No-synovectomy improves the health-related quality of life after total knee arthroplasty: A randomised clinical trial

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Background
This study assessed the clinical outcomes of total knee replacement with and without synovectomy among patients with osteoarthritis.
Methods
A randomised controlled trial of 70 patients with advanced knee osteoarthritis was conducted by individually randomizing (simple randomization) patients to either no synovectomy (group 1 *n*=35) or synovectomy (group 2 *n*=35). Clinical outcomes were assessed by Western Ontario and McMaster Universities Arthritis Index, WOMAC score, knee pain by visual analogue score, health related quality of life by Short Form 12, postoperative blood loss, and hemoglobin levels immediately after surgery and one year postoperative.
Results
Postoperatively, The WOMAC score was 87 (82, 97) in group 1 and 84 (76, 96) in group 2. The VAS score was 6 (5.00, 8.00) and 7 (5.00, 8.00) in group 1 and 2 respectively. The physical composite score (PCS) of the SF-12 score was 52 (46, 56) in group 1 and 50 (43, 54) in group 2. The mental composite score of the SF-12 was 58(55, 61) and 51 (45, 57) in group 1 and 2 respectively with significant difference between groups. The median hemoglobin drop was 1.7 (1.35, 2.00) grams in group 1 and 3 (2.45, 3.30) grams in group 2. The median drain blood loss was 250 ml (200, 350) and 800 ml (450, 1200) in group 1 and 2 respectively. Patients in group 1 had a better flexion range than group 2.
Conclusion
Total knee arthroplasty performed without synovectomy reduces postoperative blood loss, improves the flexion range and patients' quality of life scores.

Keywords:
synovectomy, total knee arthroplasty, quality of life

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Introduction

Total joint replacement is the main treatment for end-stage knee osteoarthritis [1,2]. Despite the recent advances in the intraoperative techniques and devices and postoperative care, About 15% of patients with total knee arthroplasty are unsatisfied with their operations and one third of them experience patellofemoral complications [3–6]. Synovial proliferation is a characteristic feature of advanced knee osteoarthritis confirmed by radiographic and biopsy changes, which increases with disease progression [7–9]. Removal of the synovium may reduce pain and improve function in inflammatory knee diseases [10,11]. However, there is no consensus on the role of synovectomy in total knee arthroplasty; a management strategy usually considered to reduce pain. It is uncertain what is the added benefit of synovectomy as a crucial step during surgery, as evidence of the benefits of this procedure among patients with inflammatory arthritis is conflicting [12,13].

Some studies reported increased total blood loss and operation time, with no improvement in postoperative inflammatory response; pain or functional scores among patients receiving routine synovectomy with primary total knee replacement compared primary total knee replacement alone [12,14].

Other studies reported no clear benefit for synovectomy in patients undergoing TKA for primary knee osteoarthritis in regards to improve pain, range of motion (ROM) and functional outcomes. However, this practice is still common among surgeons performing routine synovectomy in total knee replacement [15,16]. Our aim is to study the effect of synovectomy on patient functional outcome scores and quality of life scores.

Aim and objectives

The aim of the study was to assess the benefits and harms of synovectomy among patients with

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osteoarthritis undergoing primary knee arthroplasty with synovectomy, compared to patients undergoing primary knee arthroplasty without synovectomy.

Methods

A randomised control trial was conductd at the orthopaedic department based at University hospitals. We recruitd Seventy patients with end-stage knee osteoarthritis from April 2019 through January 2021. Participants were randomised 1:1 into two groups assigned by a computer-generated sequence. Patients assigned to (group 1) received surgery without synovectomy. While patients in the (group 2), received surgery with synovectomy. The surgeons were blinded to the randomisation sequence but were informed to perform either synovectomy intraoperatively or not.

We included adult patients 40 years and older with advanced knee primary osteoarthritis evident on standing AP radiographs. We excluded patients assigned for revision surgery, inflammatory arthritis. Ethical considerations as recommended by the University Research/Ethics Committee based at Ain Shams University were followed. We obtained a written informed and signed consents from included patients.

Preoperative diagnosis and evaluation

Clinical Evaluation, history, general and local examination. Data were collected by a blinded assessor (an orthopaedic registrar).

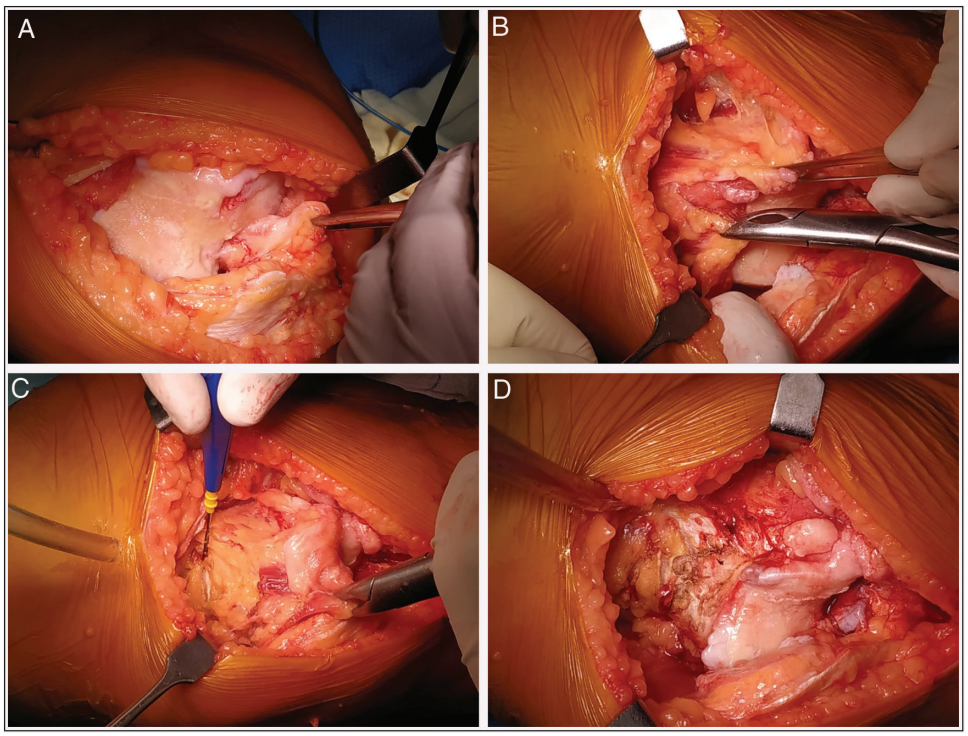
Radiological evaluation

(1) Standing AP and lateral radiographs to determine the degree of osteoarthritis among included patients.

Operative technique

Total knee arthroplasty was performed by using the medial parapatellar approach. A medline skin incision was performed then we opened the extensor mechanism. We performed a near total synovectomy removing the suprapatellar synovial fold, and the retropatellar fat pad in (group 2) (Fig. 1). In (group 1) the synovium was not removed (Fig. 2). Posterior stabilized prosthesis (Zimmer-Biomet, Warsaw, IN, USA) was used in all patients. The tourniquet was deflated before wound closure and cauterization of bleeders and haemostasis was ensured, Local anesthesia of 20 ml bupivacaine (Marcaine®) was injected locally and one gram of tranexamic acid (kapron®) diluted on 50 ml normal saline was injected locally in the drain after closure.

Figure 1



(A): Removal of the retropatellar fat pad. (B): Full exposure and medial and lateral dissection of the knee synovial layer. (C): Surgical removal of the synovial layer. (D): The synovial bed after synovial layer removal.

Postoperative management

Primary outcomes

Functional outcome scores e.g. Western Ontario and McMaster Universities Arthritis Index (WOMAC) score at one year [17], Health related quality of life e.g. short form (SF12) scale at one year [18].

Secondary outcomes

Knee pain e.g. visual analogue score (VAS) score immediately postoperative [19], revision rate at one year, reoperation rate at one year, range of motion at one year, Postoperative blood loss immediately postoperative, postoperative hemoglobin drop level immediately postoperative, Infection rate in first postoperative three months, wound complications in first three months, number of patients requiring transfusion immediately after postoperative management.

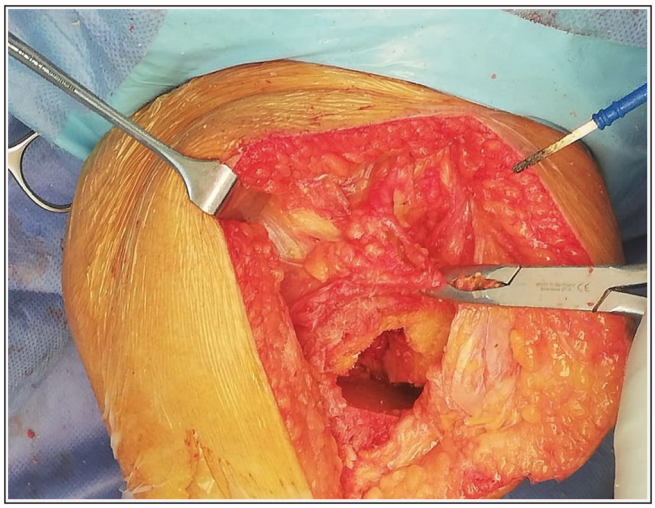
Expected complications were wound complication, venous thrombosis, and neurovascular injury, and other intervention - related events due to study treatments were recorded as adverse events.

Sample size

By using Power Analysis and Sample Size Software (PASS 15) (Version 15.0.10) for sample size calculation, setting power at 80% at significance level 0.05 and after reviewing previous study results (Rankin *et al.* 2018) showing that the rate of patients' satisfaction as regards return to recreational activities in those had total knee arthroplasty with synovectomy was lower than those with no synovectomy (77% vs. 100% respectively); based on that and after considering 10% dropout rate, a sample size of at least 70 patients undergoing total knee arthroplasty divided randomly into 2 groups (35 patients in each group) will be sufficient to achieve study objective.

Trial registration No.: The study was registered on clinicaltrials.gov with the number NCT03778463.

Figure 2



Preserved synovial layer after total knee bone cuts.

Results

We recruited patients between April 2019 and January 2021. We assessed 106 for eligibility of which 36 were excluded and 35 were included in each group. Exclusion criteria were revision knee surgery, inflammatory arthritis and patients refusing participation in the study. The median follow-up period was twelve months. The mean age is 62.5 (6.63) years, 53 females and 17 males. The mean weight was 86.9 ± 13.3 kg and the mean height was 166.14 ± 9.6 cm (Table 1).

Knee ROM ranged between 5.5°±3.9° and 66.4°±20.8°, of which 37 patients had fixed flexion deformity (FDD). The mean preoperative WOMAC score was 45 ± 18.6. Radiological investigations showed 10 patients with valgus deformity and 60 patients with varus deformity. The mean coronal alignment was of 7.47°±6.61° (Mean valgus alignment -9.9° and varus alignment 9.4°). Both groups were comparable with no statistical differences (NS) between groups in all parameters (Table 2).

Postoperatively, the WOMAC score was 87 in group 1 and 84 in group 2 (NS). The median postoperative VAS score was six and seven in group1 and 2, respectively (NS) (Table 3). The physical composite score (PCS) of the SF-12 score was 52 in group 1 and 50 in group 2 with no significant difference between groups. The mental composite score (MCS) of the SF-12 was 58 and 51 in group 1 and 2 respectively with significant

Table 1 Baseline demographic and clinical characteristics of participants

Characteristics	Overall (*n*=70) baseline (Pre-operative)	Group 1 (*n*=35)	Group 2 (*n*=35)	Difference	
Age [Median (min, max)]	61.0 (50.0, 81.0)	61 (60, 66)	61 (58, 65)	*P* value=0.9	insignificant
Sex (F/M)	33 (66%)	27 (77%) 8 (23%)	26 (74%)		
	17 (34)		9 (26%)		
Weight [Mean (sd)]	86.9 ± 13.3	87.7 ± 14.2	86.1 ± 7.8	*P* value=0.3461	insignificant
Height [Mean (sd)]	166.14 ± 9.6	164.96 ± 11.3	167.3 ± 12.6	*P* value=0.6458	insignificant
ASA score		1–10 (29%)	1–13 (37%)		
		2–24 (69%)	2–18 (51%)	*P* value=0.2	insignificant
		3-1 (2.9%)	3–4 (11%)		

Table 2 Preoperative clinical data

Characteristics	Overall (*n*=50) baseline (Pre-operative)	Group 1 (*n*=25)	Group 2 (*n*=25)	Difference	
Extension range	5.5 ± 3.9	4.8 ± 3.947573	6.1 ± 3.8	*P* value=0.2407	insignificant
Flexion range	66.4 ± 20.8	68.4 ± 22.85461	64.4 ± 18.7	*P* value=0.6415	insignificant
WOMAC	45.0 ± 18.6	37.0 ± 14.01931	53.0 ± 19.5	*P* value=0.003327	significant
Preoperative radiological criteria:					
Valgus	10 (14.28%)	5 (7.1%)	5 (7.1%)		
Varus	60 (90%)	30 (42.85%)	30 (42.85%)		
Coronal alignment	7.47 ± 6.61	7.36 ± 7.29	8.3 ± 4.76	*P* value=0.6825	Insignificant

Table 3 Postoperative clinical data:

Variable	N	1=No synovectomy, *N*=35[1]	2=Synovectomy, *N*=35[1]	*P* value[2]
WOMAC	70	87 (82, 97)	84 (76, 96)	0.061
VAS	70	6.00 (5.00, 8.00)	7.00 (5.00, 8.00)	0.5
PCS	70	52 (46, 56)	50 (43, 54)	0.5
MCS	70	58 (55, 61)	51 (45, 57)	<0.001
revision	70			
no		35 (100%)	35 (100%)	
HB drop	70	1.70 (1.35, 2.00)	3.00 (2.45, 3.30)	<0.001
blood transfusion	70	2 (5.7%)	13 (37%)	0.004
drain blood loss	70	250 (200, 350)	800 (450, 1200)	<0.001
wound comp	70	1 (2.9%)	2 (5.7%)	>0.9
infection	70	0 (0%)	2 (5.7%)	0.5
flexion	70			0.047
80		1 (2.9%)	0 (0%)	
90		4 (11%)	10 (29%)	
100		9 (26%)	14 (40%)	
105		1 (2.9%)	1 (2.9%)	
110		20 (57%)	10 (29%)	
extension	70			0.2
0		32 (91%)	27 (77%)	
5		3 (8.6%)	7 (20%)	
10		0 (0%)	1 (2.9%)	

[1]Statistics presented: median (IQR); *n* (%).
[2]Statistical tests performed: Wilcoxon rank-sum test; chi-square test of independence; Fisher's exact test.

difference between groups. The median hemoglobin drop was 1.7 grams in group 1 and 3 grams in group 2(NS). Two patients needed blood transfusion in group 1 compared to thirteen patients in group 2. The median drain blood loss was 250 ml and 800 ml in group 1 and 2 respectively with a statistical significant difference in all the blood loss parameters. One patient developed wound complications in group 1 compared to two patients in group 2(NS). Two patients developed wound infection in group 2 with no wound infection in group 1. Patients in group 1 had a better flexion range than group 2 (Table 3).

Discussion

The aim of our study was to assess the benefits and harms of the synovectomy as a surgical procedure among patients undergoing total knee arthroplasty. We randomized seventy patients into two groups. Patients in group1 did not receive synovectomy, but in group 2 received synovectomy with TKA.

Our study showed that no synovectomy group had less postoperative haemoglobin drop, less possibility for the need of blood transfusion, and less postoperative drain blood loss. Patients in the group without synovectomy had also better MCS score and better flexion range.

Knee osteoarthritis and Rheumatoid arthritis (RA) are the most common indications for total knee joint replacement worldwide [20,21]. Knee osteoarthritis (i.e., a non-inflammatory, progressive erosion of the articular cartilage) is associated with aging, trauma, and occupational injury. Knee osteoarthritis (OA) is the most common joint disorder, such that more than 10% of men and 18% of women older than 60 years of age have symptomatic knee osteoarthritis [22]. Synovial proliferation and progressive worsening of an arthritic joint is a characteristic pathological feature of advanced knee OA and rheumatoid arthritis [7–9,23].

Knee arthroplasty, that is replacement of the knee joint articular surface, is the gold standard treatment

for advanced knee osteoarthritis and rheumatoid arthritis. Total knee arthroplasty (TKA) is a common surgical intervention that has proven to be successful at reducing pain and enhancing physical function with long term survival rates and good functional scores long term [1,2]. Knee arthroplasty can be performed with the partial or total surgical removal of the joint surface. This usually depends on the severity of the affected part of the knee cartilage. Nonetheless, both procedures have shown to produce similar outcomes of reduced pain and improved functional outcomes [24].

Synovectomy, the surgical removal of the synovial membrane may further reduce pain and improve function in inflammatory knee diseases [10,11]. A common cause of post-operative knee pain after TKA is synovitis (i.e inflammation of the synovial membranes) and persistent knee effusion due to inflammation of the synovium. Surgeons commonly remove the synovium during routine knee exposure to assist in the visualization of the knee joint, and to reduce postoperative pain [25,26]. However, there is conflicting evidence on the benefits of this procedure even among people with inflammatory arthritis [12,13]. Furthermore, outcomes after synovectomy during TKA depend on surgeon preference [14], and possibly, clinical equipoise [27].

Randomised controlled trials (RCTs) investigating the use of routine synovectomy with primary total knee replacement among patients with primary osteoarthritis have been reported. The authors from these trials have reported increased total blood loss and operation time, with no improvement in postoperative inflammatory response, pain, or functional scores, among patients receiving primary total knee replacement with routine synovectomy compared with primary total knee replacement without synovectomy [13]. Bernal-Fortich 2018 in their trial did not report any improvement in patient related quality of life and showed better pain control in total synvectomy group. Rankin 2018 included only patients with inflamed synovium based on surgeons' intraoperative evaluation [28,29]. Tanavalee 2011 reported that whether to do synovectomy or not does not affect the level of postoperative inflammatory markers or the duration of postoperative inflammatory response [14]. Zhaoning 2013 added that synovectomy lengthens the operating time when added to total knee arthroplasty [12].

In addition, a meta-analysis of the 3 clinical trials (*N*=354 participants) by Kooner *et al.* compared the addition of synovectomy to TKA among patients undergoing surgery for primary knee osteoarthritis. Kooner and colleagues reported no clear benefit of performing synovectomy for these patients in regard to postoperative pain, range of motion (ROM), and functional outcome, using the Knee Society Score (KSS). Based on these results, Kooner and colleagues concluded that there was no currently available evidence to support the use of synovectomy in TKA for primary knee osteoarthritis [15].

More recently, a meta-analysis of ten RCTs comparing synovectomy to synovial retaining by Zhao *et al.* reported outcomes of total blood loss, knee society scores, range of motion, and operative time for synovectomy among patients undergoing TKA for primary knee osteoarthritis. The authors reported findings similar to the previous review [16].

Currently, evidence from most studies advise against using synovectomy in total knee arthroplasty whereas some patient groups with severe disease or patients with rheumatoid arthritis may benefit from this procedure and our study add that no synovectomy with total knee improves postoperative knee range of motion and health related quality of life [11].

Limitation to our study is the small sample size and short follow up, but it shows improvement of the postoperative range of motion and health related quality of life in the non-synovectomy group. So a larger sample size in a multicentre randomized trial may strengthen the results of quality of life improvement with no synovectomy. Further research is needed to identify the indication of synovectomy in inflammatory arthritis e.g. rheumatoid arthritis and evidently inflamed synovium.

Conclusion

Synovectomy with total knee arthroplasty increases postoperative blood loss. Leaving the synovium intact in total knee arthroplasty improves the flexion range and patients' quality of life scores.

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Conflicts of interest

There are no conflicts of interest.

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