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CLINICAL RESEARCH

Is Obesity a Contraindication for Minimal Invasive Total Knee Replacement? A Prospective Randomized Control Trial

Byron E. Chalidis · George Petsatodis · Anastasios G. Christodoulou · John Christoforidis · Pericles P. Papadopoulos · John Pournaras

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Abstract
Background Although total knee replacement (TKR) has been proven a very successful treatment modality for the end-stage knee osteoarthritis (OA) in obese patients, the rehabilitation period often is long and painful. Minimal invasive surgery (MIS) has gained much attention in TKR promising fast and less painful recovery. However, little is known about the effectiveness of the technique in the obese adult population.
Methods One hundred consecutive patients with body mass index (BMI)>30 kg/m^2 and tricompartmental knee OA were randomly assigned to undergo either standard TKR (50 patients) or MIS-TKR (50 patients). The patients were assessed clinically and radiologically before the procedure and at subsequent postoperative follow-up visits, until 2 years after the operation.
Results Knee society function and pain scores were significantly higher in MIS group for 3 months following surgery. Patients after MIS had also lower levels of pain during hospitalization. Tourniquet time was on average 7 min longer during MIS-TKR (p=0.03) but operative time was almost equal in both groups (p=0.11). No statistical significant difference was found between groups regarding the amount of blood loss (p=0.49) or incidence of allogeneic blood transfusion (p=0.27). Active straight leg raising was achieved 2.2 days earlier, on average, after MIS-TKR (p<0.001). No severe complications or residual coronal and sagittal imbalance were identified. Component alignment was in normal limits and similar in both groups. In MIS group, higher BMI did not have a negative predictive effect on knee pain and function.
Conclusions MIS is a reliable and safe option in obese patients undergoing TKR regardless the level of BMI. It is associated with improved early clinical outcome without sacrificing radiographic positioning of the implants.

Keywords Total knee replacement · Obesity · Minimal invasive surgery · Knee society score · Oxinium · Knee flexion · BMI

B. E. Chalidis (✉) · G. Petsatodis · A. G. Christodoulou · J. Christoforidis · P. P. Papadopoulos · J. Pournaras
1st Orthopaedic Department, G. Papanikolaou Hospital, Aristotle University of Thessaloniki, Exohi, 57010 Thessaloniki, Greece
e-mail: byronchalidis@gmail.com

Introduction

Obesity has been linked to initiation and development of knee osteoarthritis and increased incidence of total knee replacement (TKR) [1]. It was found that the odds ratio for incident symptomatic knee osteoarthritis (OA) raised dramatically with increasing of body mass index (BMI)—taking BMI≤25.5 the odds ratio was 1.0, at BMI=25.5–30 the odds ratio was 3.8, and at BMI>30 the odds ratio increased to 9.3 [2]. Similarly, each unit in age-adjusted BMI can raise the prevalence of knee OA by 4% [3]. Although the mechanism by which obesity causes knee OA remains unclear, it is hypothesized that repetitive application of high axial loading forces results in faster degeneration of articular cartilage [4]. In addition, excessive fat may lead to irregular growth of articular cartilage and inhibition of its repair [4, 5].

Even though perioperative and postoperative complications may be more frequent in obese people undertaking TKR, meaningful functional benefits can be seen in terms of pain, knee mobility, and function [6]. In obese patients,

higher peak stresses and cyclical loading across the knee joint pose a theoretical risk for early implant failure and poor outcome [7]. However, the above concern has not been clearly demonstrated and the available clinical data have failed to support that supposition. Probably the lower activity levels in the obese population could potentially offset the greater mechanical load due to increased weight and keep the complication rates within acceptable values [8, 9].

Minimal invasive surgery (MIS) has been introduced the last decade in TKR with the aim to decrease the postoperative pain and need for analgesia, the hospitalization time, and the duration of postoperative recovery. These benefits are achieved through the short skin incision, limited soft-tissue dissection, and preservation of the integrity of knee extensor mechanism. On the other hand, there is a clinical impression that MIS may increase the risks of wound complications and malpositioning of the prosthesis due to inadequate visualization of the operative field [10]. So far, the overall efficacy of the technique in obese people with end-stage knee OA has not been conclusively established. The inherent difficulty of applying the technique in knees with high levels of subcutaneous fat has precluded its widespread use, as many surgeons are reluctant to utilize small incisions and extensor mechanism sparing approaches in obese patients undergoing TKR. The primary aim of this prospective randomized study was to compare the clinical and radiologic outcomes between MIS-TKR and standard TKR in obese population (BMI> 30 kg/m^2) with knee OA. The secondary goal was to identify any differences between different obese BMI categories in patients receiving MIS-TKR.

Methods

Trial Design

The trial was designed as a prospective randomized controlled study and conducted at our institution after Local Ethics Committee approval. Since March 2005, 100 consecutive obese patients (BMI>30 kg/m^2) with primary tricompartmental knee osteoarthritis who had been scheduled to undergo TKR were considered eligible for the study. Measurements of weight and height were obtained using a portable digital scale and a stadiometer. Patients with (1) medical history of previous knee lesions, infections, or operations; (2) cancer or irradiation to the knee joint; (3) rheumatoid or inflammatory arthritis; (4) knee disability and <90° range of motion (ROM); (5) valgus deformity > 10°; (6) varus deformity >20°; (7) flexion contracture >10°; (8) neuromuscular deficiency; and (9) cognitive–behavioral lesions or inability to guarantee postoperative regular attendance were not amenable for participation in the study.

Randomization

The patients were counseled by the operating surgeon regarding the purpose and nature of the trial the day before the surgery and were enrolled in the study after informed consent was obtained. They were randomized in two groups of 50 patients each by using a random number generator (SPSS, Chicago, Illinois) to receive a standard TKR or a MIS-TKR. No patients declined randomization or participation in the study. One patient from MIS group and two patients from standard group were withdrawn from analysis, as they did not attend all the appointments for different reasons not related to the study. Other three patients replaced these excluded patients in accordance with the randomization procedure, so that 50 patients remained under investigation in each group. The last patient was recruited in January 2007. All interventions were performed by two senior surgeons who were experienced in MIS-TKR and in the use of the prosthetic model.

Surgical Technique

All procedures were performed under spinal anesthesia. No intrathecal analgesia, pre-emptive analgesics, or multimodal pain pathways were used. Postoperatively, the patients received parenteral and oral medication for pain control.

The standard procedure was performed using a midline skin incision, extending about 5 to 10 cm into the quadriceps tendon, and a median parapatellar arthrotomy with eversion of the patella. Intramedullary instrumentation was used for femoral alignment, with a 5° valgus cut selected for all knees. The tibial cut was performed with extramedullary instrumentation, with a goal for tibial placement perpendicular to the anteroposterior anatomic tibial axis and parallel to the anatomic posterior slope.

The MIS technique was performed via a slightly medial longitudinal skin incision started 2 cm proximal to the superior pole of the patella and ended 2 cm below the joint line (Fig. 1). The length of skin incision varied between 9 and 13 cm. Afterwards, a mini-midvastus capsular approach without patella eversion was used. During the procedure the knee was flexed and extended as necessary to move the soft-tissue "mobile window" to allow proximal or distal exposure. Differential force was also applied on side retractors to facilitate medial and lateral exposure. In addition, less cumbersome instruments were utilized to minimize soft-tissue damage. The remaining surgical technique was similar as with the standard replacement group.

In both groups, the posterior cruciate ligament was retained and the patella was not resurfaced. The same

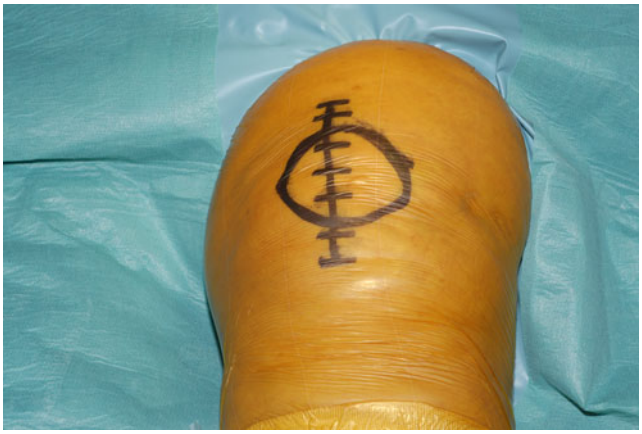

Fig. 1 Skin incision in MIS technique. Its length remains below 13 cm and it is performed in the medial side of the patella

posterior cruciate retaining condylar knee (Genesis II, Smith and Nephew, Memphis, TN) with an Oxinium femoral component was used in all cases (Fig. 2). Both femoral and tibial components were cemented in using third-generation cementation techniques and a reinfusion suction drain was placed for 48 h.

Physiotherapy and use of a continuous passive movement machine was initiated on the first day after surgery. Weight bearing with an assistive device along with active and active-assisted ROM exercises were also begun at the same time and progressed as tolerated by the patient. Prophylactic antibiotics were administrated for 48 h. Particularly, all patients received 1.5 gr cefuroxime 20–30 min before the skin incision and every 8 h thereafter. Thromboprophylaxis consisted of low molecular weight heparin in combination with compression stockings worn for 6 weeks after surgery. All patients planned to be discharged on the sixth postoperative day.

Study Outcome Variables

The patients were scheduled to be assessed preoperatively and at subsequent postoperative follow-up visits (2 weeks, 1 month, 3 months, 6 months, 1 year, and 2 years) by outcomes questionnaires completed by the patient without the surgeons present and by clinical evaluation by an independent observer. These data were used to obtain Knee Society Score (KSS) for pain and function [11]. Knee flexion was determined using a goniometer.

Weight-bearing anteroposterior and lateral knee radiographs were received for measuring the preoperative and postoperative alignment. Our criteria of normality regarding the coronal alignment of the components were 93–98° for the femur and 87–93° for the tibia. In sagittal plane, the relevant normal values for the femoral and tibial (posterior slope) components were 87–93° and 86–90°, respectively [12]. The normal tibiofemoral angle was considered to be 3–7° of valgus [8]. Plain X-rays were also scrutinized for signs of implant loosening or failure and polyethylene wear. Patellar skyline views were additionally used to grossly assess patellar tilt and/or dislocation.

Besides, we recorded any complications including deep vein thrombosis (DVT) and wound problems such as persistent drainage, fat, and skin edge necrosis, cellulitis and infection. A wound infection was considered to be superficial if it resolved with oral antibiotics alone and deep if a re-operation or revision procedure was required. All cases of DVT were confirmed by duplex ultrasonography.

The measured intraoperative variables were the length of skin incision, skin-to-skin operative time, and tourniquet time. The latter was defined as the time from cuff inflation before skin incision to its release after cementing of prosthesis and prior to wound closure.

During patient hospitalization, the total volume of suction drainage collected and the incidence of allogeneic blood transfusion were recorded. The time to do an unassisted straight leg raising maneuver was also evaluated. This has been used as a marker for return of quadriceps function. Patients were also asked to rate the pain intensity using a visual analog scale (VAS) pain score ranging from 0 (no pain) to 10 (unbearable pain).

Statistical Analysis

Statistical evaluation was carried out with use of the SPSS software package (SPSS 16.0, Chicago, Illinois). Chi-square test was used for comparing nominal variables and *t* test for numeric variables. Statistical significance was assumed for $p<0.05$. All values given in the results are presented as mean with standard deviation (SD) and range in brackets.

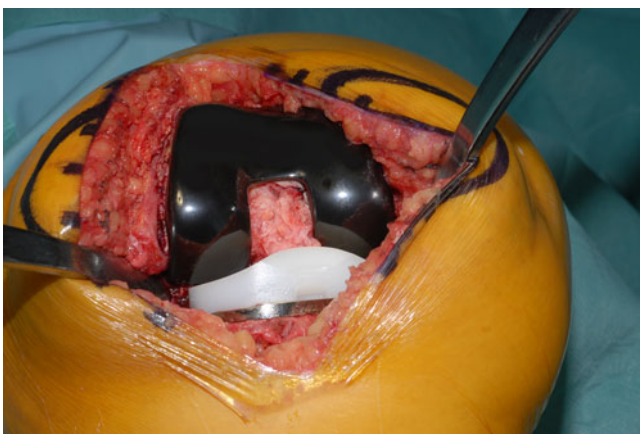

Fig. 2 Intraoperative view of knee prosthesis in MIS group. The joint can be adequately visualized by flexing and extending the knee in different angles ("mobile window"). The femoral component is made from oxidized zirconium

Table 1 Patient demographics

Variable	MIS group	Standard group	*P* value
Age (years)[a]	70.1 (45 to 85)	71.2 (53 to 81)	0.32 (*t* test)[c]
Gender (male/female)[b]	4/46	6/44	0.74 (Chi-square test)[c]
Bone mass index (BMI)[a]	34.6 (30.9 to 42.1)	34.2 (30.4 to 41.8)	0.79 (*t* test)[c]
Side (right–left)[b]	29/21	23/27	0.32 (Chi-square test)[c]
Tibiofemoral angle (degrees)[d]	−1.40 (−8 to 11)	−1.10 (−4 to 2)	0.63 (*t* test)[c]

[a] Data are given as mean with range (min and max) in brackets

[b] Data are given as number of patients

[c] Non-statistically significant (95% confidence interval)

[d] Negative values denoted varus alignment

Results

Clinical Evaluation

The two groups were comparable concerning the baseline variables of age, gender, affected limb, BMI, and standing tibiofemoral alignment of the leg (Table 1).

The length of skin incision was significantly shorter in MIS group compared to standard group ($p<0.001$). Tourniquet time was on average 7 min longer in MIS group ($p=0.03$). However, the skin-to-skin time was almost equal in both groups ($p=0.11$). No statistical significant difference was found in the estimated blood loss (from the drains; $p=0.49$) or incidence of allogeneic blood transfusion ($p=0.27$). Hospitalization time was similar in both groups ($p=0.27$) as few patients stayed more than 6 days after the operation. Active straight leg raising was achieved 2.2 days earlier, on average, in the MIS group ($p<0.001$; Table 2).

Knee flexion was greater in MIS group even 6 weeks postoperatively. After that time point, no difference was found between the groups (Fig. 3a). Although flexion contracture or lag of extension were seen in three patients in standard group and in two patients in MIS group ($p=0.65$), they did not interfere with knee function as the relevant values were less than 10°.

Knee society function and pain scores were significantly higher in MIS group for 3 months after surgery but were equalized thereafter (Fig. 3b, c). The MIS group had also less pain in the first 6 days after TKR. Two weeks postoperatively, the pain intensity was virtually identical in both groups ($p=0.25$; Fig. 3d).

No severe intraoperative problems were encountered and none of the patients undergoing MIS required conversion to a standard approach. In two knees in MIS group, partial avulsion of the insertion of the patellar ligament from tibial tubercle occurred without jeopardizing the integrity of extensor mechanism.

The overall postoperative complication rate was low and comparable in both groups ($p=0.68$). Distal DVT was recognized in three cases in MIS group and in two cases in standard group. No cases of proximal DVT or pulmonary embolism were identified. One patient in MIS group and two patients in standard group had increased wound drainage that resolved without any specific treatment. Joint hematoma and erythema, which raised a concern of infection, were identified in two patients in MIS group

Table 2 Clinical parameters[a]

Variable	MIS group	Standard group	*P* value (*t* test)
Incision length (cm)	12.1±0.8 (9 to 13)	21±2.2 (18 to 25)	<0.001[b]
Tourniquet time (min)	85.2±13.5 (60 to 110)	78.3±10 (60 to 100)	0.03[b]
Skin-to-skin time (min)	112.7±12.3 (85 to 135)	107.5±12.6 (75 to 135)	0.11[c]
Blood loss (mL)	585±175.8 (200 to 1,000)	615±150 (350 to 900)	0.49[c]
Blood transfusion (units)	1.1±0.9 (0 to 3)	1.4±0.7 (0 to 3)	0.29[c]
Hospitalization time (days)	6.1±0.6 (6 to 10)	6.3±1.6 (6 to 12)	0.27[c]
Time to straight leg raising (days)	2.1±0.6 (1 to 4)	4.3±1.1 (2 to 6)	<0.001[b]

[a] Data are given as mean with standard deviation (SD) and range (min and max) in brackets

[b] Statistically significant (95% confidence interval)

[c] Non-statistically significant (95% confidence interval)

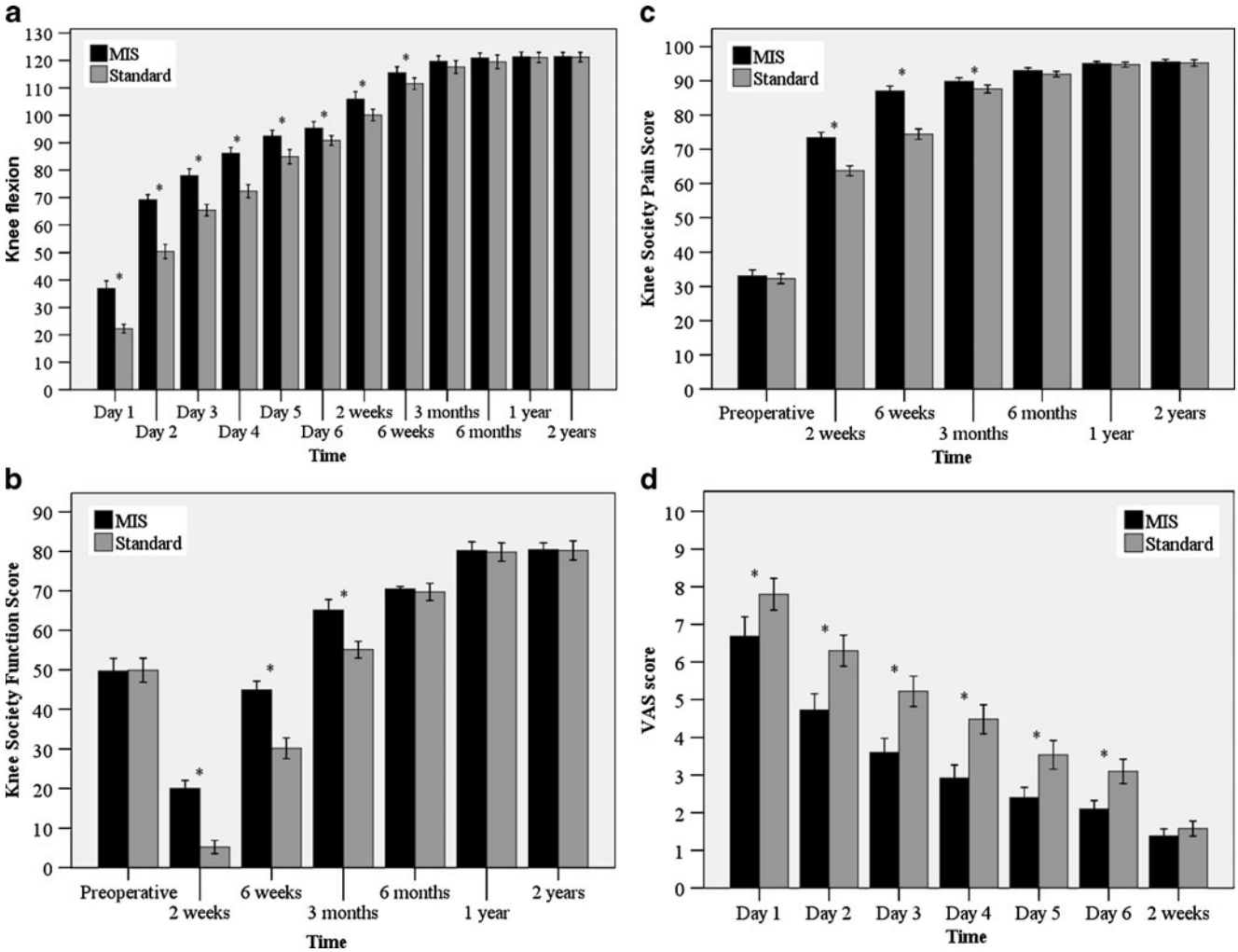

Fig. 3 Comparison of mean **a** knee flexion, **b** knee society pain score, **c** knee society function score, and **d** visual analog scale (VAS) pain score for the groups of MIS-TKR and standard TKR. *Error bars* show the 95% confidence interval. *$p<0.05$ indicates statistical significance

and in one patient in standard group. These were transient and were effectively treated with antibiotics without compromising knee motion or patient rehabilitation.

Radiologic Evaluation

In standard TKR group, the average tibiofemoral alignment was improved from 1.1° varus [SD±1.5, (range, −6° to 2°)] preoperatively to 4.2° valgus [SD±1.2, (range, 2° to 8°)] postoperatively ($p<0.001$). Similarly, in MIS-TKR group the tibiofemoral alignment was shifted from 1.4° varus [SD± 2.7, (range, −8° to 4°)] before the operation to 4.8° valgus [SD±1.6, (range, 1° to 7°)] after the operation ($p<0.001$). However, there were no differences in postoperative alignment between the two groups ($p=0.1$).

There were no significant differences between the groups with regard to the position of the femoral and tibial components in coronal and sagittal planes (Table 3). Neither any radiolucency around femoral and tibial components nor lateral dislocation or subluxation of the patella was identified in any of the operated cases (Fig. 4).

MIS and BMI

MIS group was further evaluated according to the level of BMI. Twenty-six patients had a BMI between 30 and 34.99 (obese), 21 patients between 35 and 39.99 (severely obese), and three patients more than 40 (morbidly obese). However, higher BMI was not related to inferior outcome in terms of knee flexion (Fig. 5a), KSS pain and function score (Fig. 5b, c), and postoperative pain (Fig. 5d) during all time points.

Discussion

According to study results, obesity cannot be considered a contraindication for MIS-TKR as the complication rates are

Table 3 Component alignment[a]

Variable		MIS group	Standard group	*P* value (*t* test)
Femoral component alignment (degrees)	Coronal plane	95.1±0.9 (94 to 97)	95±0.7 (93 to 96)	0.62[b]
	Saggital plane	89.7±1.1 (87 to 92)	89.7±1 (87 to 92)	0.91[b]
Tibial component alignment (degrees)	Coronal plane	89.3±1.5 (85 to 95)	89.2±1 (87 to 90)	0.72[b]
	Saggital plane	87.8±0.9 (86 to 90)	88±0.7 (87 to 89)	0.23[b]

[a] Data are given as mean with standard deviation (SD) and range (min and max) in brackets

[b] Non-statistically significant (95% confidence interval)

very low and similar to that measured using a standard knee replacement technique. Minimal invasive approach is associated with less postoperative pain and higher clinical outcome scores compared to standard approach without leading to implant malpositioning. However, the functional benefits are somewhat temporarily as the values of outcome variables are generally equalized between both groups at 3 months following TKR.

Laskin [13] reported that MIS-TKR in patients with BMI>30 provided good results and no modification in the standard mini-midvastus approach was required for observation of the knee and implantation of the components. Although patients with BMI<30 had better knee motion, this failed to reach significance. Neither the Knee Society Scores nor the implant and entire limb alignment showed statistical significant differences between obese and non-obese patients. The procedure was also successful in six morbidly obese patients (BMI>40) despite the 2–3-cm extension of the midvastus split into the vastus medialis obliquus muscle. No extensor lag or quadriceps atrophy was reported and the knee flexion was 110° at 6 weeks postoperatively. Total blood loss and amounts of analgesics required were virtually the same compared with patients with a BMI<40. Similarly, we found that in obese MIS population group, increased BMI (>35) was not a predictor of poorer outcome with regards to knee pain and function during the first 2 years after surgery.

It seems that even in obese patients, soft tissue and muscle pliability allow a successful MIS-TKR [13, 14]. Scuderi et al. [14] noted that BMI could not be used in an algorithmic fashion to predict candidates for MIS-TKR. Agletti et al. [15] mentioned that fat distribution and consistency were probably more important and reliable factors in identifying candidates for mini-incision approaches. The authors believed that obese patients with relatively thin lower limbs and elastic tissues were suitable for short incisions. They suggested that limb length should be also taken under consideration as short, fatty lower limbs might often not eligible for this technique, even if there were no absolute guidelines in this regard. Likewise, Dalury and Dennis [10] indicated that short, muscular, and obese legs constituted a problem at the time of MIS-TKR. Lozano et al. [12, 16] reported that the anthropometric characteristics of the limb might also affect the difficulty of a knee replacement. They advocated that the diameter of the knee in the suprapatellar and anterior tibial tubercle regions and its relationship with the limb length should be determined to predict the degree of surgical difficulty. In our study, MIS was not associated with major surgical difficulties as no conversion to a standard approach was taken place and the incidence of wound problems or implant malpositioning was almost negligible.

The overall value of MIS in the outcome of TKR and the duration of its benefits are still debatable due to the variety of available data. Some authors have proved the superiority of MIS against traditional approaches in terms of knee

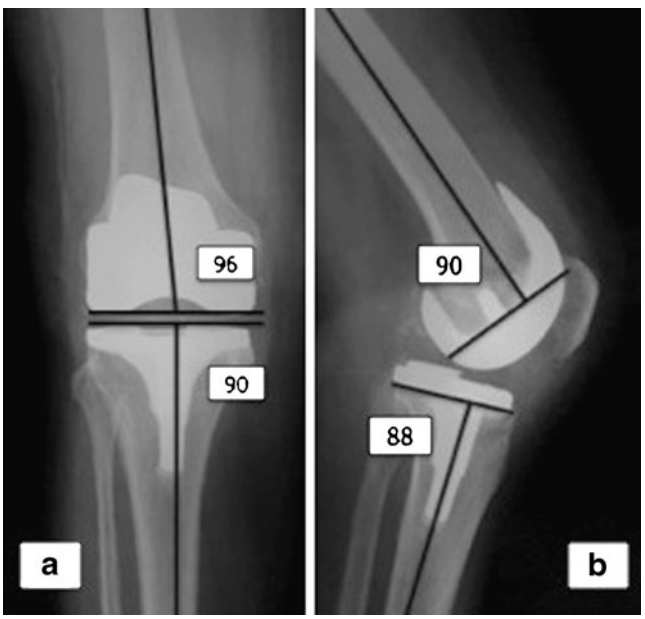

Fig. 4 Postoperative **a** anteroposterior and **b** lateral radiographs of a right knee 2 years after MIS-TKR. Implants position in relation to anatomical axis has been shown in coronal and sagittal planes. The presented values are in normal limits

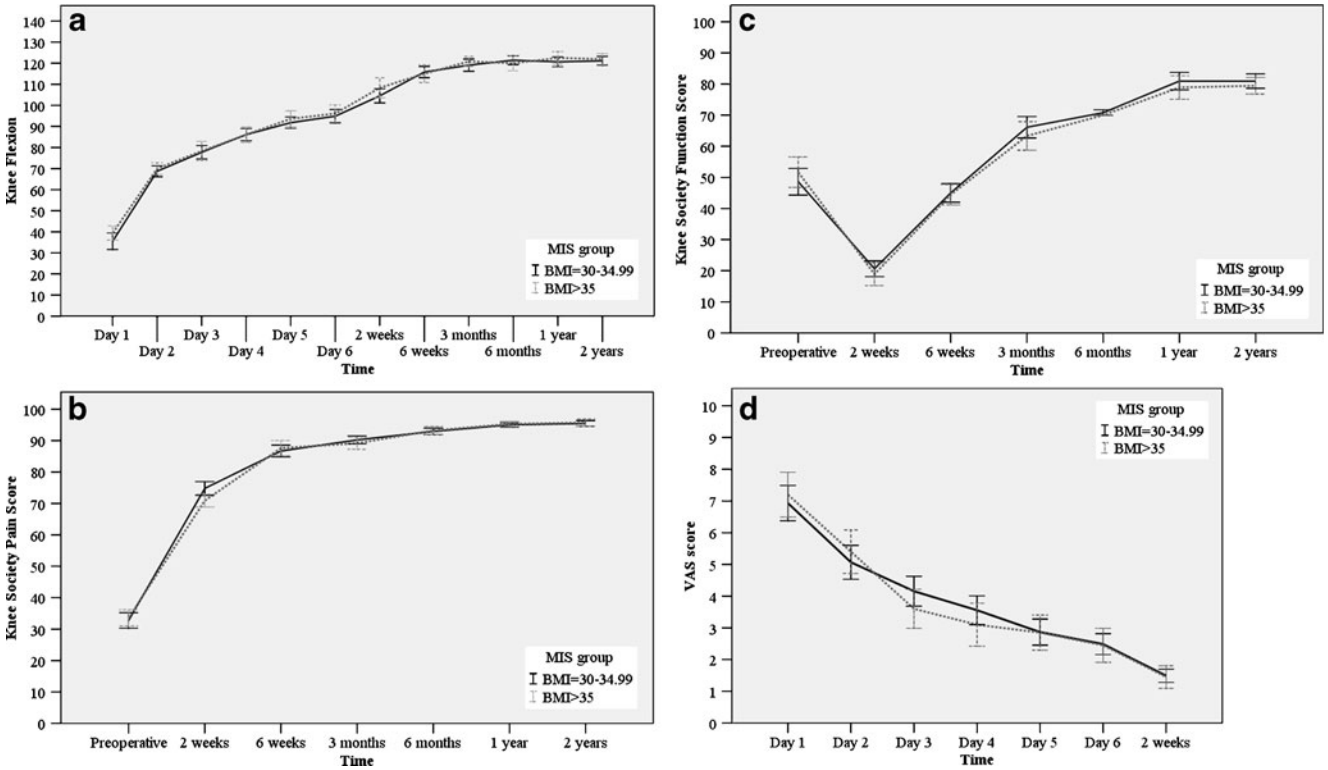

Fig. 5 Line graphs comparing mean **a** knee flexion, **b** knee society pain score, **c** knee society function score and **d** visual analog scale (VAS) pain score after MIS-TKR in obese patients with BMI<35 and BMI≥35. As only three patients had BMI≥40 but no higher than 42.1, only two (<35 and ≥35) instead of three (<35, 35–40 and ≥40) BMI categories were used. *Error bars* show the 95% confidence interval. No statistical significant difference is evident at all time points (overlap of the 95% confidence intervals)

function and ROM for 6 weeks to 3 months [17], others even for 1 year [18], and others have been unable to identify any detectable differences [10]. However, all the studies have demonstrated that MIS has been associated with 1–4 days faster return of active straight leg raising and less pain or narcotic analgesic requirement during the immediate postoperative period [10, 17, 19].

Due to shorter incision and limited knee arthrotomy during MIS, the immediate postoperative blood loss and transfusion requirements are expected to be lower than after standard approach [20]. However, this assumption was not confirmed in the current study. Our result was in agreement with that obtained by Laskin et al. [13] who found that the estimated total blood loss (from the drains) did not significantly defer between the two study groups [713 mL (SD±289 mL) for the MIS group and 573 mL (SD± 171 mL) for the standard group (p=0.04)]. We believe that as bleeding from the cut cancellous bone constitutes a major source of blood loss in knee arthroplasty, the length of skin incision or the extent of soft-tissue dissection may not primarily influence the total drain output [21]. Moreover, visualization and ligation of all the bleeding points especially from the posterior and lateral capsule is quite difficult even during the standard approaches. Apart from all the standardized ways to reduce postoperative bleeding such as use of bone cement or firmly applied dressing, the application of autologous transfusion drains can further reduce the requirement for donor blood products [21, 22].

Minimal invasive knee approaches have been largely accused for increasing the tourniquet time and frequency of wound complications. Dalury and Dennis [10] and Tenholder et al. [20] did not find any differences in tourniquet time between MIS-TKR and traditional TKR while Kim [23] and Kolisek et al. [24] reported significant difference in this variable between the two techniques. In spite of this, the total operative time may be equalized among the two treatment groups, as wound closure after MIS is faster and easier [10, 25]. It has been also proposed that wound problems should be more frequent in patients undergoing MIS-TKR as the skin is under excessively high tension throughout the procedure [24]. However, the majority of published trials, including this one, have failed to verify such an association [14, 20, 25, 26].

Although in the current study the implants were not malpositioned and there was no residual coronal or sagittal imbalance, exposure difficulties may raise concerns regarding the accurate orientation of the components, mainly on the tibial side. Dalury and Dennis [10] found four out of 30

tibial components to be malaligned (>4° from the mechanical axis). Aglietti et al. [27] recorded that in seven out of 55 knees that were operated with less invasive TKR, the tibial component showed a medial shift of 3 to 5 mm compared to the resected bone surface. According to authors, this was probably related to component undersizing attributable to limited intraoperative visualization of the posterolateral corner of the tibial plateau. We believe that the optimal use of soft-tissue "mobile window" from medial to lateral and from superior to inferior as necessary in association with administration of smaller instrumentation and cutting guides can substantially decrease the applying undue tension to the skin and capsular tissues and facilitate a satisfactory knee exposure.

The major limitations of the study were the relatively short follow-up period and the low number of morbidly obese patients. The follow-up for this study was 2 years because only early differences between the groups were of interest. As no major technical problems or side effects were encountered, the replacements done using the MIS approach are expected to have the same longevity seen by other knee replacements done using the traditional incision. The morbidly obese patients participating in the study represented only a small proportion of patients selected for TKR (three in MIS group and two in standard group). Therefore, they were not amenable to further statistical analysis. Another limitation of the study is the fact that the correlation between MIS and BMI was evaluated only in obese BMI classes. A future study based on all BMI categories will better clarify the clinical significance of obesity on the outcome of MIS-TKR.

In conclusion, obesity per se is not a contraindication to MIS-TKR, regardless the level of BMI. The technique can be effectively applied in obese patients (BMI>30) without expecting any unmanageable intraoperative difficulties or increased complication rates. Although knee mobility and function, patient satisfaction, and pain relief are considerably greater after MIS approach, the total benefits are usually temporary. Therefore, the decision for proceeding to a MIS or a standard TKR should be individualized based more on physician experience and patients' expectations or preferences rather than on leg fat distribution.

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