Outcomes of Open Wedge High Tibial Osteotomy with Puddu Plate, with a Minimum Follow-up of 5 Years

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ABSTRACT

Objectives: To determine the survival rate of high tibial osteotomy for medial knee osteoarthritis and describe functional outcomes and the satisfaction rate. **Materials and Methods:** Observational, analytical study with retrospective data collection. A total of 51 patients were operated on between 2011 and 2017. Variables studied included age, sex, preoperative BMI, VAS for pre- and postoperative pain, WOMAC and Lysholm functional scores, SF-12 quality of life scores, satisfaction with the procedure, and conversion to arthroplasty. **Results:** The average age at the time of surgery was 55.7 years, with an average BMI of 29.7. Follow-up ranged from 5 to 11 years. We observed a statistically significant decrease in VAS scores from 7.96 ± 2.27 to 3.04 ± 2.73. The average survival time of the osteotomy was 10.53 years (95% CI, 9.6–11.4). Patient satisfaction was positive in 76.5% of cases, showing a statistically significant difference and better outcomes in the evaluated scores. The conversion rate to total knee arthroplasty (TKA) was 19.6%. There was no statistically significant relationship between conversion to TKA and the initial age, BMI, or VAS score. **Conclusions:** Open wedge high tibial osteotomy showed excellent outcomes with a minimum follow-up of 5 years, with a survival rate and conversion to arthroplasty comparable to international literature. There was a statistically significant reduction in pain according to VAS scores, and younger patients reported higher satisfaction with the procedure.

Keywords: Tibial valgus osteotomy; tibial opening wedge osteotomy; Puddu plate; genu varum; medial compartment osteoarthritis.
Level of Evidence: IV

Resultados de la osteotomía valguizante de apertura tibial con placa Puddu. Seguimiento mínimo de 5 años

RESUMEN

Objetivos: Determinar la supervivencia de la osteotomía valguizante tibial, en genu varo artrósico, y valorar los resultados funcionales y el grado de satisfacción. **Materiales y Métodos:** Estudio observacional, analítico con recolección retrospectiva de datos en 51 pacientes operados entre 2011 y 2017. Las variables estudiadas fueron: edad, sexo, índice de masa corporal preoperatorio, escala analógica visual para dolor pre y posoperatorio, puntajes funcionales WOMAC y Lysholm, SF-12, grado de satisfacción con el procedimiento y conversión a artroplastia. **Resultados:** El promedio de edad al operarse fue de 55.7 años, el índice de masa corporal, de 29,7. El seguimiento fue de 5 a 11 años. El puntaje de la escala analógica visual disminuyó de 7,96 ± 2,27 a 3,04 ± 2,73. El tiempo promedio de supervivencia de la osteotomía fue de 10.53 años (IC95% 9,6-11,4). El 76,5% estaba satisfecho con el procedimiento, se observaron una diferencia estadísticamente significativa y mejores resultados en los puntajes calculados. La tasa de conversión a artroplastia total de rodilla fue del 19,6%. No hubo una relación estadísticamente significativa entre la tasa de conversión a artroplastia total de rodilla y la edad, el índice de masa corporal o la escala analógica visual inicial. **Conclusiones:** Los resultados de la osteotomía fueron muy buenos a los 5 años de seguimiento mínimo y las tasas de supervivencia y conversión a artroplastia fueron comparable con las de la bibliografía internacional. Se destaca la disminución estadísticamente significativa del dolor y que los pacientes más jóvenes estaban más satisfechos con el procedimiento.

Palabras clave: Osteotomía valguizante de tibia; osteotomía tibial de apertura; placa Puddu; genu varo; artrosis de compartimento interno.
Nivel de Evidencia: IV

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INTRODUCTION

Tibial valgus osteotomy is an established procedure for the non-prosthetic treatment of arthritic genu varum in young, active patients and for medial osteochondral lesions.[1]

Over time, the treatment of this condition has evolved, and arthroplasties have been replaced by osteotomies. Over the past 20 years, osteotomies have been extensively studied and refined, with the best results seen in patients under 60 years of age, who have medial unicompartmental osteoarthritis and remain active at work.[2]

This procedure aims to decompress the medial compartment in the early stages and improve knee function by shifting the mechanical axis toward the Fujisawa point, located on the lateral tibial plateau, which should remain relatively intact.[3] This is achieved by overcorrecting the varus deviation to 2-6° of valgus. Two main approaches have been described: lateral closing wedge tibial osteotomies and medial opening wedge tibial osteotomies. Although successful, lateral closing wedge osteotomies are technically more demanding, carry a higher risk of serious complications, and can compromise the tibial bone stock for future prosthesis use. These factors have led to the growing popularity of medial opening wedge osteotomies between 1990 and 2000.[1,4,5]

Medial opening wedge tibial osteotomies are a safe procedure that provide good functional outcomes in the medium to long term, especially with the advent of new implants.[5] Among the fixation methods designed, the two most commonly used in our setting are the Puddu plate (Tibial Opening Wedge Osteotomy Plate, Arthrex Inc., Naples, Florida, USA) and the TomoFix system (TomoFix Plate, DePuy Synthes, West Chester, PA, USA) (Figure 1).

The Puddu plate uses the principle of dynamic compression and has two generations: the first with four conventional screws, and the second with two locking and two conventional screws. On the other hand, the TomoFix system consists of an anatomically designed implant that follows the principle of locking osteosynthesis. This system has been shown to provide greater resistance to compressive and rotational forces, allow biological consolidation without the need for bone grafting, and enable early rehabilitation with very good functional outcomes (Figure 1).[5-8]

Figure 1. Puddu and TomoFix plates (Images extracted from the implant suppliers' web catalogs).

Somewhat unfavorable outcomes have been reported for total knee arthroplasty (TKA) in younger patients, with revision rates of 35% in men aged 50-54 years and a median survival rate of 4.4 years in patients under 60. These outcomes are thought to be associated with work, leisure, and lifestyle activities.[9] Currently, the published survival rate for medial opening wedge tibial osteotomy is 94% at 5 years and 85% at 10 years.[10]

The primary objective of this study was to determine the survival time of tibial valgus osteotomy using the Puddu plate in a population of patients with arthritic genu varum, classified as Ahlbäck type 2. The endpoint for this study was defined as the time when patients required conversion to TKA. Secondary objectives were to evaluate postoperative functional outcomes and assess patient satisfaction with the procedure.

MATERIALS AND METHODS

This was an observational, analytical study with retrospective data collection. The population consisted of all patients with symptomatic Ahlbäck type 2 genu varum, treated with tibial valgus osteotomy using the Puddu plate by the same surgical team at a single center between January 2011 and December 2017, with a minimum follow-up of 5 years.

Data were collected through a review of medical records and telephone interviews. The interviews were conducted between August 2022 and March 2023, ensuring a minimum of 5 years after osteotomy. The following instruments were used: the SF12 (*Short Form 12 Health Survey*) questionnaire (for quality of life), the Lysholm scale (for function), the WOMAC (*Western Ontario and McMaster Universities Osteoarthritis Index*) questionnaire (for function), the visual analog scale (VAS) for pain, and a satisfaction survey regarding the procedure.

Variables were analyzed by two investigators who reviewed surgical descriptions, available preoperative and postoperative images (Figure 2), and assessed qualitative variables.

Figure 2. Female patient operated at 64 years of age. Anteroposterior weight-bearing radiograph of the knee before surgery (**A**) and at 8 years of follow-up (**B**). Goniometry before surgery (**C**) and at 8 years of follow-up (**D**).

Patient characteristics such as sex, age at surgery, height, and weight were recorded. During the telephone interview, patients were asked about their satisfaction with the procedure, their SF12 scores, Lysholm scale scores, and WOMAC scores.

Pain before and after the procedure was assessed using the VAS. For the preoperative VAS score, patients were asked to recall the pain they experienced prior to the osteotomy. For the postoperative VAS score, the pain at the time of the interview was considered for patients who still had the osteotomy, and the pain prior to TKA was considered for those who underwent the conversion. For other variables (Lysholm, SF12, and WOMAC), data were recorded at the time of the interview for those who still had the osteotomy, while retrospective data were used for patients who underwent TKA.

Radiographic analysis could not be performed on all patients, as radiographic digitization was not available during the early years of the study.

Possible complications, such as infections, thrombosis, nonunion, implant breakage, tibial plateau fracture, and implant intolerance, were recorded through the telephone interview, medical records, and radiographic analysis when applicable.

This study received institutional approval and was endorsed by the Ethics Committee. All patients provided informed consent.

Statistical Analysis

Data were entered into Microsoft Office Excel®. Qualitative variables are expressed as absolute and relative frequencies; associations between these variables were analyzed using the Chi-squared test or Fisher's exact test, as appropriate.

Quantitative variables are expressed as means with corresponding standard deviations. Non-parametric tests were used to compare means: the Wilcoxon rank-sum test or Mann-Whitney U test for two-group comparisons, depending on whether the data were paired, and the Kruskal-Wallis test for comparisons of more than two groups.

Data processing was carried out in the IBM SPSS Statistics V23.0 program. A significance level of 0.05 was considered for all inferential analyses.

RESULTS

Demographic data

The study population consisted of 51 patients: 31 women (61%) and 20 men (39%). A total of 51 procedures were performed: 25 on right knees (49%) and 26 on left knees (51%). The characteristics of the patients are detailed in Table 1. The reason for the intervention in all cases was to treat symptomatic degenerative genu varum, classified as Ahlbäck type 2. The mean age at the time of surgery was 55.7 ± 7.6 years.

The distribution according to body mass index (BMI) at the time of surgery was as follows: normal weight (6 patients, 11.8%), overweight (17 patients, 33.3%), and obese (28 patients, 54.9%).

Table 1. Characteristics of the patients in the sample.

Age (years)	55.7 ± 7.6
Initial weight (kg)	81.7 ± 13.8
Size (m)	1.66 ± 0.10
Initial body mass index	29.7 ± 4.7

Complications

Ten patients (19.6%) experienced one or more complications (Table 2). Five patients suffered a fracture of the lateral cortical hinge: in one case, the implant broke before consolidation, necessitating a second operation with a Puddu plate; one did not consolidate, requiring the placement of a TomoFix plate; and three achieved consolidation without problems. Four patients experienced intolerance to the implant, which was subsequently removed. Two patients developed deep vein thrombosis, which was successfully treated with medical management. One patient's osteotomy did not consolidate (as previously mentioned with the lateral cortical fracture), and another patient suffered a fracture of the external tibial plateau, which was treated with the same implant, deferring weight-bearing for a longer period. The overall evolution in these cases was excellent.

Table 2. Complications.

Complication	n	%
Lateral cortical hinge fracture	5	14.3
Intolerance after consolidation	4	11.6
Deep vein thrombosis	2	5.7
Implant breakage before consolidation	1	2.9
Lateral tibial plateau fracture	1	2.9
Nonunion	1	2.9

Clinical Scores Analyzed

The mean preoperative VAS score was 7.96 ± 2.27, which decreased to 3.04 ± 2.73 after surgery. This difference was significant ($p < 0.001$), indicating a clear reduction in pain scores following the procedure (Table 3, Figure 3).

Table 3. Pre- and postoperative variables analyzed, expressed as mean and confidence interval.

Variable		Mean (SD) or frequencies		p
Survival time (years)		10.53 (95% CI 9.6-11.4)		-
Would you undergo surgery again? (Yes)		39	76.5%	-
VAS score	Pre-op	7.96 ± 2.27		<0.001*
	Post-op	3.04 ± 2.73		
Lysholm Scale		72.9 ± 26.1		-
SF-12 Questionnaire (Physical)		44.3 ± 11.7		-
SF-12 Questionnaire (Mental)		59.4 ± 8.9		-
WOMAC Pain		4.22 ± 4.66		-
WOMAC Stiffness		1.29 ± 1.63		-
WOMAC Function		13.06 ± 15.95		-
WOMAC Total		18.06 ± 21.61		-

(*) Statistically significant value. (-) does not apply to p-value calculation since it cannot be compared. SD = standard deviation. VAS = visual analog scale. WOMAC = *Western Ontario and McMaster Universities Osteoarthritis Index.*

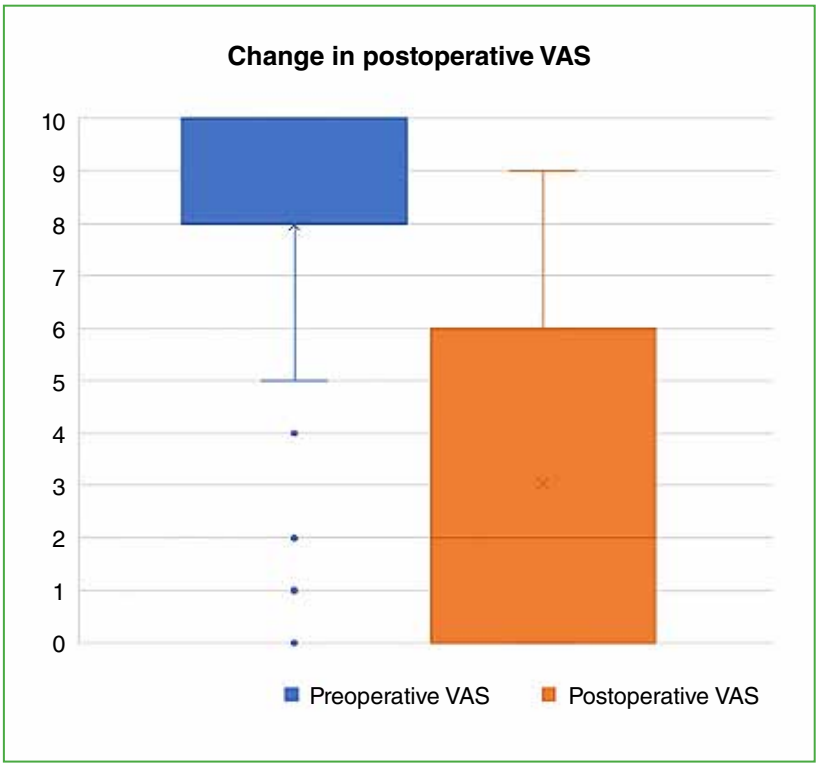

Figure 3. Box plot for the preoperative and postoperative visual analog scale variable.

The SF-12 questionnaire score at the end of follow-up showed a mean of 44.3 ± 11.7 for the Physical component and 59.4 ± 8.9 for the Mental component.

The mean WOMAC score at the end of follow-up was 18.06 ± 21.61, broken down into categories: 4.22 ± 4.66 (Pain), 1.29 ± 1.63 (Stiffness), and 13.06 ± 15.95 (Function).

The mean score on the Lysholm scale at the end of follow-up was 72.9 ± 26.1.

Intervention Survival Time

The median survival time post-intervention was 10.53 years (95% confidence interval [95% CI] 9.595-11.370). This calculation was based on the time at which conversion to total knee arthroplasty (TKA) became necessary due to the progression of degenerative disease and increasing pain.

Osteotomy survival rates were 86.3% (95% CI 76.9-95.7) at 5 years and 79.2% (95% CI 67.4-91.0) at 10 years.

Degree of satisfaction with the procedure

76.5% (39 patients) reported satisfaction with the procedure and indicated that they would undergo the surgery again. Reasons for dissatisfaction included difficulties in rehabilitation and postoperative pain. Table 4 presents the degree of satisfaction according to preoperative variables such as age, BMI, and preoperative VAS score. It was noted that patients who would not undergo surgery again had an average age of 59.8 years, which represents a statistically significant difference. No significant relationship was found between satisfaction rates and BMI or preoperative VAS scores.

Table 4. Degree of satisfaction according to preoperative variables.

Preoperative variables	Would you undergo surgery again?		p
	Yes (n = 39)	No (n =12)	
Age	54.4 ± 7.7	59.8 ± 5.9	0.037*
Body mass index	29.1 ± 4.6	31.7 ± 4.5	0.157
VAS score	7.9 ± 2.2	8.1 ± 2.7	0.434

(*) Statistically significant value. VAS = visual analog scale.

Table 5 illustrates the degree of satisfaction with the procedure according to postoperative variables. Notably, the significantly lower pain reported in the VAS after surgery among satisfied patients (those who would undergo surgery again) was 2.23 ± 2.19, while in those who were not satisfied (who would not undergo surgery again), it was 5.67 ± 2.71. Additionally, patients who were satisfied with the surgery had an average osteotomy survival that was three years longer (9.05 vs. 6.08) compared to those who were not satisfied.

Table 5. Degree of satisfaction according to postoperative variables.

Postoperative variables	Would you undergo surgery again?		p
	Yes (n = 39)	No (n = 12)	
VAS score	2.23 ± 2.19	5.67 ± 2.71	0.001*
Osteotomy survival time	9.05 ± 2.21	6.08 ± 3.15	0.003*
Lysholm Scale	78.41 ± 24.27	51.60 ± 22.75	0.003*
SF-12 Questionnaire (Physical)	46.58 ± 10.84	35.53 ± 11.20	0.010*
SF-12 Questionnaire (Mental)	60.91 ± 6.19	53.61 ± 14.69	0.080
WOMAC Pain	3.10 ± 4.14	8.60 ± 4.06	0.002*
WOMAC Stiffness	0.85 ± 1.39	3.00 ± 1.14	0.001*
WOMAC Function	9.41 ± 14.27	27.30 ± 14.62	0.001*

(*) Statistically significant value. VAS = visual analog scale. WOMAC = *Western Ontario and McMaster Universities Osteoarthritis Index*.

All analyzed scores, except for the SF-12 Mental component, demonstrated statistical significance in the values obtained between those who would undergo surgery again and those who would not. Thus, it can be concluded that those who would consider reoperation achieved better clinical outcomes, as well as longer osteotomy survival times.

Conversion to TKA

Ten patients (19.6%) required conversion to TKA. When comparing the rate of TKA based on the analyzed preoperative variables, no statistical significance was found; however, a higher rate of TKA was observed in patients with a BMI > 30, those older than 55 years, and those experiencing disabling pain (VAS > 7) (Table 5). Patients who would not consider reoperation had a higher rate of conversion to TKA, which was statistically significant (Table 6).

Table 6. Conversion rate to total knee arthroplasty as a function of preoperative variables and degree of satisfaction with the procedure.

		Conversion to total knee arthroplasty		p
		Yes (n = 10)	No (n = 41)	
Age >55	Yes (n = 29)	7	22	0.483
	No (n = 22)	3	19	
Body mass index >30	Yes (n = 27)	7	20	0.300
	No (n = 24)	3	21	
VAS score	Not disabling (n = 10)	0	10	0.178
	Invalidating (n = 41)	10	31	
Would you undergo surgery again?	Yes (n = 39)	3	36	0.001*
	No (n = 12)	7	5	

(*) Statistically significant value. VAS = visual analog scale.

DISCUSSION

There is consensus in the literature that the results of tibial valgus osteotomy are favorable in the first 5 to 10 years, but they tend to deteriorate after this period.[11] As previously mentioned, the aim of surgery is to slow down the degenerative process of the knee, improve pain and function, and delay early total knee arthroplasty (TKA) in occupationally active patients.[12-14] In our series, there was a statistically significant difference between the preoperative and postoperative VAS scores for pain. The mean preoperative VAS score was 7.96 ± 2.27, which decreased to 3.04 ± 2.73 postoperatively.

Regarding the average survival time of the osteotomy, different systematic reviews and meta-analyses have reported average results at 5 and 10 years (88.6%-97.1% and 64-94.8%, respectively).[2,10,15] In our population, the survival rate of the osteotomy was 86.3% at 5 years and 79.2% at 10 years, which is somewhat lower than in published international studies. Considering that the mean survival time was 10.53 years (95% CI 9.6-11.4), we believe that our result is acceptable, especially given that the average age of our population was 55.7 years at the time of surgery and that the average age of retirement in our country is between 60 and 65 years.

Concerning the relationship between conversion to TKA and osteotomy, 19.6% of patients required TKA. Historically, in 1984, Insall reported a conversion rate of 23% in patients who had previously undergone osteotomy, and more recent data retain this percentage.[1,13,15] It was not possible to determine a statistically significant relationship between the TKA rate and the analyzed preoperative variables; however, a higher rate of TKA was observed in patients with a BMI >30, those older than 55 years, and those experiencing severe pain (VAS >7). On the other hand, a statistically significant relationship was found between patients who would not return for surgery and those with a higher rate of TKA.

An important factor to consider when evaluating a surgical technique is the degree of patient satisfaction with the procedure. 76.5% of patients reported being satisfied and indicated that they would undergo the procedure again. This result is quite similar to those reported by Schallberger and Jacobi and Han et al. (85.2% and 80%, respectively).[13,14] Patients who would undergo reoperation were younger than those who would not, and this relationship was statistically significant. Although we did not observe statistically significant differences in BMI between satisfied and dissatisfied patients, both groups had a BMI in the overweight/obese range. Higher BMI levels can lead to a greater number of complications, such as an increased rate of pseudarthrosis due to the greater mechanical stress placed on the osteotomy; however, these conditions are not contraindications for the procedure.[16] Likewise, a BMI >28 is a factor that negatively impacts outcomes, as it can cause painful dysmetria in medial opening wedge osteotomies.[17] According to the ISAKOS consensus published in 2005, ideal candidates for osteotomy are those with a BMI <30.[18] In our sample, only 45.1% met this criterion.

The WOMAC questionnaire evaluates knee symptomatology and functionality, assessing pain, stiffness, and function. It comprises values ranging from 0 to 96, where lower values indicate better outcomes. The WOMAC score in our series at the end of follow-up was 18.06 ± 21.61. In patients operated on with TomoFix, Han et al. reported scores of 10.3 in satisfied patients and 14.4 in unsatisfied patients two years after the intervention.[14] Likewise, Han et al. and Saier et al. reported similar scores (8.1 and 11.4, respectively) in their series using TomoFix, with two years of follow-up. [5,19]

The Lysholm scale is widely used to measure knee symptoms and daily function and can be applied in various conditions. It consists of 8 items, with total scores ranging from 5 to 100; higher scores indicate fewer symptoms or better functional levels.[20] The mean Lysholm score at the end of our follow-up was 72.9 ± 26.1, which was somewhat lower than the scores reported by Saier et al. (with TomoFix) and Osti (with Puddu) (75.6 and 82.5, respectively).

The SF-12 questionnaire is an accepted tool for evaluating the patient's quality of life, assessing physical capacity related to specific issues and the psychological impact of these issues on interpersonal relationships. In our series, the mean scores at the end of follow-up were 44.3 ± 11.7 (Physical) and 59.4 ± 8.9 (Mental). These values can be compared with those from the studies by Hantes et al. and Jacquet (both using TomoFix) (49.3 and 42.5 [Physical]; 54.4 and 53.9 [Mental], respectively).[6,21]

Among the strengths of our study, we highlight that it comprises a cohort of patients treated by the same surgical team, which included an experienced knee surgeon who consistently employed the same surgical technique. We also emphasize that the study was conducted by two principal investigators who analyzed all surgical descriptions, preoperative and postoperative imaging, and qualitative variables separately. On the other hand, the weaknesses are based on the well-known limitations of retrospective analyses, including difficulty in obtaining complete data, variability in patient follow-up, and the loss of one patient who refused to participate in the survey.

CONCLUSIONS

In our series, the mean survival time of the osteotomy was 10.53 years, with an overall survival rate of 79.2% at 10 years and a conversion rate to TKA of 19.6%. A statistically significant relationship was found between the decrease in preoperative and postoperative pain according to VAS, with younger patients reporting higher satisfaction and a greater likelihood of undergoing surgery again. Conversely, there was a non-statistically significant increase in the rate of conversion to TKA in patients with a BMI >30, those older than 55 years, and those with a VAS score >7 for pain.

Therefore, we can conclude that, in our series, opening wedge high tibial osteotomy with Puddu plate yielded very satisfactory outcomes at 5 years of follow-up.

Conflict of interest: The authors declare no conflicts of interest.

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