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Joint Line Obliquity Does Not Affect the Outcomes of Opening Wedge High Tibial Osteotomy at an Average 10-Year Follow-up

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Abstract

Background:

A significant number of high tibial osteotomies (HTOs) result in an overcorrected tibia and subsequent excessive lateral joint line obliquity (JLO). The correlation between excessive JLO and poor outcomes is controversial.

Purpose:

To evaluate the prognostic factors (including a pathological postoperative JLO) related with the outcomes of opening wedge HTO at 10 years of follow-up.

Study Design:

Case series; Level of evidence, 4.

Methods:

All patients undergoing HTO between 2004 and 2017 for medial osteoarthritis and with a postoperative hip-knee-ankle angle between 176° and 185° were included. Clinical evaluation included Knee Society Score (KSS; knee score and function score), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and visual analog scale for pain. Several mechanical and anatomic angles were measured pre- and postoperatively on long-leg weightbearing radiographs. Abnormal JLO was defined as a Mikulicz–joint line angle (MJL) $\geq 94^\circ$ or a mechanical medial proximal tibial angle (mMPTA) $\geq 95^\circ$. Regression analysis was

performed to evaluate the association between independent variables and each outcome. A Kaplan-Meier cumulative survival analysis was performed.

Results:

A total of 92 knees in 76 patients were included. The mean age of the patients was 53.5 years (SD, 9.7 years), and the mean follow-up was 129.4 months (SD, 44.4 months). Increased JLO was associated with a significant preoperative varus deformity (small preoperative hip-knee-ankle angle), increased mechanical lateral distal femoral angle, increased joint line congruency angle, and increased knee-ankle joint angle. Male sex was associated with better WOMAC scores ($P = .0277$), and increased body mass index (BMI) was associated with inferior WOMAC scores ($P = .0024$). A good preoperative range of motion was associated with better knee score ($P = .0399$) and function score ($P = .0366$) on the KSS. An increased BMI was associated with inferior KSS function scores ($P = .0317$). $MJL \geq 94^\circ$ and $mMPTA \geq 95^\circ$ were not associated with inferior WOMAC or KSS outcomes. With indication to total knee arthroplasty as an endpoint, Kaplan-Meier analysis showed a survival rate of 98.7% at 5 years, 95.5% at 10 years, and 92.7% at 12 years.

Conclusion:

Increased lateral JLO ($MJL \geq 94^\circ$ or $mMPTA \geq 95^\circ$) was not correlated with the clinical outcomes of opening wedge HTO at 10 years of follow-up.

High tibial osteotomy (HTO) is a valid option for the treatment of medial compartment overload/arthritis in young active patients with varus malaligned knees.² Several studies have shown that a significant number of HTOs result in an overcorrected tibia and subsequent excessive lateral joint line obliquity (JLO).^{4,8,11} Excessive JLO has been shown to be correlated with different factors: combined femoral- and tibial-based varus deformity, significant intra-articular deformity with a markedly increased joint line congruency angle (JLCA), severe preoperative varus malalignment (in these cases, a femoral deformity, an intra-articular deformity, or both, are often associated with tibia vara), and overcorrected knees resulting in excessive valgus alignment. In other words, HTO may result in altered JLO when the surgeon tries to compensate for intra-articular or femoral deformities with a tibial correction only, or when there is a technical error resulting in excessive valgus overcorrection of the lower limb. Different angles have been proposed in the literature for JLO measurement (Table 1), and some authors have described their criteria for unacceptable JLO. Babis et al⁴ theorized that operated knees with a JLO angle $>4^\circ$ had a higher risk of short survivorship. Lobenhoffer et al¹⁸ defined a pathological JLO as a Mikulicz-joint line angle (MJL) $>94^\circ$. Nakayama et al¹⁹ defined a mechanical medial proximal tibial angle (mMPTA) $>95^\circ$ as unacceptable.

Double-level osteotomies have been proposed to address complex deformity and minimize abnormal JLO.^{4,8} However, some clinically relevant issues are still debated regarding this topic. First and foremost, the correlation between excessive JLO and poor outcomes or inferior HTO survivorship has not yet been demonstrated. Furthermore, the most reliable

method (Table 1) to quantify and measure the JLO is not clear. In addition, the cutoff values for unacceptable JLO have not yet been defined.

The main goal of the present study was to evaluate the prognostic factors (including a pathological postoperative JLO) related to outcomes of opening wedge HTO (OWHTO) at 10 years of follow-up. The second aim of the study was to identify the factors related to an increased risk of postoperative pathological JLO, defined as an MJL $\geq 94^\circ$ or an mMPTA $\geq 95^\circ$.

Methods

This study was approved by the local ethical committee (University of Torino; protocol 01032021).

Data on all OWHTOs performed between 2004 and 2017 were collected. OWHTO was indicated in patients affected by medial compartment overload/arthritis who were < 65 years old with medial arthritic changes of grade < 3 according to the Ahlbäck classification and with varus malalignment. Absolute contraindications included symptomatic degenerative changes in the patellofemoral and lateral compartments, active infection, and markedly limited range of motion (flexion contracture $> 5^\circ$ or flexion $< 100^\circ$).⁷ The inclusion criteria for this study were as follows: isolated OWHTO or OWHTO associated with meniscectomy or minor cartilage procedures (eg, chondral abrasion or microfractures); complete pre- and postoperative radiographs available for review (weightbearing long leg, weightbearing anteroposterior and lateral views of the knee, and Merchant views); availability of prospectively collected clinical and subjective evaluation; a minimum 36 months of follow-up; and postoperative hip-knee-ankle angle (HKA) between 176° and 185° . An HKA $< 176^\circ$ or $> 185^\circ$, respectively representing a pathological varus or valgus lower limb alignment according to Hirschmann et al,¹⁴ was considered a major technical error with consequent lower limb malalignment and a potential bias for outcomes. For this reason, these patients were not included in the study.

Surgical Technique

Preoperatively, all osteotomies were planned as described by Dugdale et al.¹⁰ The degree of correction was based on the patient's age and severity of medial cartilage wear. Valgus correction of 3° to 5° was planned in cases of severe cartilage wear and older age, and a correction to neutral alignment was planned in younger patients with lower degrees of cartilage degeneration. Figure 1 shows an example of the preoperative planning.

In surgery, spinal or general anesthesia was administered. The patient was positioned supine with a tourniquet around the proximal thigh. If necessary, arthroscopy was performed first to treat chondral and meniscal lesions or rule out significant degeneration of the lateral and patellofemoral compartments. A 5-cm longitudinal incision was performed, extending from 1 cm below the medial joint line midway between the medial border of the tibial tubercle and the posteromedial border of the tibia. The sartorius fascia was incised and the pes anserinus retracted, and the distal insertion of the superficial medial collateral ligament was partially detached. Posterior neurovascular structures and patellar tendon were protected with a retractor throughout the whole procedure. A guide wire was inserted under fluoroscopy from the anteromedial tibia (approximately 4 cm distal from the joint line) to the tip of the fibular

head (approximately 1 cm below the lateral articular surface). A monoplanar osteotomy was performed parallel to the tibial slope and immediately distal to the guide wire. Thin osteotomes were used to advance the osteotomy within 1 cm of the lateral tibial cortex, under fluoroscopic guidance. The mobility of the osteotomy site was checked, and graduated wedges were used to open the osteotomy until the desired correction was achieved. Fluoroscopy was used to check the gap opening and limb alignment with dedicated long rods. Once the desired correction was achieved, the osteotomy was fixed using a Puddu spacer plate (Arthrex Inc). The gap was filled with bone allograft or bone substitutes only if the opening was >10 mm. Postoperatively the knee was placed in a hinged knee brace (unlocked from 0° to 90° of flexion) with toe-touch weightbearing for 6 weeks. After 6 weeks, radiographs were obtained, and depending on the healing of the osteotomy site, patients were progressed to full weightbearing. The brace was discontinued between 6 and 10 weeks after surgery. If microfractures were associated with OWHTO, patients were kept nonweightbearing for the first 30 days and then progressed as for isolated OWHTO.

Clinical and Radiographical Evaluations

Clinical and radiographical evaluations were prospectively recorded. Clinical evaluation included Knee Society Score (KSS; knee score and function score),¹⁵ Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score⁶ (reverse scored as recently suggested,²⁶ with 0 being the worst possible score), and visual analog scale for pain. The satisfaction of all patients regarding their surgery was evaluated with the following questions: “Would you undergo this surgery again?” and “Can you score your knee and your surgery from 0 to 10, with 10 being an excellent result?”

Long-leg weightbearing radiographs and weightbearing anteroposterior, lateral, and Merchant views were obtained preoperatively and during follow-up. Different angles were measured pre- and postoperatively by 2 sports medicine fellowship-trained orthopaedic surgeons (F.R. and D.E.B.) (Figure 2):

Mechanical lateral distal femoral angle (mLDFA): angle between the line tangent to distal femoral condyles and the mechanical axis of the femur. Values >90° were considered suggestive for a concomitant femoral-based varus deformity.^{22,23}

Mechanical medial proximal tibial angle (mMPTA): angle between the line tangent to proximal tibia and the mechanical axis of the tibia. Values <85° were considered suggestive for tibial-based varus deformity.^{22,23}

Joint line congruency angle (JLCA): angle between a line tangent to distal femoral condyles and a line tangent to the proximal tibial plateau. Values >2° with a lateral opening indicated a concomitant intra-articular deformity.^{22,23}

Mikulicz–joint line angle (MJL): the angle between the Mikulicz line^{10,22} (also known as the weightbearing line) and the bisector of the JLCA (the angle was measured medially). This angle measured the joint line inclination based on the mechanical axis (Mikulicz line). We decided to use the MJL to determine the JLO, instead of the JLO angle (angle between line tangent to the tibial condyles and the ground), because the JLO angle can be affected by the adduction/abduction of the lower limb in the long-leg radiographs and the MJL does not have

this limitation. The MJL angle was considered normal between 87° and 93°. Values >94° indicated a pathological valgus JLO according to Lobenhoffer et al.¹⁸

Knee-ankle joint line angle (KAJA): angle between the line tangent to the articular surface of the proximal and distal tibia. Positive values indicated a valgus orientation of the knee joint line.²⁹

Hip-knee-ankle angle (HKA): angle between a line from the center of the femoral head to the center of the knee and the line from the center of the knee to the center of the ankle joint (angle measured medially). Varus deformity was defined for values <180°. ^{22,23}

All measurements were performed with TraumaCAD (BrainLAB).

Data regarding patients' characteristics and surgery were collected: sex, body mass index (BMI), associated procedures, amount of gap opening, gap filling, subsequent hardware removal, and failures. Failure was defined as indication to total knee arthroplasty (TKA). Regression analysis was performed to evaluate the association between independent variables and each outcome (dependent variables). The variables tested are summarized in Appendix Table A1 (available in the online version of this article).

Based on previous studies, a pathological JLO was defined as an MJL >94° or mMPTA >95°. ^{18,19} In addition, a subgroup analysis was performed comparing patients with an MJL ≥94° and <94° as well as those with an mMPTA ≥95° and <95°.

Statistical Analysis

Data were reported as mean and standard deviation. A paired t test was used to compare KSS, WOMAC, radiographical angles, and other continuous variables before and after surgery. A chi-square test was used to compare categorical data.

Independent variables were initially tested to evaluate the correlation with each outcome (dependent variables), using the Pearson correlation coefficient for parametric variables and the Kendall rank coefficient for nonparametric variables. All variables that were close to significance ($P < .1$) were retested in a multiple or logistic regression model for continuous or dichotomous outcome variables, respectively. A logistic regression analysis was performed to evaluate risk factors for an increased JLO, defined as an MJL >94° or mMPTA >95°, and to evaluate the association between independent variables and postoperative KSS. A multiple regression analysis was also performed to evaluate risk factors associated with inferior WOMAC scores. A power analysis was performed for multiple and logistic regression analyses. For multiple regression analysis, a post hoc statistical power calculation was performed.⁹ For logistic regression, a post hoc power analysis with required sample size calculation was performed, using the area under the receiver operating characteristic (ROC) curve (obtained with the regression) with a null hypothesis value of 0.5, $\alpha = .05$, and $\beta = 0.2$, and comparing it with the sample size of the regression.¹³

For the subgroup analysis (MJL ≥94° vs <94°, mMPTA ≥95° vs <95°), a Student t test and chi-square test were used to compare continuous and categorical variables, respectively. An intraclass correlation coefficient was used to assess the interobserver reliability of the radiographical measurements. A Kaplan-Meier survival analysis was performed, with

indication to TKA as the endpoint. Statistics was performed with MedCalc Statistical Software (Version 16.4.3).

Results

Patients Demographics

A total of 92 knees (76 patients, 16 bilateral knees) met the inclusion criteria. Figure 3 shows the inclusion process according to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) criteria.

The mean age at the time of surgery was 53.5 ± 9.7 years and the mean BMI was 27.3 ± 3.6 . Of the total, 39 patients (51.3%) were male, and the average follow-up was >10 years (129.4 ± 44.4 months), with 30 patients having <10 years of follow-up. Simultaneous arthroscopic treatment of associated lesions was performed in 43 cases (46.7%): 13 cases (30.2%) of microfractures or chondral abrasion, 19 cases (44.2%) of medial meniscectomy, and 11 cases (25.6%) of both. In 63% of the cases, the gap was filled with bone substitute wedges, iliac bone autograft, or allograft. Hardware removal was performed in 18 cases (19.6%) at 33.6 ± 18.3 months after index surgery.

Clinical Evaluation

The range of motion slightly but significantly decreased pre- to postoperatively (123.7° to 122.4° , $P = .0425$); however, this difference can be considered clinically irrelevant. There was a statistically significant improvement in all scores. For the KSS, the mean knee score improved from 66.2 ± 13.3 to 79.6 ± 15.4 ($P < .0001$) and the function score from 62.7 ± 20.5 to 79.3 ± 18.1 ($P < .0001$). The WOMAC score significantly improved from 47.3 ± 18.5 preoperatively to 73.8 ± 18.7 ($P < .0001$) at last follow-up. The visual analog scale score significantly decreased from 7.7 ± 1.7 to 2.8 ± 2.6 . The patients stated that they would undergo HTO again in 82.6% of the cases. The average satisfaction score for the surgery was 8.5 ± 2 and that for the knee was 7.5 ± 2 .

Radiographical Evaluation

The intraclass correlation coefficient was >0.96 for all radiographical measurements, showing excellent interobserver reliability. Eighty-five knees (92.4%) had an Ahlbäck grade of osteoarthritis <3 . The average preoperative HKA was $174.1^\circ \pm 3.1^\circ$ and was corrected to $180.2^\circ \pm 2.4^\circ$ postoperatively ($P < .0001$). Preoperatively, 47.8% of cases (44 knees) had an mMPTA $<85^\circ$, indicating a tibial-based varus deformity, and 32.6% of cases (30 knees) had an mL DFA $>90^\circ$, indicating some degree of femoral-based varus deformity. The JLCA was $>2^\circ$ in 30.4% of cases (28 knees), indicating some degree of intra-articular deformity. Postoperatively, the percentage of knees with a JLCA $>2^\circ$ slightly increased (30 knees; 32.6%). The average MJL angle significantly changed from $88.3^\circ \pm 2.3^\circ$ preoperatively to $90.6^\circ \pm 2.7^\circ$ postoperatively ($P < .0001$). The postoperative MJL was $>94^\circ$ in 10 knees (10.9%). The KAJA significantly changed preoperatively to last follow-up ($-2.5^\circ \pm 4.5^\circ$ to $3.2^\circ \pm 4.2^\circ$; $P < .0001$). Last, 10 knees (10.9%) demonstrated an mMPTA $\geq 95^\circ$ postoperatively.

All radiographical measurements are summarized in Table 2.

Prognostic Factors Evaluation

As previously mentioned, one of the aims of the present study was to evaluate the factors associated with postoperative increased JLO, defined as an MJL $\geq 94^\circ$. With logistic regression analysis, different independent variables were correlated with an MJL $\geq 94^\circ$. A preoperative HKA close to 180° (which means a less significant varus deformity) was associated with a lower risk of postoperative MJL $\geq 94^\circ$ (odds ratio [OR], 0.5; 95% CI, 0.3-0.9; $P = .0218$). Conversely, a preoperative mL DFA $>90^\circ$ (ie, an associated femoral-based varus deformity) was strongly associated with an increased risk of a postoperative MJL $\geq 94^\circ$ (OR, 31.2; 95% CI, 1.4-700.6; $P = .0302$). As expected, the variable with the strongest association with an increased risk of a postoperative MJL $\geq 94^\circ$ was a postoperative mMPTA $\geq 95^\circ$ (OR, 76.1; 95% CI, 3.6-1601.3; $P = .0053$). Full results of this analysis are described in Appendix Table A2 (available online). Statistically significant results are summarized in Table 3.

With an area under the ROC curve of 0.971, $\alpha = .05$, and $\beta = 0.2$, the sample size required for 80% power was 10 per group (MJL was $\geq 94^\circ$ in 10 patients). Considering the strong relationship between an mMPTA $\geq 95^\circ$ and an increased risk of postoperative JLO, a regression analysis was performed searching for variables associated with a postoperative mMPTA $\geq 95^\circ$. As shown in Table 3, a preoperative HKA close to 180° (less significant varus deformity) was associated with a lower risk of a postoperative mMPTA $\geq 95^\circ$ (OR, 0.58; 95% CI, 0.4-0.9; $P = .0323$). Conversely, a preoperative JLCA $>2^\circ$ was associated with an increased risk of a postoperative mMPTA $\geq 95^\circ$ (OR, 14.1; 95% CI, 1.1-179.6; $P = .0423$). Also, a large preoperative KAJA was associated with an increased risk of a postoperative mMPTA $\geq 95^\circ$ (OR, 1.5; 95% CI, 1.1-2.1; $P = .0188$). Appendix Table A3 (available online) fully describes the results of the regression analysis.

The main goal of this study was to investigate independent variables related with the outcomes. With multiple regression analysis, 2 factors correlated with the postoperative WOMAC score. Male sex was associated with a better postoperative WOMAC score (coefficient, 8.2; $P = .0277$) as compared with female sex. Conversely, an increased BMI was associated with inferior postoperative WOMAC scores (coefficient, -1.6 ; $P = .0024$). However, no variables relative to the deformity (ie, preoperative mL DFA and JLCA or postoperative pathological JLO) were associated with inferior WOMAC scores. Significant results are summarized in Table 3, with the whole statistical analysis reported in Appendix Table A4 (available online).

This multiple regression analysis demonstrated good power at the post hoc calculation (0.96; observed $R^2 = 0.1716$; $\alpha = .05$; $n = 92$). A logistic regression was performed to evaluate associations between different variables and a suboptimal KSS knee or function score, defined as <80 points (Table 3).³ Preoperative range of motion was the only variable associated with postoperative KSS knee score: good preoperative range of motion was associated with a low probability of a suboptimal (<80 points) postoperative KSS knee score (OR, 0.7; 95% CI, 0.5-0.9; $P = .0399$) or KSS function score (OR, 0.7; 95% CI, 0.5-0.9; $P = .0366$). Conversely, an increased BMI was associated with an increased risk of a suboptimal KSS function score (OR, 1.2; 95% CI, 1-1.3; $P = .0317$). As shown in Appendix Table A5 (available online), no variables related to the deformity or postoperative JLO were associated with KSS knee and function scores.

With an area under the ROC curve of 0.726, $\alpha = .05$, and $\beta = 0.2$, the sample size required for 80% power for the KSS knee score in regression analysis was 50 cases, demonstrating low power for this analysis (38 cases with a postoperative KSS knee score <80 points). Conversely, with an area under ROC curve of 0.769, $\alpha = .05$, and $\beta = 0.2$, the sample size required for 80% power for the KSS function score in regression analysis was 35 cases, resulting in good power for this analysis (37 cases with postoperative KSS function score <80 points).

The subgroup analyses (patients with MJL $\geq 94^\circ$ vs $< 94^\circ$ and mMPTA $\geq 95^\circ$ vs $< 95^\circ$) basically confirmed the results of the regression analysis. Patients with a postoperative MJL $\geq 94^\circ$ and mMPTA $\geq 95^\circ$ had a significantly lower preoperative HKA (more significant preoperative varus deformity), a higher preoperative mL DFA (concomitant femoral-based deformity), and a higher preoperative JLCA (concomitant intra-articular deformity), as compared with patients with an MJL $< 94^\circ$ and mMPTA $< 95^\circ$. Between these groups, no differences were found in terms of clinical scores. This information is fully described in Appendix Table A6 (available online), with the clinically relevant data summarized in Table 4.

Complications

Intraoperative complications included 3 nondisplaced intra-articular fractures and 11 lateral hinge disruptions. Intra-articular fractures were recognized intraoperatively and treated with a 6.5-mm cannulated screw. Lateral hinged disruption was recognized intraoperatively in 8 cases and treated with a 6.5-mm cannulated screw from lateral to medial and from distal to proximal. In the remaining cases, the lateral hinge fracture was recognized during postoperative radiographical evaluation. No secondary displacement or loss of correction was detected during follow-up in these patients.

Major postoperative complications included 3 cases of deep venous thrombosis. Minor complications comprised painful proximal tibial hematoma (5 cases), delayed surgical wound healing (4 cases), and superficial infection (2 cases) successfully treated with oral antibiotics. All these complications completely resolved within 6 weeks from surgery.

Failures

Four knees (4.3%) were indicated for TKA during the follow-up and were therefore considered failures. In all 4 cases, the postoperative MJL was $< 94^\circ$ (2 patients with 88° , 1 with 89° , and 1 with 90°). A logistic regression analysis to evaluate possible risk factors for failure was not performed because the power analysis was significantly underpowered, with a required sample size of 10 patients for 80% power. With indication to TKA as the endpoint, a Kaplan-Meier cumulative survival analysis was performed (Figure 4), showing a survival rate of 98.7% at 5 years, 95.5% at 10 years, and 92.7% at 12 years.

Discussion

The main finding of this study was that increased lateral JLO (MJL $\geq 94^\circ$ or mMPTA $\geq 95^\circ$) was not correlated with the clinical outcomes (WOMAC and KSS function) of OWHTO at 10 years of follow-up. As a second finding, increased JLO was correlated with preoperative HKA, mL DFA, JLCA, and KAJA. Third, as expected, a postoperative MJL $\geq 94^\circ$ was strongly correlated

with a postoperative mMPTA $\geq 95^\circ$. Last, inferior outcomes were correlated with increased BMI and female sex.

Lateral JLO is a common postoperative finding after HTO, mostly in cases of combined femoral and tibial varus deformity and significant intra-articular deformity or because of a technical error resulting in excessive valgus overcorrection of the lower limb. In the present study, this is demonstrated by the correlation found between JLO parameter (MJL $\geq 94^\circ$ or mMPTA $\geq 95^\circ$) and preoperative HKA, mL DFA, and JLCA. This is not a new finding and confirms the results of other studies.^{21,28} For example, in a study of 69 knees, Oh et al²¹ found that preoperative HKA and JLCA were significant predictors of abnormal JLO after OWHTO. In the present study, increased KAJA also was correlated with postoperative JLO parameters, as shown in other studies.²⁹

A few laboratory studies showed that abnormal JLO after OWHTO is more common than previously thought, and they theorized its detrimental effect on the lateral compartment of the knee. Feucht et al¹¹ evaluated 303 long-leg weightbearing radiographs of patients with varus malalignment. A tibial deformity was observed in 28%, a femoral deformity in 23%, a combined deformity in 4%, and no bony deformity in 45%. The authors concluded that if anatomic correction (mMPTA $\leq 90^\circ$) was intended, only 12% of cases could be corrected via isolated HTO, whereas 63% would require a double-level osteotomy. In another laboratory study, Nakayama et al²⁰ performed a 3-dimensional finite element model showing that a JLO $>5^\circ$ induced excessive shear stress on the tibial articular cartilage, and they hypothesized that this could result in detrimental stress to the cartilage in vivo.

Despite these well-designed in vitro studies, the association between postoperative JLO and clinical outcomes of OWHTO has not yet been proven. Some studies reported inferior outcomes in patients with postoperative abnormal JLO. Schuster et al²⁵ retrospectively reviewed 79 knees with severe medial osteoarthritis (Kellgren-Lawrence grades 3 and 4), concluding that an overcorrected mMPTA ($>95^\circ$) was associated with inferior functional outcome at final follow-up. However, the authors performed this study in a unique population of severely degenerated knees. They also did not use logistic regression, and possible confounding factors combined with overcorrected mMPTA (ie, excessive valgus overcorrection of the lower limb) were not excluded. Akamatsu et al¹ divided patients after OWHTO into 2 groups: 43 patients with a postoperative mMPTA $\leq 95^\circ$ (healthy group) and 43 with an mMPTA $>95^\circ$. The authors concluded that at 2 years of follow-up, American Knee Society score and the Knee injury and Osteoarthritis Outcome Score (KOOS) in the healthy group were higher than in the increased mMPTA group ($P < .001$). However, the authors did not exclude patients with significant valgus overcorrection from their study. The amount of overcorrection in the increased group was higher than that in the healthy group ($P < .001$), and the postoperative weightbearing line ratio in the increased group (73.6) was higher than that in the healthy group (63.5%; $P < .001$). For these reasons, determining whether the inferior outcomes were due to the oblique joint line or the overcorrection was very difficult from the data presented by the authors.

Kubota et al¹⁶ reviewed 68 patients after OWHTO, at short-term follow-up (2.5 years on average), with the goal of assessing the correlation between JLO and clinical or functional results. With logistic regression, the authors found significant correlations between the

postoperative JLO and the KOOS in the subcategories of Pain, Activities of Daily Living, and Sport/Recreation. However, the postoperative JLO was not significantly correlated with the KSS, knee function, or muscle strength. Song et al²⁷ retrospectively reviewed 109 patients who underwent OWHTO, at midterm follow-up (mean, 55 months), with the goal of investigating the correlation between JLO and radiological or clinical outcomes. With a JLO cutoff of 4° in the multivariate regression analysis, JLO was associated with inferior KSS objective and functional scores but not with radiological results (medial joint space width). The adverse effect of JLO on radiological outcomes was evident with a JLO $\geq 6^\circ$.

Other studies did not find a significant correlation between outcomes of OWHTO and JLO. Among these studies, Goshima et al¹² retrospectively reviewed 94 patients, with a mean follow-up of 73.3 months. The patients were divided into 2 groups according to postoperative mMPTA: a healthy group (mMPTA $< 95^\circ$) and an overcorrected group (mMPTA $\geq 95^\circ$). No significant differences were noted in all clinical scores between the groups at the final follow-up. The authors concluded that a certain degree of overcorrected MPTA ($> 95^\circ$) did not affect the clinical outcomes because of compensatory changes in the hip and ankle joints. Similarly, Lee et al¹⁷ reviewed 50 patients who underwent HTO and, in the multiple regression analyses, found that the postoperative radiographical measures (including JLO) were not associated with the clinical outcomes 1 year after surgery.

The reasons for the conflicting results regarding the correlation between JLO and clinical results are not fully understood. Many studies with conflicting results used unreliable methods to measure the JLO—specifically, the JLO angle is measured between the floor and the line tangent to the tibial condyles and is significantly affected by the position of the lower limb with respect to the floor. Some studies finding no correlation between JLO and outcomes are definitely underpowered. Most studies supporting the negative effect of excessive JLO on outcomes and survivorship did not exclude overcorrected valgus knees or they omitted regression analyses, raising the question of whether these patients performed poorly because of the excessive JLO or the excessive valgus correction. We can also speculate regarding some other factors potentially affecting the outcomes: first, the ankle and subtalar joints could be responsible for some degrees of compensation in case of JLO, but this aspect is still poorly understood⁵; second, in all studies, including the present one, the JLO evaluation is performed in a static manner, and the role of an oblique joint line during gait is still unclear. In the present study, we tried to avoid some of the limitations described earlier.

The strengths of this study were as follows: long-term follow-up (mean, 10 years); exclusion of patients with mechanical axis overcorrection, which represents a confounding factor often associated with increased JLO and poor outcomes; and use of radiographical parameters for JLO (MJL and mMPTA) that are not affected by the abduction/adduction of the hip in long-leg standing radiographs (as opposed to other angles using the ground as a reference). Well-designed studies with large populations and long follow-up and without confounding factors are required to better elucidate the effects of JLO on HTO survivorship and possible lateral cartilage wear.

Despite the results of the present study, we believe that double-level osteotomies have a fundamental role among the realignment procedures around the knee, with good reported outcomes.^{4,8,24} Double-level osteotomies are definitely more invasive and costly (with 2

incisions, 2 osteotomies, and 2 fixation devices), but they also have significant advantages for the correction of large deformities, with a relatively low complication rate (3%).²⁴ There are other advantages of double-level osteotomies: retaining joint line orientation, avoiding large corrections at a single osteotomy site, reducing the complications of a large correction at a single osteotomy site (lateral hinge fractures, intra-articular fractures, nonunion, etc), and preserving the normal anatomy and joint line orientation and allowing for an easier conversion to TKA.

This study has several limitations. First, the study design was retrospective, and the cartilage status was not evaluated with magnetic resonance imaging during follow-up. Next, the correlation between failure (indication to TKA) and JLO could not be investigated, given the low number of failures (4 knees) and the consequent low power of the analysis. Similarly, the correlation between outcomes and the knee score subitem of the KSS was underpowered. In addition, we could not determine the critical values for postoperative MJL and mMPTA that would represent an indication for double-level osteotomy. Finally, this analysis was limited to patients with a postoperative HKA between 176° and 185° (which was considered an acceptable postoperative alignment) and may not be valid for knees outside this range (significantly under- or overcorrected knees).

In conclusion, based on the findings of the present study, JLO did not affect the outcomes of OWHTO at 10 years of follow-up, and different factors were related to an increased risk of pathological JLO, including preoperative femoral-based or intra-articular deformity, as well as increased postoperative mMPTA. Therefore, although double-level osteotomies have a fundamental role among the realignment procedures around the knee, the indications still need to be clearly elucidated and should not be based solely on postoperative JLO parameters (MJL $\geq 94^\circ$ or mMPTA $\geq 95^\circ$), as previously described.^{18,19}

Competing Interests

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Article - Knee

Joint Line Obliquity Does Not Affect the Outcomes of Opening Wedge High Tibial Osteotomy at an Average 10-Year Follow-up

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Background:A significant number of high tibial osteotomies (HTOs) result in an overcorrected tibia and subsequent excessive lateral joint line obliquity (JLO). The correlation between excessive JLO and poor outcomes is controversial.

Purpose:To evaluate the prognostic factors (including a pathological postoperative JLO) related with the outcomes of opening wedge HTO at 10 years of follow-up.

Study Design:Case series; Level of evidence, 4.

Methods:All patients undergoing HTO between 2004 and 2017 for medial osteoarthritis and with a postoperative hip-knee-ankle angle between 176° and 185° were included. Clinical evaluation included Knee Society Score (KSS; knee score and function score), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and visual analog scale for pain. Several mechanical and anatomic angles were measured pre- and postoperatively on long-leg weightbearing radiographs. Abnormal JLO was defined as a Mikulicz–joint line angle (MJL) $\geq 94^\circ$ or a mechanical medial proximal tibial angle (mMPTA) $\geq 95^\circ$. Regression analysis was performed to evaluate the association between independent variables and each outcome. A Kaplan-Meier cumulative survival analysis was performed.

Results:A total of 92 knees in 76 patients were included. The mean age of the patients was 53.5 years (SD, 9.7 years), and the mean follow-up was 129.4 months (SD, 44.4 months). Increased JLO was associated with a significant preoperative varus deformity (small preoperative hip-knee-ankle angle), increased mechanical lateral distal femoral angle, increased joint line congruency angle, and increased knee-ankle joint angle. Male sex was associated with better WOMAC scores ($P = .0277$), and increased body mass index (BMI) was associated with inferior WOMAC scores ($P = .0024$). A good preoperative range of motion was associated with better knee score ($P = .0399$) and function score ($P = .0366$) on the KSS. An increased BMI was associated with inferior KSS function scores ($P = .0317$). MJL $\geq 94^\circ$ and mMPTA $\geq 95^\circ$ were not associated with inferior WOMAC or KSS outcomes. With indication to total knee arthroplasty as an endpoint, Kaplan-Meier analysis showed a survival rate of 98.7% at 5 years, 95.5% at 10 years, and 92.7% at 12 years.

Conclusion:Increased lateral JLO (MJL $\geq 94^\circ$ or mMPTA $\geq 95^\circ$) was not correlated with the clinical outcomes of opening wedge HTO at 10 years of follow-up.

Keywords

osteotomy, HTO, arthritis, malalignment, joint line obliquity, clinical outcomes

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High tibial osteotomy (HTO) is a valid option for the treatment of medial compartment overload/arthritis in young active patients with varus malaligned knees.² Several studies have shown that a significant number of HTOs result in an overcorrected tibia and subsequent excessive lateral joint line obliquity (JLO).^{4,8,11} Excessive JLO has been shown to be correlated with different factors: combined femoral- and tibial-based varus deformity, significant intra-articular deformity with a markedly increased joint line congruency angle (JLCA), severe preoperative varus malalignment (in these cases, a femoral deformity, an intra-articular deformity, or both, are often associated with tibia vara), and overcorrected knees resulting in excessive valgus alignment. In other words, HTO may result in altered JLO when the surgeon tries to compensate for intra-articular or femoral deformities with a tibial correction only, or when there is a technical error resulting in excessive valgus overcorrection of the lower limb. Different angles have been proposed in the literature for JLO measurement (Table 1), and some authors have described their criteria for unacceptable JLO. Babis et al⁴ theorized that operated knees with a JLO angle $>4^\circ$ had a higher risk of short survivorship. Lobenhoffer et al¹⁸ defined a pathological JLO as a Mikulicz–joint line angle (MJL) $>94^\circ$. Nakayama et al¹⁹ defined a mechanical medial proximal tibial angle (mMPTA) $>95^\circ$ as unacceptable.

Double-level osteotomies have been proposed to address complex deformity and minimize abnormal JLO.^{4,8} However, some clinically relevant issues are still debated regarding this topic. First and foremost, the correlation between excessive JLO and poor outcomes or inferior HTO survivorship has not yet been demonstrated. Furthermore, the most reliable method (Table 1) to quantify and measure the JLO is not clear. In addition, the cutoff values for unacceptable JLO have not yet been defined.

The main goal of the present study was to evaluate the prognostic factors (including a pathological postoperative JLO) related to outcomes of opening wedge HTO (OWHTO) at 10 years of follow-up. The second aim of the study was to identify the factors related to an increased risk of postoperative pathological JLO, defined as an MJL $\geq 94^\circ$ or an mMPTA $\geq 95^\circ$.

Methods

This study was approved by the local ethical committee (University of Torino; protocol 01032021).

Data on all OWHTOs performed between 2004 and 2017 were collected. OWHTO was indicated in patients affected by medial compartment overload/arthritis who were <65 years old with medial arthritic changes of grade <3 according to the Ahlbäck classification and with varus malalignment. Absolute contraindications included symptomatic degenerative changes in the patellofemoral and lateral compartments, active infection, and markedly limited range of motion (flexion contracture $>5^\circ$ or flexion $<100^\circ$).⁷ The inclusion criteria for this study were as follows: isolated OWHTO or OWHTO associated with meniscectomy or minor cartilage procedures (eg, chondral abrasion or microfractures); complete pre- and postoperative radiographs available for review (weightbearing long leg, weightbearing anteroposterior and

lateral views of the knee, and Merchant views); availability of prospectively collected clinical and subjective evaluation; a minimum 36 months of follow-up; and postoperative hip-knee-ankle angle (HKA) between 176° and 185°. An HKA <176° or >185°, respectively representing a pathological varus or valgus lower limb alignment according to Hirschmann et al,¹⁴ was considered a major technical error with consequent lower limb malalignment and a potential bias for outcomes. For this reason, these patients were not included in the study.

Surgical Technique

Preoperatively, all osteotomies were planned as described by Dugdale et al.¹⁰ The degree of correction was based on the patient's age and severity of medial cartilage wear. Valgus correction of 3° to 5° was planned in cases of severe cartilage wear and older age, and a correction to neutral alignment was planned in younger patients with lower degrees of cartilage degeneration. Figure 1 shows an example of the preoperative planning.

Figure 1. (A) Long-leg weightbearing anteroposterior view of a right knee showing the weightbearing line, also known as Mikulicz line (white line), with the angle of correction (α). a_1 is determined first: the point on the tibial plateau where the mechanical axis should pass after correction. This can be planned at 50%, 55%, or 62.5% of the tibial plateau width, based on the patient's age and cartilage degeneration. The α is then determined; α is defined by 2 lines: 1 from the center of the femoral head to a_1 and 1 from the center of the ankle joint to a_1 (red lines). (B) Detail of the long-leg weightbearing anteroposterior view of a right knee. The osteotomy line is drawn (ab) and transferred on both rays of the α (a_1b_1 and a_1c_1). The distance b_1c_1 corresponds to the opening of the osteotomy site to achieve the planned correction.

In surgery, spinal or general anesthesia was administered. The patient was positioned supine with a tourniquet around the proximal thigh. If necessary, arthroscopy was performed first to treat chondral and meniscal lesions or rule out significant degeneration of the lateral and patellofemoral compartments. A 5-cm longitudinal incision was performed, extending from 1 cm below the medial joint line midway between the medial border of the tibial tubercle and the posteromedial border of the tibia. The sartorius fascia was incised and the pes anserinus retracted, and the distal insertion of the superficial medial collateral ligament was partially detached. Posterior neurovascular structures and patellar tendon were protected with a retractor throughout the whole procedure. A guide wire was inserted under fluoroscopy from the anteromedial tibia (approximately 4 cm distal from the joint line) to the tip of the fibular head (approximately 1 cm below the lateral articular surface). A monoplanar osteotomy was performed parallel to the tibial slope and immediately distal to the guide wire. Thin osteotomes were used to advance the osteotomy within 1 cm of the lateral tibial cortex, under fluoroscopic guidance. The mobility of the osteotomy site was checked, and graduated wedges were used to open the osteotomy until the desired correction was achieved. Fluoroscopy was used to check the gap opening and limb alignment with dedicated long rods. Once the desired correction was achieved, the osteotomy was fixed using a Puddu spacer plate (Arthrex Inc). The gap was filled with bone allograft or bone substitutes only if the opening was >10 mm. Postoperatively the knee was placed in a hinged knee brace (unlocked from 0° to 90° of flexion) with toe-touch weightbearing for 6 weeks. After 6 weeks, radiographs were obtained, and depending on the healing of the osteotomy site, patients were progressed

to full weightbearing. The brace was discontinued between 6 and 10 weeks after surgery. If microfractures were associated with OWHTO, patients were kept nonweightbearing for the first 30 days and then progressed as for isolated OWHTO.

Clinical and Radiographical Evaluations

Clinical and radiographical evaluations were prospectively recorded. Clinical evaluation included Knee Society Score (KSS; knee score and function score), 15 Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score⁶ (reverse scored as recently suggested,²⁶ with 0 being the worst possible score), and visual analog scale for pain. The satisfaction of all patients regarding their surgery was evaluated with the following questions: “Would you undergo this surgery again?” and “Can you score your knee and your surgery from 0 to 10, with 10 being an excellent result?”

Long-leg weightbearing radiographs and weightbearing anteroposterior, lateral, and Merchant views were obtained preoperatively and during follow-up. Different angles were measured pre- and postoperatively by 2 sports medicine fellowship-trained orthopaedic surgeons (F.R. and D.E.B.) (Figure 2):

Mechanical lateral distal femoral angle (mLDFA): angle between the line tangent to distal femoral condyles and the mechanical axis of the femur. Values $>90^\circ$ were considered suggestive for a concomitant femoral-based varus deformity.^{22,23}

Mechanical medial proximal tibial angle (mMPTA): angle between the line tangent to proximal tibia and the mechanical axis of the tibia. Values $<85^\circ$ were considered suggestive for tibial-based varus deformity.^{22,23}

Joint line congruency angle (JLCA): angle between a line tangent to distal femoral condyles and a line tangent to the proximal tibial plateau. Values $>2^\circ$ with a lateral opening indicated a concomitant intra-articular deformity.^{22,23}

Mikulicz–joint line angle (MJL): the angle between the Mikulicz line^{10,22} (also known as the weightbearing line) and the bisector of the JLCA (the angle was measured medially). This angle measured the joint line inclination based on the mechanical axis (Mikulicz line). We decided to use the MJL to determine the JLO, instead of the JLO angle (angle between line tangent to the tibial condyles and the ground), because the JLO angle can be affected by the adduction/abduction of the lower limb in the long-leg radiographs and the MJL does not have this limitation. The MJL angle was considered normal between 87° and 93° . Values $>94^\circ$ indicated a pathological valgus JLO according to Lobenhoffer et al.¹⁸

Knee-ankle joint line angle (KAJA): angle between the line tangent to the articular surface of the proximal and distal tibia. Positive values indicated a valgus orientation of the knee joint line.²⁹

Hip-knee-ankle angle (HKA): angle between a line from the center of the femoral head to the center of the knee and the line from the center of the knee to the center of the ankle joint (angle measured medially). Varus deformity was defined for values $<180^\circ$.^{22,23}

All measurements were performed with TraumaCAD (BrainLAB).

Figure 2. Radiographical measurements. HKA, hip-knee-ankle angle; JLCA, joint line congruency angle; KAJA, knee-ankle joint angle (the green line represents a line parallel to the distal tibia); MJL, Mikulicz–joint line; mL DFA, mechanical lateral distal femoral angle; mMPTA, mechanical medial proximal tibial angle.

Data regarding patients' characteristics and surgery were collected: sex, body mass index (BMI), associated procedures, amount of gap opening, gap filling, subsequent hardware removal, and failures. Failure was defined as indication to total knee arthroplasty (TKA). Regression analysis was performed to evaluate the association between independent variables and each outcome (dependent variables). The variables tested are summarized in Appendix Table A1 (available in the online version of this article).

Based on previous studies, a pathological JLO was defined as an MJL $>94^\circ$ or mMPTA $>95^\circ$.^{18,19} In addition, a subgroup analysis was performed comparing patients with an MJL $\geq 94^\circ$ and $<94^\circ$ as well as those with an mMPTA $\geq 95^\circ$ and $<95^\circ$.

Statistical Analysis

Data were reported as mean and standard deviation. A paired t test was used to compare KSS, WOMAC, radiographical angles, and other continuous variables before and after surgery. A chi-square test was used to compare categorical data.

Independent variables were initially tested to evaluate the correlation with each outcome (dependent variables), using the Pearson correlation coefficient for parametric variables and the Kendall rank coefficient for nonparametric variables. All variables that were close to significance ($P < .1$) were retested in a multiple or logistic regression model for continuous or dichotomous outcome variables, respectively. A logistic regression analysis was performed to evaluate risk factors for an increased JLO, defined as an MJL $>94^\circ$ or mMPTA $>95^\circ$, and to evaluate the association between independent variables and postoperative KSS. A multiple regression analysis was also performed to evaluate risk factors associated with inferior WOMAC scores. A power analysis was performed for multiple and logistic regression analyses. For multiple regression analysis, a post hoc statistical power calculation was performed.⁹ For logistic regression, a post hoc power analysis with required sample size calculation was performed, using the area under the receiver operating characteristic (ROC) curve (obtained with the regression) with a null hypothesis value of 0.5, $\alpha = .05$, and $\beta = 0.2$, and comparing it with the sample size of the regression.¹³

For the subgroup analysis (MJL $\geq 94^\circ$ vs $<94^\circ$, mMPTA $\geq 95^\circ$ vs $<95^\circ$), a Student t test and chi-square test were used to compare continuous and categorical variables, respectively. An intraclass correlation coefficient was used to assess the interobserver reliability of the radiographical measurements. A Kaplan-Meier survival analysis was performed, with indication to TKA as the endpoint. Statistics was performed with MedCalc Statistical Software (Version 16.4.3).

Results

Patients Demographics

A total of 92 knees (76 patients, 16 bilateral knees) met the inclusion criteria. Figure 3 shows the inclusion process according to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) criteria.

Figure 3. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) diagram for inclusion process. OWHTO, opening wedge high tibial osteotomy.

The mean age at the time of surgery was 53.5 ± 9.7 years and the mean BMI was 27.3 ± 3.6 . Of the total, 39 patients (51.3%) were male, and the average follow-up was >10 years (129.4 ± 44.4 months), with 30 patients having <10 years of follow-up. Simultaneous arthroscopic treatment of associated lesions was performed in 43 cases (46.7%): 13 cases (30.2%) of microfractures or chondral abrasion, 19 cases (44.2%) of medial meniscectomy, and 11 cases (25.6%) of both. In 63% of the cases, the gap was filled with bone substitute wedges, iliac bone autograft, or allograft. Hardware removal was performed in 18 cases (19.6%) at 33.6 ± 18.3 months after index surgery.

Clinical Evaluation

The range of motion slightly but significantly decreased pre- to postoperatively (123.7° to 122.4° , $P = .0425$); however, this difference can be considered clinically irrelevant. There was a statistically significant improvement in all scores. For the KSS, the mean knee score improved from 66.2 ± 13.3 to 79.6 ± 15.4 ($P < .0001$) and the function score from 62.7 ± 20.5 to 79.3 ± 18.1 ($P < .0001$). The WOMAC score significantly improved from 47.3 ± 18.5 preoperatively to 73.8 ± 18.7 ($P < .0001$) at last follow-up. The visual analog scale score significantly decreased from 7.7 ± 1.7 to 2.8 ± 2.6 . The patients stated that they would undergo HTO again in 82.6% of the cases. The average satisfaction score for the surgery was 8.5 ± 2 and that for the knee was 7.5 ± 2 .

Radiographical Evaluation

The intraclass correlation coefficient was >0.96 for all radiographical measurements, showing excellent interobserver reliability. Eighty-five knees (92.4%) had an Ahlbäck grade of osteoarthritis <3 . The average preoperative HKA was $174.1^\circ \pm 3.1^\circ$ and was corrected to $180.2^\circ \pm 2.4^\circ$ postoperatively ($P < .0001$). Preoperatively, 47.8% of cases (44 knees) had an mMPTA $<85^\circ$, indicating a tibial-based varus deformity, and 32.6% of cases (30 knees) had an mL DFA $>90^\circ$, indicating some degree of femoral-based varus deformity. The JLCA was $>2^\circ$ in 30.4% of cases (28 knees), indicating some degree of intra-articular deformity. Postoperatively, the percentage of knees with a JLCA $>2^\circ$ slightly increased (30 knees; 32.6%). The average MJL angle significantly changed from $88.3^\circ \pm 2.3^\circ$ preoperatively to $90.6^\circ \pm 2.7^\circ$ postoperatively ($P < .0001$). The postoperative MJL was $>94^\circ$ in 10 knees (10.9%). The KAJA significantly changed preoperatively to last follow-up ($-2.5^\circ \pm 4.5^\circ$ to $3.2^\circ \pm 4.2^\circ$; $P < .0001$). Last, 10 knees (10.9%) demonstrated an mMPTA $\geq 95^\circ$ postoperatively.

All radiographical measurements are summarized in Table 2.

Prognostic Factors Evaluation

As previously mentioned, one of the aims of the present study was to evaluate the factors associated with postoperative increased JLO, defined as an MJL $\geq 94^\circ$. With logistic regression

analysis, different independent variables were correlated with an MJL $\geq 94^\circ$. A preoperative HKA close to 180° (which means a less significant varus deformity) was associated with a lower risk of postoperative MJL $\geq 94^\circ$ (odds ratio [OR], 0.5; 95% CI, 0.3-0.9; $P = .0218$). Conversely, a preoperative mL DFA $>90^\circ$ (ie, an associated femoral-based varus deformity) was strongly associated with an increased risk of a postoperative MJL $\geq 94^\circ$ (OR, 31.2; 95% CI, 1.4-700.6; $P = .0302$). As expected, the variable with the strongest association with an increased risk of a postoperative MJL $\geq 94^\circ$ was a postoperative mMPTA $\geq 95^\circ$ (OR, 76.1; 95% CI, 3.6-1601.3; $P = .0053$). Full results of this analysis are described in Appendix Table A2 (available online). Statistically significant results are summarized in Table 3.

With an area under the ROC curve of 0.971, $\alpha = .05$, and $\beta = 0.2$, the sample size required for 80% power was 10 per group (MJL was $\geq 94^\circ$ in 10 patients). Considering the strong relationship between an mMPTA $\geq 95^\circ$ and an increased risk of postoperative JLO, a regression analysis was performed searching for variables associated with a postoperative mMPTA $\geq 95^\circ$. As shown in Table 3, a preoperative HKA close to 180° (less significant varus deformity) was associated with a lower risk of a postoperative mMPTA $\geq 95^\circ$ (OR, 0.58; 95% CI, 0.4-0.9; $P = .0323$). Conversely, a preoperative JLCA $>2^\circ$ was associated with an increased risk of a postoperative mMPTA $\geq 95^\circ$ (OR, 14.1; 95% CI, 1.1-179.6; $P = .0423$). Also, a large preoperative KAJA was associated with an increased risk of a postoperative mMPTA $\geq 95^\circ$ (OR, 1.5; 95% CI, 1.1-2.1; $P = .0188$). Appendix Table A3 (available online) fully describes the results of the regression analysis.

The main goal of this study was to investigate independent variables related with the outcomes. With multiple regression analysis, 2 factors correlated with the postoperative WOMAC score. Male sex was associated with a better postoperative WOMAC score (coefficient, 8.2; $P = .0277$) as compared with female sex. Conversely, an increased BMI was associated with inferior postoperative WOMAC scores (coefficient, -1.6 ; $P = .0024$). However, no variables relative to the deformity (ie, preoperative mL DFA and JLCA or postoperative pathological JLO) were associated with inferior WOMAC scores. Significant results are summarized in Table 3, with the whole statistical analysis reported in Appendix Table A4 (available online).

This multiple regression analysis demonstrated good power at the post hoc calculation (0.96; observed $R^2 = 0.1716$; $\alpha = .05$; $n = 92$). A logistic regression was performed to evaluate associations between different variables and a suboptimal KSS knee or function score, defined as <80 points (Table 3).³ Preoperative range of motion was the only variable associated with postoperative KSS knee score: good preoperative range of motion was associated with a low probability of a suboptimal (<80 points) postoperative KSS knee score (OR, 0.7; 95% CI, 0.5-0.9; $P = .0399$) or KSS function score (OR, 0.7; 95% CI, 0.5-0.9; $P = .0366$). Conversely, an increased BMI was associated with an increased risk of a suboptimal KSS function score (OR, 1.2; 95% CI, 1-1.3; $P = .0317$). As shown in Appendix Table A5 (available online), no variables related to the deformity or postoperative JLO were associated with KSS knee and function scores.

With an area under the ROC curve of 0.726, $\alpha = .05$, and $\beta = 0.2$, the sample size required for 80% power for the KSS knee score in regression analysis was 50 cases, demonstrating low power for this analysis (38 cases with a postoperative KSS knee score <80 points). Conversely,

with an area under ROC curve of 0.769, $\alpha = .05$, and $\beta = 0.2$, the sample size required for 80% power for the KSS function score in regression analysis was 35 cases, resulting in good power for this analysis (37 cases with postoperative KSS function score <80 points).

The subgroup analyses (patients with MJL $\geq 94^\circ$ vs $< 94^\circ$ and mMPTA $\geq 95^\circ$ vs $< 95^\circ$) basically confirmed the results of the regression analysis. Patients with a postoperative MJL $\geq 94^\circ$ and mMPTA $\geq 95^\circ$ had a significantly lower preoperative HKA (more significant preoperative varus deformity), a higher preoperative mL DFA (concomitant femoral-based deformity), and a higher preoperative JLCA (concomitant intra-articular deformity), as compared with patients with an MJL $< 94^\circ$ and mMPTA $< 95^\circ$. Between these groups, no differences were found in terms of clinical scores. This information is fully described in Appendix Table A6 (available online), with the clinically relevant data summarized in Table 4.

Complications

Intraoperative complications included 3 nondisplaced intra-articular fractures and 11 lateral hinge disruptions. Intra-articular fractures were recognized intraoperatively and treated with a 6.5-mm cannulated screw. Lateral hinged disruption was recognized intraoperatively in 8 cases and treated with a 6.5-mm cannulated screw from lateral to medial and from distal to proximal. In the remaining cases, the lateral hinge fracture was recognized during postoperative radiographical evaluation. No secondary displacement or loss of correction was detected during follow-up in these patients.

Major postoperative complications included 3 cases of deep venous thrombosis. Minor complications comprised painful proximal tibial hematoma (5 cases), delayed surgical wound healing (4 cases), and superficial infection (2 cases) successfully treated with oral antibiotics. All these complications completely resolved within 6 weeks from surgery.

Failures

Four knees (4.3%) were indicated for TKA during the follow-up and were therefore considered failures. In all 4 cases, the postoperative MJL was $< 94^\circ$ (2 patients with 88° , 1 with 89° , and 1 with 90°). A logistic regression analysis to evaluate possible risk factors for failure was not performed because the power analysis was significantly underpowered, with a required sample size of 10 patients for 80% power. With indication to TKA as the endpoint, a Kaplan-Meier cumulative survival analysis was performed (Figure 4), showing a survival rate of 98.7% at 5 years, 95.5% at 10 years, and 92.7% at 12 years.

Figure 4. Kaplan-Meier cumulative survivorship, with indication to total knee arthroplasty as an endpoint.

Discussion

The main finding of this study was that increased lateral JLO (MJL $\geq 94^\circ$ or mMPTA $\geq 95^\circ$) was not correlated with the clinical outcomes (WOMAC and KSS function) of OWHTO at 10 years of follow-up. As a second finding, increased JLO was correlated with preoperative HKA, mL DFA, JLCA, and KAJA. Third, as expected, a postoperative MJL $\geq 94^\circ$ was strongly correlated with a postoperative mMPTA $\geq 95^\circ$. Last, inferior outcomes were correlated with increased BMI and female sex.

Lateral JLO is a common postoperative finding after HTO, mostly in cases of combined femoral and tibial varus deformity and significant intra-articular deformity or because of a technical error resulting in excessive valgus overcorrection of the lower limb. In the present study, this is demonstrated by the correlation found between JLO parameter (MJL $\geq 94^\circ$ or mMPTA $\geq 95^\circ$) and preoperative HKA, mL DFA, and JLCA. This is not a new finding and confirms the results of other studies.^{21,28} For example, in a study of 69 knees, Oh et al²¹ found that preoperative HKA and JLCA were significant predictors of abnormal JLO after OWHTO. In the present study, increased KAJA also was correlated with postoperative JLO parameters, as shown in other studies.²⁹

A few laboratory studies showed that abnormal JLO after OWHTO is more common than previously thought, and they theorized its detrimental effect on the lateral compartment of the knee. Feucht et al¹¹ evaluated 303 long-leg weightbearing radiographs of patients with varus malalignment. A tibial deformity was observed in 28%, a femoral deformity in 23%, a combined deformity in 4%, and no bony deformity in 45%. The authors concluded that if anatomic correction (mMPTA $\leq 90^\circ$) was intended, only 12% of cases could be corrected via isolated HTO, whereas 63% would require a double-level osteotomy. In another laboratory study, Nakayama et al²⁰ performed a 3-dimensional finite element model showing that a JLO $>5^\circ$ induced excessive shear stress on the tibial articular cartilage, and they hypothesized that this could result in detrimental stress to the cartilage in vivo.

Despite these well-designed in vitro studies, the association between postoperative JLO and clinical outcomes of OWHTO has not yet been proven. Some studies reported inferior outcomes in patients with postoperative abnormal JLO. Schuster et al²⁵ retrospectively reviewed 79 knees with severe medial osteoarthritis (Kellgren-Lawrence grades 3 and 4), concluding that an overcorrected mMPTA ($>95^\circ$) was associated with inferior functional outcome at final follow-up. However, the authors performed this study in a unique population of severely degenerated knees. They also did not use logistic regression, and possible confounding factors combined with overcorrected mMPTA (ie, excessive valgus overcorrection of the lower limb) were not excluded. Akamatsu et al¹ divided patients after OWHTO into 2 groups: 43 patients with a postoperative mMPTA $\leq 95^\circ$ (healthy group) and 43 with an mMPTA $>95^\circ$. The authors concluded that at 2 years of follow-up, American Knee Society score and the Knee injury and Osteoarthritis Outcome Score (KOOS) in the healthy group were higher than in the increased mMPTA group ($P < .001$). However, the authors did not exclude patients with significant valgus overcorrection from their study. The amount of overcorrection in the increased group was higher than that in the healthy group ($P < .001$), and the postoperative weightbearing line ratio in the increased group (73.6) was higher than that in the healthy group (63.5%; $P < .001$). For these reasons, determining whether the inferior outcomes were due to the oblique joint line or the overcorrection was very difficult from the data presented by the authors.

Kubota et al¹⁶ reviewed 68 patients after OWHTO, at short-term follow-up (2.5 years on average), with the goal of assessing the correlation between JLO and clinical or functional results. With logistic regression, the authors found significant correlations between the postoperative JLO and the KOOS in the subcategories of Pain, Activities of Daily Living, and Sport/Recreation. However, the postoperative JLO was not significantly correlated with the

KSS, knee function, or muscle strength. Song et al²⁷ retrospectively reviewed 109 patients who underwent OWHTO, at midterm follow-up (mean, 55 months), with the goal of investigating the correlation between JLO and radiological or clinical outcomes. With a JLO cutoff of 4° in the multivariate regression analysis, JLO was associated with inferior KSS objective and functional scores but not with radiological results (medial joint space width). The adverse effect of JLO on radiological outcomes was evident with a JLO $\geq 6^\circ$.

Other studies did not find a significant correlation between outcomes of OWHTO and JLO. Among these studies, Goshima et al¹² retrospectively reviewed 94 patients, with a mean follow-up of 73.3 months. The patients were divided into 2 groups according to postoperative mMPTA: a healthy group (mMPTA $< 95^\circ$) and an overcorrected group (mMPTA $\geq 95^\circ$). No significant differences were noted in all clinical scores between the groups at the final follow-up. The authors concluded that a certain degree of overcorrected MPTA ($> 95^\circ$) did not affect the clinical outcomes because of compensatory changes in the hip and ankle joints. Similarly, Lee et al¹⁷ reviewed 50 patients who underwent HTO and, in the multiple regression analyses, found that the postoperative radiographical measures (including JLO) were not associated with the clinical outcomes 1 year after surgery.

The reasons for the conflicting results regarding the correlation between JLO and clinical results are not fully understood. Many studies with conflicting results used unreliable methods to measure the JLO—specifically, the JLO angle is measured between the floor and the line tangent to the tibial condyles and is significantly affected by the position of the lower limb with respect to the floor. Some studies finding no correlation between JLO and outcomes are definitely underpowered. Most studies supporting the negative effect of excessive JLO on outcomes and survivorship did not exclude overcorrected valgus knees or they omitted regression analyses, raising the question of whether these patients performed poorly because of the excessive JLO or the excessive valgus correction. We can also speculate regarding some other factors potentially affecting the outcomes: first, the ankle and subtalar joints could be responsible for some degrees of compensation in case of JLO, but this aspect is still poorly understood⁵; second, in all studies, including the present one, the JLO evaluation is performed in a static manner, and the role of an oblique joint line during gait is still unclear. In the present study, we tried to avoid some of the limitations described earlier.

The strengths of this study were as follows: long-term follow-up (mean, 10 years); exclusion of patients with mechanical axis overcorrection, which represents a confounding factor often associated with increased JLO and poor outcomes; and use of radiographical parameters for JLO (MJL and mMPTA) that are not affected by the abduction/adduction of the hip in long-leg standing radiographs (as opposed to other angles using the ground as a reference). Well-designed studies with large populations and long follow-up and without confounding factors are required to better elucidate the effects of JLO on HTO survivorship and possible lateral cartilage wear.

Despite the results of the present study, we believe that double-level osteotomies have a fundamental role among the realignment procedures around the knee, with good reported outcomes.^{4,8,24} Double-level osteotomies are definitely more invasive and costly (with 2 incisions, 2 osteotomies, and 2 fixation devices), but they also have significant advantages for the correction of large deformities, with a relatively low complication rate (3%).²⁴ There are

other advantages of double-level osteotomies: retaining joint line orientation, avoiding large corrections at a single osteotomy site, reducing the complications of a large correction at a single osteotomy site (lateral hinge fractures, intra-articular fractures, nonunion, etc), and preserving the normal anatomy and joint line orientation and allowing for an easier conversion to TKA.

This study has several limitations. First, the study design was retrospective, and the cartilage status was not evaluated with magnetic resonance imaging during follow-up. Next, the correlation between failure (indication to TKA) and JLO could not be investigated, given the low number of failures (4 knees) and the consequent low power of the analysis. Similarly, the correlation between outcomes and the knee score subitem of the KSS was underpowered. In addition, we could not determine the critical values for postoperative MJL and mMPTA that would represent an indication for double-level osteotomy. Finally, this analysis was limited to patients with a postoperative HKA between 176° and 185° (which was considered an acceptable postoperative alignment) and may not be valid for knees outside this range (significantly under- or overcorrected knees).

In conclusion, based on the findings of the present study, JLO did not affect the outcomes of OWHTO at 10 years of follow-up, and different factors were related to an increased risk of pathological JLO, including preoperative femoral-based or intra-articular deformity, as well as increased postoperative mMPTA. Therefore, although double-level osteotomies have a fundamental role among the realignment procedures around the knee, the indications still need to be clearly elucidated and should not be based solely on postoperative JLO parameters (MJL $\geq 94^\circ$ or mMPTA $\geq 95^\circ$), as previously described.^{18,19}

Conflict of Interest

One or more of the authors has declared the following potential conflict of interest or source of funding: D.E.B. has received consulting fees from Arthrex and editorial royalties from Elsevier and Springer. R.R. has received speaking fees from Arthrex, Zimmer-Biomet, Lima, Medacta, Smith & Nephew, and DePuy. AOSSM checks author disclosures against the Open Payments Database (OPD). AOSSM has not conducted an independent investigation on the OPD and disclaims any liability or responsibility relating thereto.

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TABLE 1
Different Angles Described for Joint Line Obliquity Measurement

| Angle | Description |
|---|--|
| Joint line obliquity angle | Angle between a line parallel to the ground and a line tangent to the tibial condyles |
| Mikulicz-joint line angle | The angle between the Mikulicz line (also known as the weightbearing line) and the bisector of the joint line congruency angle |
| Mechanical medial proximal tibial angle | Angle between the line tangent to the proximal tibia and the mechanical axis of the tibia |

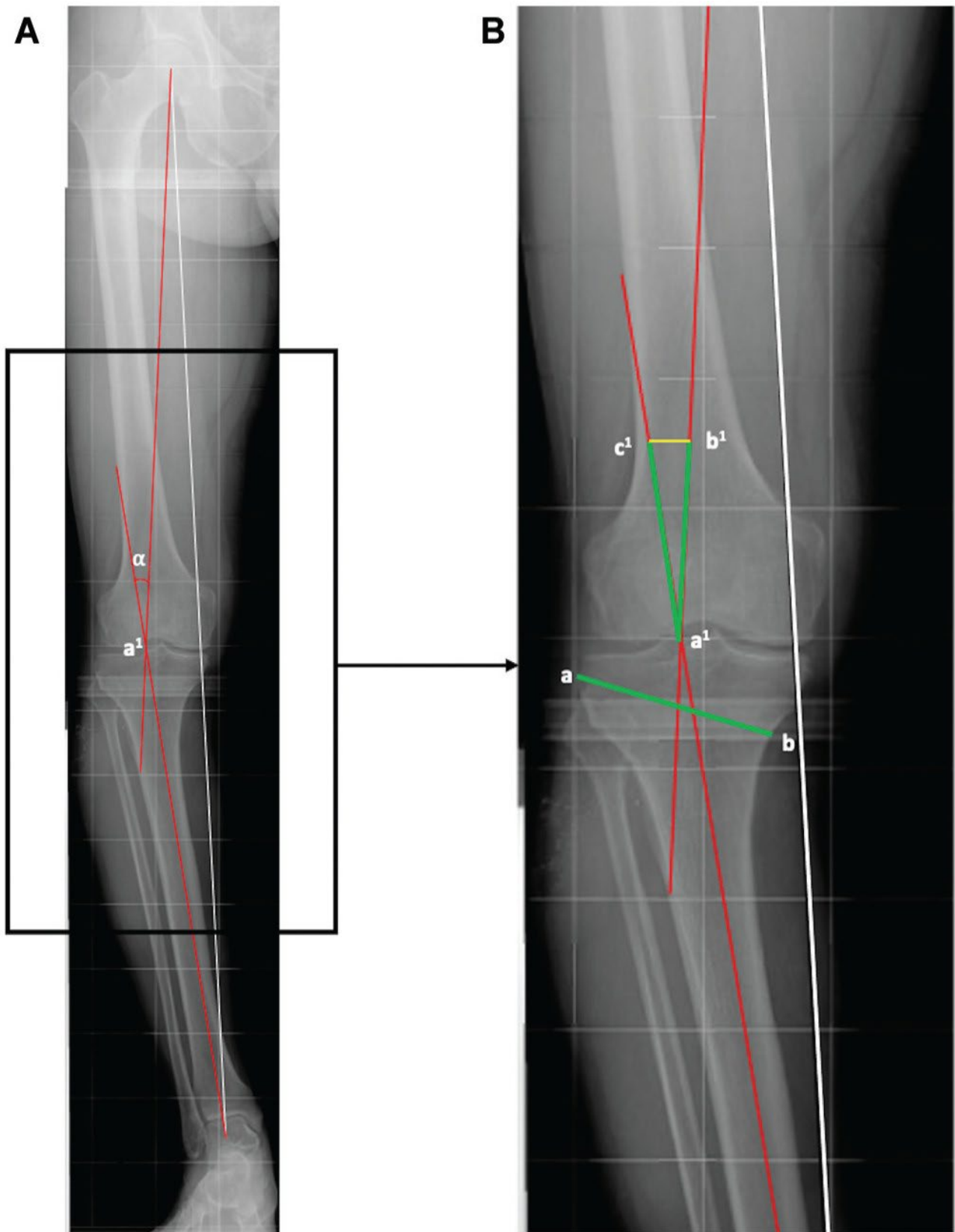


Figure 1. (A) Long-leg weightbearing anteroposterior view of a right knee showing the weightbearing line, also known as Mikulicz line (white line), with the angle of correction (α). a^1 is determined first: the point on the tibial plateau where the mechanical axis should pass after

correction. This can be planned at 50%, 55%, or 62.5% of the tibial plateau width, based on the patient's age and cartilage degeneration. The α is then determined; α is defined by 2 lines: 1 from the center of the femoral head to a1 and 1 from the center of the ankle joint to a1 (red lines). (B) Detail of the long-leg weightbearing anteroposterior view of a right knee. The osteotomy line is drawn (ab) and transferred on both rays of the α (a1b1 and a1c1). The distance b1c1 corresponds to the opening of the osteotomy site to achieve the planned correction.

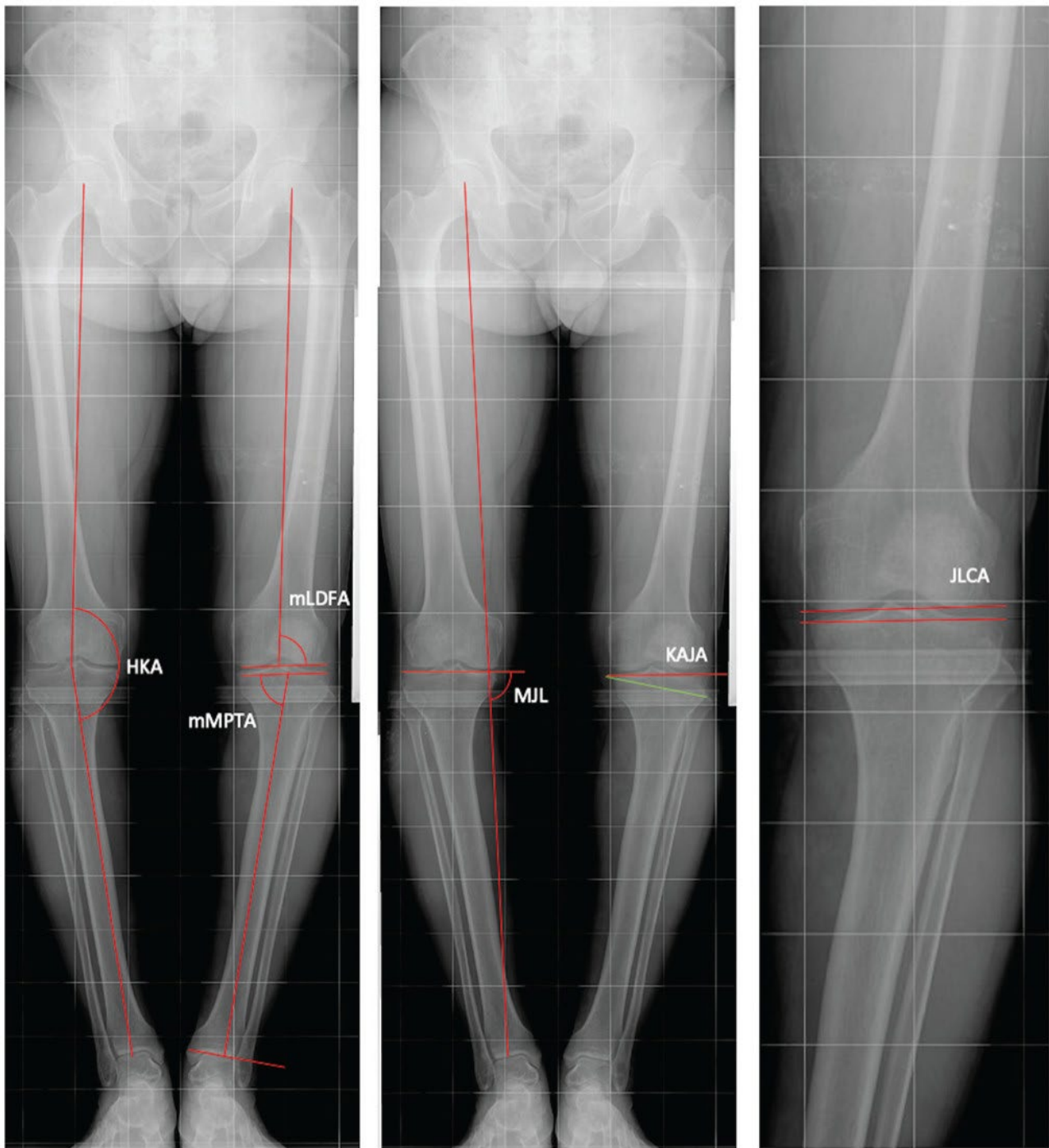


Figure 2. Radiographical measurements. HKA, hip-knee-ankle angle; JLCA, joint line congruency angle; KAJA, knee-ankle joint angle (the green line represents a line parallel to the

distal tibia); MJL, Mikulicz–joint line; mL DFA, mechanical lateral distal femoral angle; mMPTA, mechanical medial proximal tibial angle.

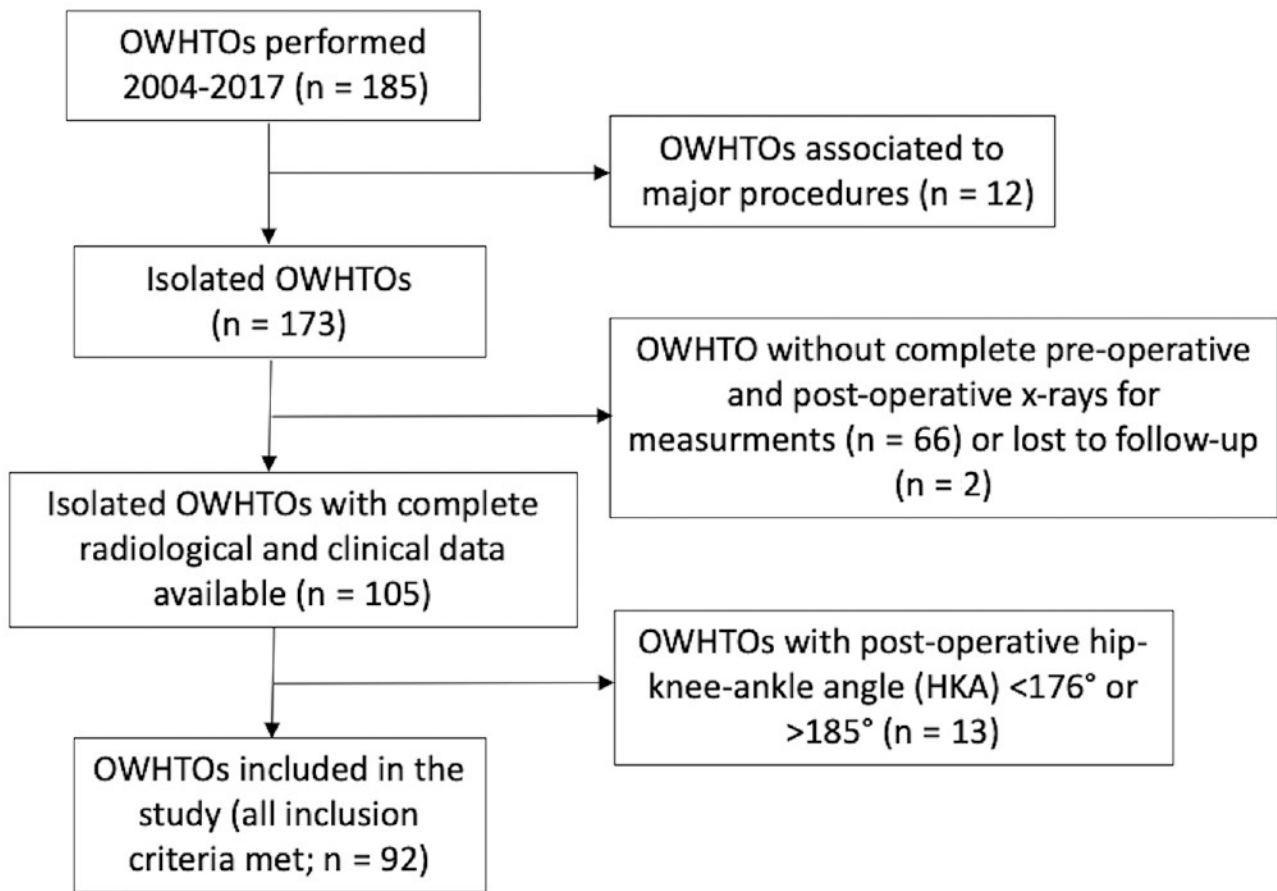


Figure 3. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) diagram for inclusion process. OWHTO, opening wedge high tibial osteotomy.

TABLE 2
Radiographical Measurements in Preoperative and Last Follow-up Evaluations^a

| Parameter: Angle | Preoperative | Last Follow-up | P Value |
|-----------------------------------|--------------|----------------|---------|
| Hip-knee-ankle | 174.1 (3.1) | 180.2 (2.4) | <.0001 |
| Mechanical lateral distal femoral | 89.6 (2.2) | 90.3 (2.6) | .0785 |
| Mechanical medial proximal tibial | 85.1 (2.8) | 91.5 (3.1) | <.0001 |
| Joint line congruency | 1.9 (1.4) | 1.6 (1.7) | .3155 |
| Knee-ankle joint | -2.5 (4.5) | 3.2 (4.2) | <.0001 |
| Mikulicz–joint line | 88.3 (2.3) | 90.6 (2.7) | <.0001 |

^aValues are presented as mean (SD; in degrees). Bold represents statistically significant differences ($P < .05$).

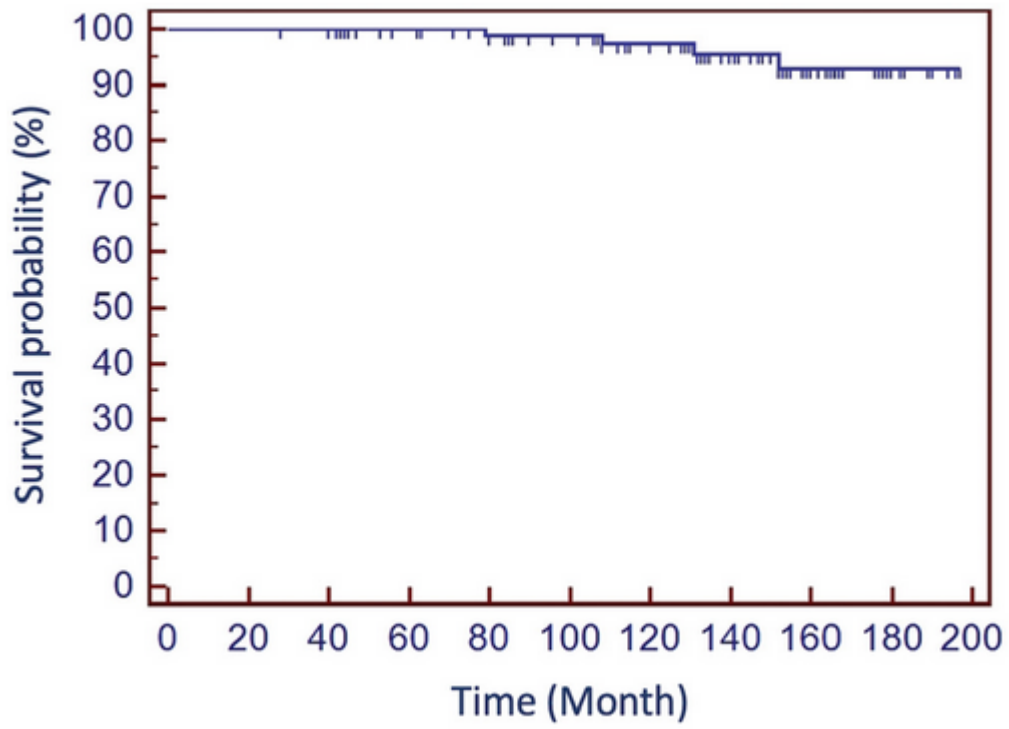


Figure 4. Kaplan-Meier cumulative survivorship, with indication to total knee arthroplasty as an endpoint.