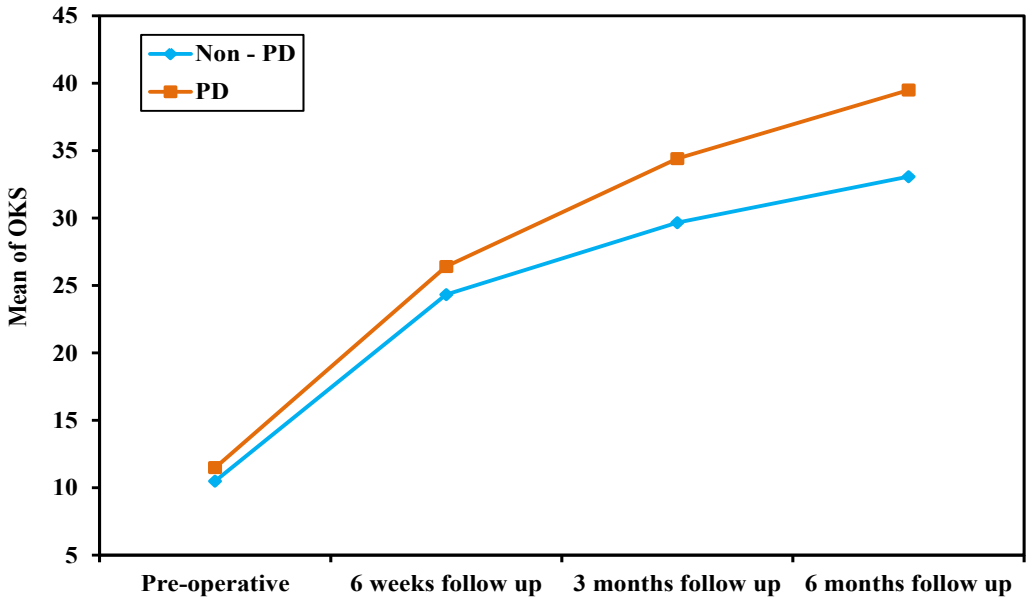

Figure 3: Comparison between the different studied periods according to OKS.

Western Ontario McMaster universities Osteoarthritis Index (WOMAC)

Preoperatively, there was no significant difference in WOMAC scores between the Non-PD and PD groups (p = 0.887).

Six weeks post operatively, the non-PD group had a significantly higher WOMAC score (23.58) compared to the PD group (24.08), with a p-value of 0.033*, indicating worse symptoms for the non-PD group.

Three months post operatively, the non-PD group had a higher WOMAC score (19.58) compared to the PD group (17.25), with a p-value of 0.028*, suggesting more severe symptoms in the non-PD group.

Six months post operatively, the non-PD group had a higher WOMAC score (17.42) compared to the PD group (11.42), with a p-value of 0.045*, indicating that the PD group experienced significantly fewer symptoms at Overall, the PD group showed significantly better outcomes in WOMAC scores at 6 weeks, 3 months, and 6 months follow-ups compared to the non-PD group, with improvements becoming more pronounced over time. (Figure 4)

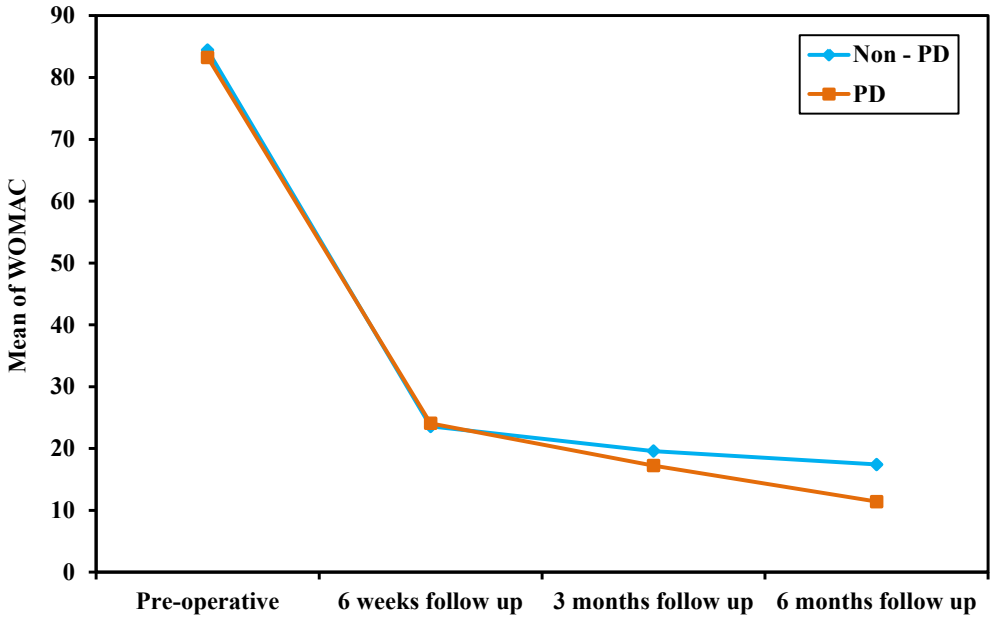

Figure 4: Comparison between the different periods studied according to WOMAC. The visual analogue score (VAS) among the two studied groups

Preoperatively, there was no significant difference in VAS scores between the Non-PD and PD groups (p = 0.443).

Six weeks post operatively, the non-PD group had a higher VAS score (3.25) compared to the PD group (2.67), but this difference is not statistically significant (p = 0.101).

Three months post operatively, the non-PD group had a significantly higher VAS score (2.50) compared to the PD group (1.25) with a p-value of 0.008*, indicating better pain control in the PD group.

Six months post-operatively, the non-PD group had a significantly higher VAS score (2.25) compared to the PD group (0.83) with a p-value of 0.007*, reflecting a significant improvement in pain levels in the PD group.

Overall, the PD group shows significantly lower VAS scores, indicating less pain at the 3 months and 6 months follow-ups compared to the non-PD group, with significant improvements in pain control over time. There is a statistically significant decrease in VAS score in both groups during follow-up as shown in (figure 5).

the Patellar score (PS) among the two studied groups

Pre-operatively, in the non-PD group the PS scores ranged from 6.0 to 13.0, with a mean of 7.58 ± 1.98 and a median of 8.0 (IQR: 6.0 – 8.0), on the other hand in the PD group the Scores ranged from 6.0 to 12.0, with a mean of 9.42 ± 1.93 and a median of 9.50 (IQR: 8.0 – 11.0). This indicates that the PD group had higher pre-operative Patellar Scores compared to the Non-PD group.

Six weeks post operatively, in the non-PD group the Scores ranged from 16.0 to 21.0, with a mean of 20.17 ± 1.40 and a median of 20.50 (IQR: 20.0 – 21.0) while in the PD group the Scores ranged from 15.0 to 24.0, with a mean of 21.67 ± 2.96 and a median of 23.0 (IQR: 22.0 – 23.0) . The t-test showed no significant difference (t = 1.584, p = 0.127) in Patellar Scores between the two groups.

Three months postoperatively, there was a significant difference (t = 2.276, p = 0.033), showing that the PD group had higher Patellar Scores compared to the non-PD group but there was no significant difference in Patellar Scores

between the two groups at 6 months (t = 1.565, p = 0.132) .

Overall, The PD group exhibited significantly higher Patellar Scores compared to the non-PD group pre-operatively and at 3 months follow-up. However, there were no significant differences between the two groups at the 6 weeks and 6 months follow-up. (table 2)

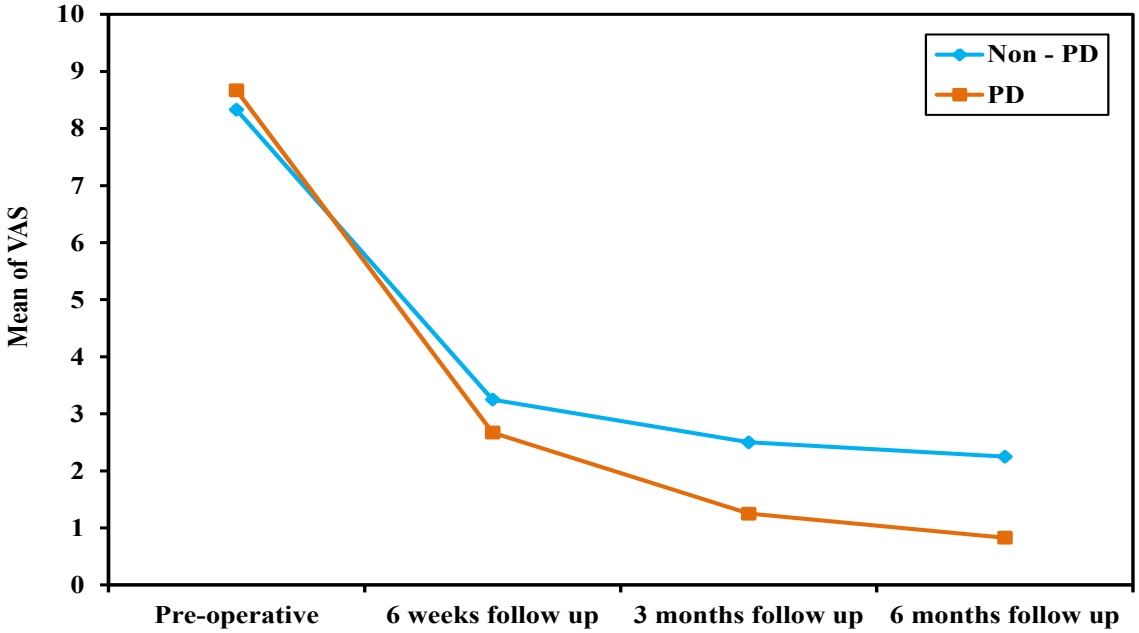

Figure 5: Comparison between the different studied periods according to VAS

Table 2: Comparison of Patellar Scores (PS) Between Non-PD and PD Groups

PS	Non-PD (n = 12)	PD (n = 12)	t	P
Pre-operative				
Mean ± SD.	7.58 ± 1.98	9.42 ± 1.93	2.300*	0.031*
Median (IQR)	8.0(6.0 – 8.0)	9.50(8.0 – 11.0)		
6 weeks follow up				
Mean ± SD.	20.17 ± 1.40	21.67 ± 2.96	1.584	0.127
Median (IQR)	20.50(20.0 – 21.0)	23.0(22.0 – 23.0)		
3 months follow up				
Mean ± SD.	22.42 ± 2.19	24.33 ± 1.92	2.276*	0.033*
Median (IQR)	22.50(21.5 – 24.0)	25.0(22.5 – 25.5)		
6 months follow up				
Mean ± SD.	24.75 ± 3.49	26.83 ± 3.01	1.565	0.132
Median (IQR)	25.0(23.0 – 27.5)	27.0(24.0 – 30.0)		

IQR: Inter quartile range SD: Standard deviation t: Student t-test
P2: p value for comparing between the two studied groups
**: Statistically significant at p ≤ 0.05*

Regarding range of motion (ROM)

Pre-operatively, in the non-PD group (n = 12): Flexion ranged from 80.0 to 95.0 degrees with a mean of 84.17 ± 5.57 and extension ranged from 0.0 to 10.0 degrees with a mean of 4.83 ± 3.49. While in the PD Group (n = 12): Flexion ranged from 75.0 to 95.0 degrees with a mean of 87.92 ± 6.56 and extension ranged from 0.0 to 10.0 degrees with a mean of 5.0 ± 3.02.

Table (3): Comparison between the two studied groups according to Extension lag						
Extension-lag	Non - PD (n = 12)		PD (n = 12)		Test of Sig.	p
	No.	%	No.	%		
6 weeks follow up						
No extension lag	11	91.7	10	83.3	χ^2= 0.381	^{FE}p= 0.53
Extension lag	1	8.3	2	16.7		
3 months follow up						
No extension lag	11	91.7	10	83.3	χ^2= 0.381	^{FE}p= 0.53
Extension lag	1	8.3	2	16.7		
6 months follow up						
No extension lag	11	91.7	10	83.3	χ^2= 0.381	^{FE}p= 0.53
Extension lag	1	8.3	2	16.7		
χ2: Chi square test FE: Fisher Exact Test p: p value for comparing between the two studied groups						

Regarding the incidence of extension-lag post operatively among the two studied groups

There were no significant differences in the distribution of extension-lag incidence between the Non-PD and PD groups across all follow-up periods (6 weeks, 3 months, and 6 months).

Discussion:

Regarding the demographic data in our study, we found that the mean age of the Non-PD group was 62.17 ± 7.35 years, compared to a slightly lower mean age of 59.42 ± 7.83 years in the PD group. Regarding sex distribution, 41.7% of the Non-PD group were males and 58.3% were females. Conversely, the PD group had a lower proportion of males (16.7%) and a higher proportion of females (83.3%). The demographic data showed no statistically significant differences between the two groups regarding age and gender.

In our results, the Oxford Knee Score (OKS) was compared across different time periods for both the Non-PD and PD groups. When comparing both groups, there was a statistically significant improvement in OKS across all follow-up periods compared to pre-operative scores. The PD group consistently achieved higher scores compared to the Non-PD group at all-time points, with both groups showing significant improvement over time.

In a meta-analysis study, Fan et al., (2015) their results concluded that circumferential electrocautery of the patella markedly improves patients' knee function (OKS). but not AKP compared with non electrocautery methods [4]

In contrast with our results, Pulavarti et al., (2014) they found that there were no statistically significant differences in Oxford knee scores during the follow-up duration.[7]

Also, contrary to our results, Thiengwittayaporn et al., (2021) they reported that the Oxford knee score was not significantly different between the two groups during the follow-up duration. [3]

Our findings revealed a comparison of the Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) scores between the Non-PD and PD groups at various time points. The scores indicated a steady decline over time, with the most notable

improvement observed at 6-month follow-up. In contrast, both groups showed significant improvements in WOMAC scores throughout the timeline, with considerable decreases at 6 weeks, 3 months, and 6 months.

Overall, although both groups experienced positive changes from the interventions, the PD group exhibited superior functional outcomes at all follow-up points when compared to the non-PD group.

In consistent with our findings, Van Jonbergen et al., (2011) the authors also reported better overall WOMAC scores in the intervention group compared with the control group . Further examination of the individual components of the WOMAC score indicated that the intervention group had a statistically superior average score on the WOMAC Function subscale. Nevertheless, there were no statistically significant differences found between the intervention and control groups regarding the average scores for the WOMAC pain or stiffness subscales.(5)

In a meta-analysis study, Fan et al., (2015) evaluated data from six articles, including 776 cases: 388 cases involved PD, and 388 cases were addressed as the control group. The results indicate that circumferential electrocautery of the patella significantly improves patients' knee function (WOMAC Score), but not AKP compared with non-electrocautery methods.(4)

Furthermore, our findings were aligning with, Alomran et al. (2015) conducted a study to assess the clinical impact of circumpatellar electrocautery on patients undergoing non-resurfaced total knee arthroplasty. They discovered that there was a statistically significant difference in the improvement of WOMAC scores between the denervation group and the non-denervation group. (6)

In the current study, a comparison of Visual Analog Scale (VAS) scores across different periods revealed significant reductions in pain levels from the pre-operative to follow-up periods in both groups. The PD group experienced a greater reduction in pain scores compared to the non-PD group across all follow-up intervals.

In addition, a comparison of Patellar Scores (PS) across different periods for both the Non-PD and PD groups revealed that both the Non-PD and PD groups experienced significant changes in Patellar Scores over time, with improvements noted at 6 weeks, 3 months, and 6 months follow-up compared to pre-operative scores. The changes were statistically significant across all periods for both groups.

In concordance with our study, Pulavarti et al., (2014) They found that the anterior knee pain component of the patellar score and the Visual Analogue Scale (VAS) for anterior knee pain were significantly improved in the denervation group at 3 months but not at 12 or 24 months. (7)

In a meta-analysis study analyzed seven randomized controlled trials involving 983 cases and found that PD can significantly reduce AKP occurrence and enhance early clinical outcomes, including patellar score, and knee ROM for the first 12 months of follow-up after TKA. Despite, after 12 months of follow-up, this advantage seems to disappear.(8)

Although, Thiengwittayaporn et al., (2021) demonstrated that PD patients had considerably greater pain relief at 3 months after surgery, but the differences between groups in the intensity of AKP at later time points during the follow-up period were not statistically significant. During the follow-up period, there was no significant difference in patellar score or VAS for total knee pain between the two groups. (3)

In our study when comparing the range of motion (ROM) between the Non-PD and PD groups, no significant differences in flexion or extension were seen at any time point. However, flexion increased significantly among both groups. Furthermore, no significant differences were found in the incidence and degree of extension-lag between the Non-PD and PD groups during all follow-up periods.

In accordance with our study, Pulavarti et al. (2014) discovered that the denervation group had higher patient satisfaction, with a greater number of patients rating the surgery as excellent. Flexion at the most recent follow-up was higher in the denervation group. At 24 months, the denervation group obtained a considerably greater range of flexion than the non-denervation group. [7]

Similarly, our results were consistent with Thiengwittayaporn et al., (2021) who demonstrated that patient satisfaction scores were significantly better in the PD group at 3 months but not at the later time points. The ROM was not significantly different between the two groups during the follow-up period. [3]

In a meta-analysis study demonstrated that PD can significantly reduce AKP incidence and improve early clinical outcomes, including knee ROM for the first 12 months of follow-up after TKA. However, after 12 months of follow-up, this advantage seems to disappear. [8]

In our study comparing the two groups for complications, the analysis reveals no statistically significant differences between the Non-PD and PD groups in the occurrence of intra-operative complications, infection, stiffness, or heterotopic ossification. Additionally, there were no cases of device failure, instability, or revision in either group.

In accordance with our study, Alomran et al., (2015) they demonstrated that no deep infection, complication or revision performed in any of the cases. Two patients in the denervation group and one patient in non-denervation group needed manipulation under anesthesia at six weeks because of limited range of motion. [6]

Conclusion:

We found that patellar denervation appears to be a valuable adjunct to total knee replacement, providing better functional and clinical outcomes and pain decrease compared to non-denervation approaches, without increasing the risk of complications.

Availability of data or materials:

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Conflict Of Interest

The authors declare no potential conflict of interest with respect to the research, authorship, and/or publication of this article .

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The authors received no financial support for the research, authorship and/or publication of this article.

Ethical approval:

All activities associated in this study were performed in accordance with the ethical standards of the Institutional and National Research Committee.

Ethical considerations:

An informed consent was obtained from all patients or their relatives before taking any data which included:

Explanation of the study aim in a simple and clear manner to be understood by the common people

Patients or relatives were informed about the techniques and their possible complications.

No harmful maneuvers were performed or used. There were no foreseen hazards to be anticipated from conducting the study on these patients.

All data was considered confidential and was not used outside this study.

Researcher phone numbers and all possible communication methods were identified to the patients or relatives to return at any time for any explanation.

All patients or relatives were informed of the result of the study.

All patients or relatives had the right to refuse participation or to withdraw from the study at any time without giving any reason and with neither jeopardizing the right of the patient to be treated nor affecting the relationship between the patient and the care provider.

Signatures or fingerprints of the patients or relatives were taken.

References:

1. Goicoechea N, Hinarejos P, Torres-Claramunt R, Leal-Blanquet J, Sánchez-Soler J and Monllau JC. A prospective randomized trial of Patellar denervation does not reduce post-operative anterior knee pain after primary total knee arthroplasty with patellar resurfacing. *Knee Surgery, Sports Traumatology, Arthroscopy 2021;* 29: 3346-51.
2. Wang Y, Feng W, Zang J and Gao H a meta-analysis of randomized controlled trials of Effect of patellar denervation on anterior knee pain and knee function in total knee arthroplasty without patellar resurfacing: *Orthopaedic Surgery 2020;* 12: 1859-69
3. Thiengwittayaporn S, Tangtrakul P, Hongku N and Tunyasuwanakul R. a randomized controlled trial of Patellar denervation reduces postoperative anterior knee pain after patellar resurfacing total knee arthroplasty. *The Journal of Arthroplasty 2021;* 36: 1295-301.
4. Fan L, Ge Z, Zhang C, Li J, Yu,Z, Dang X and Wang K. A meta-analysis and systematic review of Circumferential electrocautery of the patella in primary total knee replacement without patellar replacement: *Scientific reports 2015;* 5: 9393.
5. Van Jonbergen H, Scholtes V, Van Kampen A and Poolman R. A randomized, controlled trial of circumpatellar electrocautery in total knee replacement without patellar resurfacing. The Journal of Bone & Joint Surgery British Volume 2011; 93: 1054-9.
6. Alomran A . A randomised controlled trial of Effect of patellar denervation on mid-term results after non-resurfaced total knee arthroplasty. *Acta Orthop Belg 2015;* 81: 609-13.
7. Pulavarti RS, Raut VV and McLauchlan GJ. a randomized controlled trial with 2 years of follow-up of Patella denervation in primary total knee arthroplasty. *The Journal of Arthroplasty 2014;* 29: 977-81
8. Xie X, Pei F, Huang Z, Tan Z, Yang Z and Kang P. a meta- analysis, does patellar denervation reduce post-operative anterior knee pain after total knee arthroplasty? *Knee Surgery, Sports Traumatology, Arthroscopy2015;* 23: 1808-15