Randomized Clinical Trial Comparing Complication and Clinical Outcome of Total Synovectomy Versus Limited Synovectomy In Total Knee Arthroplasty

Eltayeb Mahmoud Nasser

lecturer of orthpaedic surgery Helwan University 01111113390

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Abstract

Background
While performing total knee arthroplasty (TKA), total synovectomy (TS) as one of the surgical steps has been expected to reduce the tissue which trigger inflammatory process after the procedure, but this is controversial because of the risk of major postsurgical bleeding. This study aimed at comparing postoperative bleeding, pain, and health-related quality of life after a TKA when TS is performed and when it is not.

Methods
The difference in pre and postoperative hemoglobin was measured, as well as postoperative pain using visual analogue scale (VAS) scores at 24 hours and 3 days after surgery, functional outcome was measured before surgery and at one year after surgery using KSS score.

Results
We assessed a total of 30 patients (15 for TS and 15 for limited synovectomy). We have found a difference of 0.4 mg/dl of pre- and postoperative hemoglobin between both groups, with a higher bleeding amount for the TS group ($P<0.001$). VAS scores were slightly lower for the TS group at 24 and 3 days after surgery, but the difference was not statistically significant($P>0.05$).. The TS group required transfusion in 12.93% and the limited synovectomy group in 6.9%. No significant differences in functional outcome were found in both groups at 1 year follow-up.

Conclusions
Total Synovectomy in TKA in patients with osteoarthrosis does not result in a significant lower postoperative pain, or in an improvement in functional outcome, but it does increase the amount of bleeding after the procedure.

Keywords
Synovectomy · Total knee arthroplasty · Osteoarthrosis.

Introduction

Osteoarthritis is the most common type of arthritis in all synovial joints. The pathology happens both at the articular cartilage and all periarticular soft tissues in knee osteoarthritis. Clinically, pain is the main symptom from which all patients with osteoarthritis are suffering from. The exact cause of the pain is still not clear yet [1].

Fernandez-Madrid et al. [2] advocated that synovitis which occurs in OA might be a contributing cause of pain, and it has been anticipated that surgical synovectomy can minimize pain and help improving function after TKA [3].

Synovitis is one of the risk factors for disappointing results after TKA; this is because of the concomitant postoperative decreased knee range of motion [4], as well as with repeated knee hemarthrosis and impingement [5]. Seeing it this way, some surgeons perform total synovectomy as a standard step in the surgical technique of a TKA as a way to debulk the inflammatory tissue, on the other hand surgeons prefer to avoid total synovectomy because they doubt its value and accuse it for a higher postoperative bleeding [6].

This study aimed at comparing the outcome of TKA with and without synovectomy regarding postoperative blood loss, pain relief and functional outcome following total knee replacement surgery.

Patient and Methods

Patient population

This is a prospective randomized controlled trial, intended to compare outcome of synovectomy on func-

tion and complication after TKA. The study was conducted in Helwan university hospital in Cairo, from January 2016 to January 2019.

A total of 30 patients with primary OA who were scheduled to undergo TKA were included in the study. Patients were divided into two groups according to a random number table generated by a computer

All patients and the health providers who assessed them before and after the surgery were blinded to the randomization. Group 1 (synovectomy plus TKA) comprised 15 patients (10 women and 5 men) with a mean age of 64years (50to78). Group 2 (TKA alone with very limited synovectomy) comprised 15 patients (9 women and 6 men) with a mean age of 62years (48to76).

Age, height and body mass index, visual analogue score (VAS) of the knee for pain grading and Knee Society score (KSS) [7] were evaluated preoperatively for all patients. The KSS includes two subscores, one assessing knee joint itself and the other assessing function. Preoperative hemoglobin and hematocrit levels were recorded prior to the procedure.

When analyzing the demographic variables, no significant differences were found in both groups; results are displayed in Table 1.

All patients who had other known inflammatory conditions, other than primary osteoarthritis of the knee, bilateral TKR, patients who had coagulopathies or using oral antiplatelet medication , patients with previous knee surgery, patients who did not agree to participate in the study and who did not sign informed consent were excluded from the study.

Table 1: Comparison of baseline data between the two groups

Mean (range)	**Limited synovectomy**	**Total synovectomy**	**P-value***
Patients (n)	15	15	
Male (n, %)	6(40%)	5(33%)	(P>0.05) †
Body mass index (kg/m2)	30(20to40)	29(20to38)	(P>0.05)
Age (yrs.)	62(48to76)	64(50to78)	(P>0.05)
Prothrombin time (s)	9.5(7.6to12.8)	9.6(7.5to12.5)	(P>0.05)
Hematocrit (%)	38.34(24.5to47.9)	38.4(28to51.5)	(P>0.05)
Hemoglobin (g/l)	12.75(7.9to16.0)	13.05(8.6to16.0)	(P>0.05)
Knee Society score **Clinical** **Function**	 34(20to48) 33(20to50)	 35(21to49) 33(20to50)	 (P>0.05) (P>0.05)
Visual analogue scale for knee pain	8.1(6.4to9.8)	7.9(6.4to9.4)	(P>0.05)

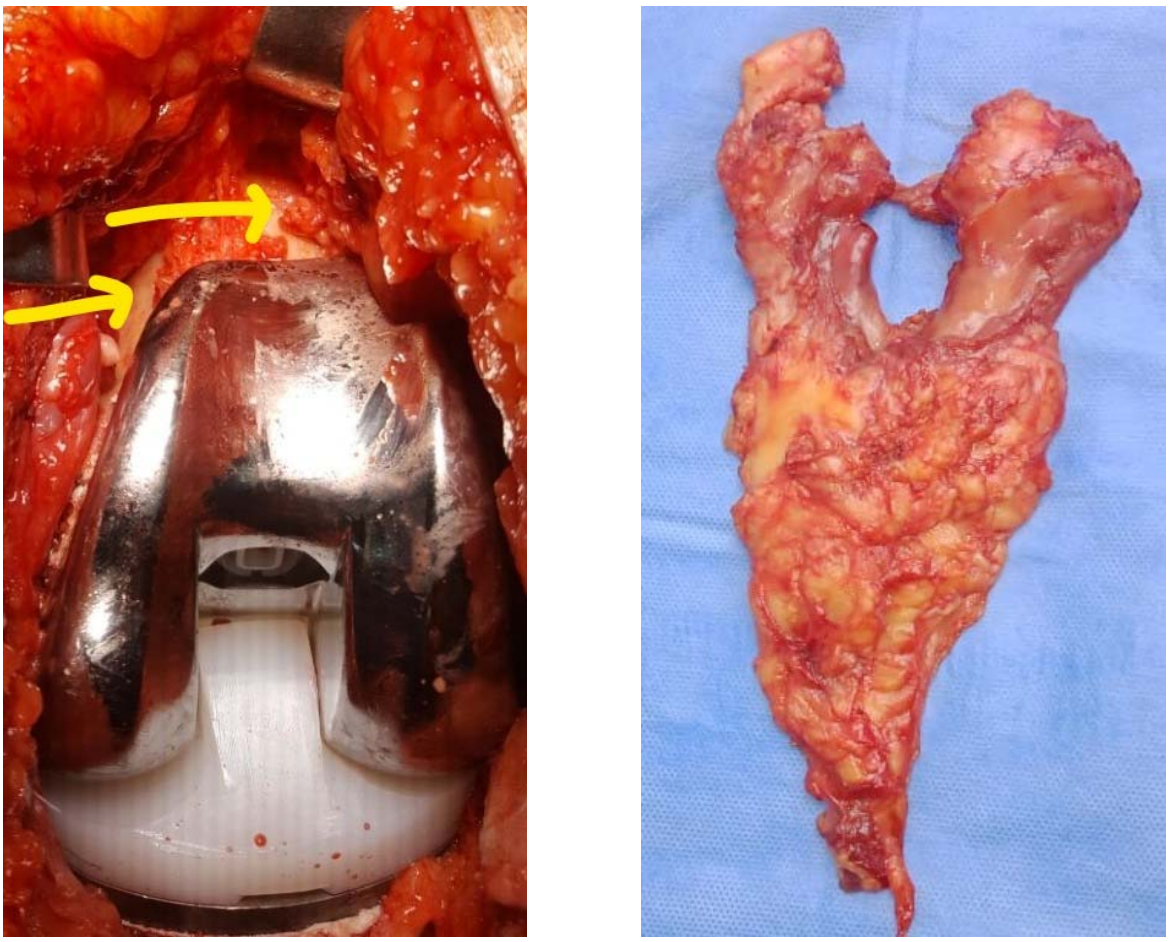
* *t*-test unless otherwise stated † chi-squared test

Operative technique

Both groups underwent primary TKA utilizing a midline skin incision and medial para-patellar arthrotomy. In the TS group (group 1), the synovial membrane underwent debulking fig.1; starting from its proximal end at the suprapatellar pouch, articular margins of femoral and tibial condyles, the posterior region was not excised, because of the high risk of injury to the neurovascular structures in this area.

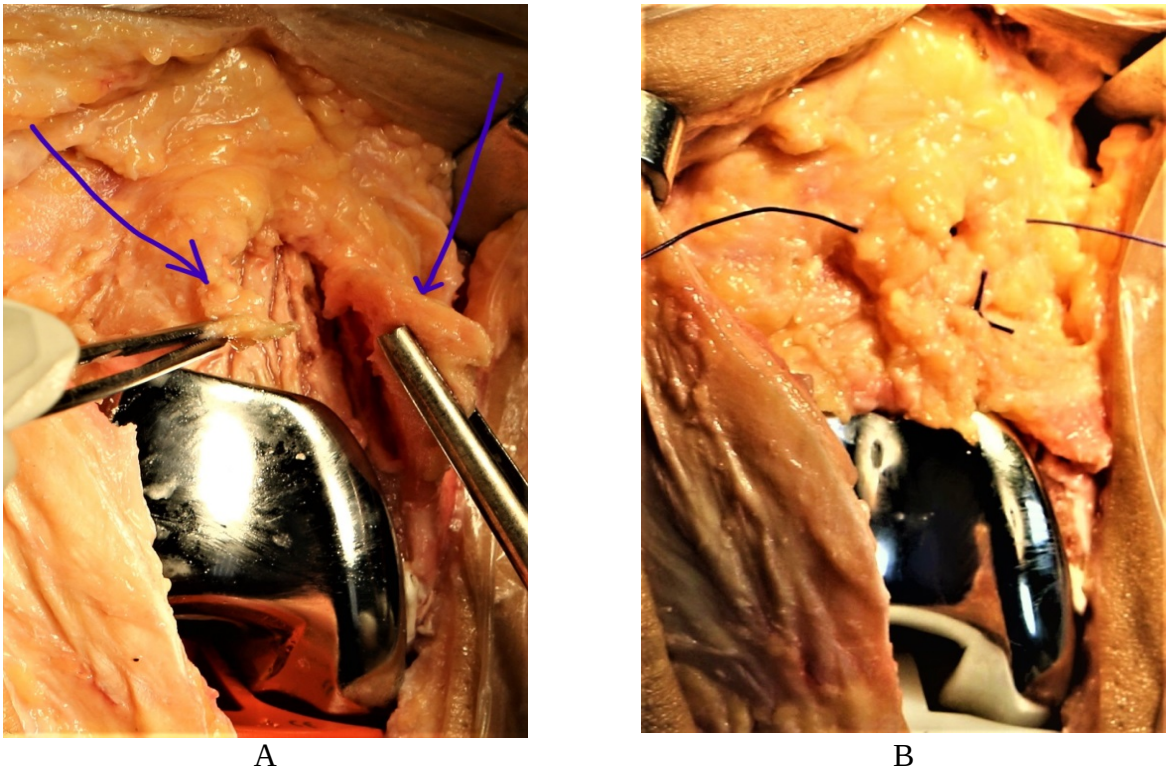
In the limited synovectomy group (group 2), suprapatellar fat pad and synovium were incised to visualize the anterior aspect of distal end of femur to avoid notching and sutured again at the end of procedure fig. 2. The fat pad and synovium were resected only to help expose the lateral tibial plateau.

All procedures were performed by orthopedic surgeons at Helwan university hospital, from 2016 to 2019. Unconstrained, cruciate sacrificing prosthesis were used and ¼ inch drainage were placed laterally and left approximately 5 cm inside the knee, then removed at 24 h after the procedure. In all the patients, the primary TKA was done under tourniquet (pressure of 360 mmHg for all patients) over the ipsilateral thigh and released before wound closure. All operations were performed under epidural anesthesia with an epidural catheter in place and the use of intravenous sedation. The epidural catheter was removed at the end of operation.



A B

Fig. 1: Total synovectomy in total knee arthtroplasty. A: after excision B: Excised synovium



A B

Fig. 2: suprapatellar fat pad and synovium A: incised and sutured at the end of procedure

Post-operative protocol

All patients were carefully monitored for the first 24 hours postoperatively. Any drop in blood pressure and remained below 90 mmHg with symptoms and signs of hypovolaemia such as dizziness, nausea, faintness, hypotension, or increased heart rate, concomitant with hemoglobin levels lower than 9, with unsatisfactory response to crystalloid volume expansion, then blood transfusion was given.

Postoperative pain control did not include any local infiltration; a single pain control protocol was standardized for all cases including combined NSAIDs (Ketorolac 30 mg IV tid, starting at the end of the surgery for 3 days) and Naluphan (50–100 mg IM tid).

Low molecular-weight heparin (40 mg/ 24 hours) was injected subcutaneously after a delay of 24 hours as routine thromboprophylaxis. After three days the heparin was substituted by Rivaroxaban (10 mg/24 hours), which was used for four weeks.

All patients were permitted to stand without walking 24 hours after the operation then all patients were subjected to the same rehabilitation protocol. Briefly, knee flexion and extension exercises were started one day after the operation. These exercises were continued with the addition of graduated walking with assistance from the second day.

Outcome measures

Health-related quality of life was assessed by applying the KSS Score. Patients were evaluated by KSS at four weeks and 12 months after surgery.

Pain was assessed at 24 hours and 3days after surgery, measured by VAS.

Bleeding was measured by the difference in preoperative and postoperative hemoglobin and hematocrit of each patient, as well as transfusion requirements. Concealed haemorrhage was calculated by the Gross equation. [8]

Statistical analysis

Analysis done with IBM1 SPSS1 Statistics software v21 (IBM Corporation, Armonk, NY, USA). The statistical description was expressed by mean and ranges. Statistical analysis was done by using the Student's t test for quantitative variables, and the Chi-square test for qualitative variables. A $P < 0.05$ was considered statistically significant.

Results

Pre-operatively there were no statistically significant differences between the two groups as shown in (Table 1).

Bleeding tendency and Transfusion requirements

In the total synovectomy group there was a statistically significant increase in both visible (mean drainage) and invisible blood loss (concealed loss). Bleeding is higher in the TS group, with mean pre- and postoperative hemoglobin values of 3.23 g/dl and 3.36 g/dl for the limited synovectomy and TS groups, respectively (P<0.001). we also observed a mean drop in hematocrit levels of 9.64% (SD = 3.79) and 10.5 %(SD = 3.31) for the limited synovectomy and TS groups, respectively (P<0.001). Percentage of patients who needed transfusion (%) was 6.9%, 12.93% for the limited synovectomy and TS groups, respectively.

Table 2: Comparison of bleeding tendency and transfusion requirements

	Limited synovectomy	**Total synovectomy**	**P value***
Post-operative haematocrit (%)	28.8(20.5to38.5)	27.3(17.5to38.5)	(P>0.05)
Post-operative haemoglobin (g/l)	9.52(6.4to13.0)	9.42(5.9to13.5)	(P>0.05)
Hemoglobin difference (g/l)	3.23(2.7to3.54)	3.63(2.9to3.85)	(P<0.001).
Hematocrit difference (%)	9.64(9to11.5)	10.5(10to13)	(P<0.001)
Concealed blood loss (l)	1.1(0.16to2.5)	1.25(0.11to3.3)	(P<0.05)
Drainage volume (l)	0.85(0.25to1.60)	0.90(0.37to1.9)	(P<0.05)
Percentage of patients who neededtransfusion (%)	6.9%	12.93%	

(P<0.001).* *t*-test unless otherwise stated † chi-squared test

Pain

We found significant differences for both groups, with a mean VAS score of 5.13 and 4.95 for the limited synovectomy and TS groups, respectively, 24 h after surgery (P<0.001)., and 2.6 and 2.3 for the limited synovectomy and TS groups, respectively, 3days after surgery (P<0.001).. However, the difference was not clinically relevant.

Table 3: Comparison of VAS

Visual analogue scale for pain	Limited synovectomy	Total synovectomy	p-value*
Pre-operative	8.1(6.4to9.8)	7.9(6.4to9.4)	(P>0.05)
24 hours post-operatively	5.13(1.2to9.33)	4.95(11to9.63)	(P<0.001).
Three days post-operatively	2.6(0.8to5.1)	2.3(0.4to4.9)	(P<0.001).
4 weeks post operatively	1.54(0.6to4)	1.52(0.4to3.5)	(P>0.05)

* *t*-test unless otherwise stated † chi-squared test

Health related quality of life

There were no statistically differences between the groups at four weeks or 12 months post-operatively in any of the parameters of KSS.

Table 4: Comparison of KSS

Knee Society score		Limited synovectomy	Total synovectomy	P-value*
Pre-operative	Clinical	34(20to48)	35(21to49)	(P>0.05)
	Function	33(20to50)	33(20to50)	(P>0.05)
4 weeks post op	Clinical	90.61(81to98)	90.45(83to97)	(P>0.05)
	Function	82.43(69to91)	81.9(74to89)	(P>0.05)
12 months post op	Clinical	91.53(77to98)	91.36(76to97)	(P>0.05
	Function	86.73(78to98)	87.97(73to99)	(P>0.05)

* *t*-test unless otherwise stated † chi-squared test

Discussion

Knee joint pain in osteoarthritis can originate from any of the richly innervated structures i.e. synovium, subchondral bone, periosteum, periarticular ligaments and muscles and joint capsule [9]. Synovectomy of pathologic synovium whether open or arthroscopic can be performed in cases of inflammatory arthritis in order to slow down the pathological process and improve pain. Some surgeons may comment that in TKA of primary osteoarthritic knee, preserving the synovium may worsen the clinical results and will negatively affect pain relief.

In this study, it has been shown that pain relief was similar during1-year follow-up period for both groups. At the end of the first year, the KSS was improved without statistically significant difference between both groups. Synovectomy has been performed to relieve pain, to prevent cartilage damage, bone or soft tissue destruction and to improve function in inflammatory arthritis like rheumatoid arthritis for many years [10].

It is almost agreed that total synovectomy while performing knee arthroplasty of inflammatory arthritis is always necessary to slow down the pathological process. [11] In this study it was found that synovectomy in primary osteoarthritis did not affect the functional scores in the early postoperative period.

The idea of this study was to assess pain, function, and perioperative morbidity in patients undergoing total synovectomy in TKA for primary OA. The results of this study showed that total synovectomy when combination with TKA for primary OA provides no added clinical benefits.

There was no significant difference in measured clinical and functional score between both groups. It was found in this study that patients undergoing synovectomy as part of the surgical technique of primary TKA showed significantly more bleeding and also greater transfusion requirements and a significant difference in VAS scores, with better pain control in the total synovectomy group, we believe that these values were not clinically relevant. This was in agreeing with the results of recently published clinical trials, which similarly find out that routine use of synovectomy in

TKA is unprofitable. [12] Studies by Kilicarslan et al. [13] and Zhaoning et al. [14] found out that there were no differences between groups that had TKA with or without synovectomy when it comes to length of hospital stay, range of motion, or clinical and functional knee score within 12 months of surgery. Kilicarslan et al observed that blood loss via drains was significantly more in the synovectomy group during the first 48 hours postoperatively (524 vs. 417 mL; $P<0.05$). Similarly, Zhaoning et al carried out randomized controlled trial, dividing patients submitted to TKA into two groups (with characteristics comparable to our population) with and without synovectomy. The VAS for pain of all patients at 24 h and 3 days after the operation was monitored, the KSS clinical and functional scores were calculated, and the drainage measured. They concluded that the patients undergoing TKA with synovectomy have no clinical or functional benefits over patients who have TKA alone. On the contrary, they have more concealed bleeding, higher drainage volumes, and a marginally longer operative time. His study showed that there was a significant difference between groups when it comes to concealed blood loss (1.24 vs. 1.03 L; $P<0.05$) and blood lost via drains in the first 24 hours (900 vs. 810 mL; $P<0.05$), which was more in the synovectomy group. This study also showed that operative time was significantly more in the synovectomy group (1.50 vs. 1.41 hours; $P<0.05$).

This study had two main limitations; first the relatively short-term follow-up period of patients. Longer term studies are required to support the results of this study. Longer follow-up of our patients is necessary; taking into consideration that synovial proliferation in the limited synovectomy group could generate pain and deterioration in functionality when patients are evaluated after one-year postsurgery. Second we advocate that intraoperative pathological examination of synovial specimen in patients undergoing TKA might help surgeons to decide whether to proceed with total synovectomy or not but this might be time consuming and added cost.

Conclusion

TKA when combined to TS had a greater blood loss and transfusion requirements if compared to TKA with limited synovectomy without showing an improvement in quality of life and postoperative complications. Although there is a statistically significant difference in pain for both groups, with better control of the pain of the total synovectomy group, but we believe that these values are not clinically relevant.

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