Tantalum is a Good Bone Graft Substitute in Tibial Tubercle Advancement

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Abstract

Background Porous tantalum is reportedly a good substitute for structural bone graft in several applications. So far, its use has not been reported in tibial tuberosity anteriorization (TTA) for treatment of isolated degenerative chondral lesions of the patellofemoral joint.

Questions/Purposes We asked whether the use of this material would produce similar standardized functional scores, pain (VAS), fusion rates, complications, and patient satisfaction to those for bone graft.

Patients and Methods We performed a randomized, controlled trial in 101 patients (108 knees) scheduled for TTA comparing a porous tantalum implant (57 knees) with an autologous local tibial bone graft (51 knees). The minimum followup was 5 years (mean, 6.2 years; range, 5–8 years).

Results At the last followup, clinical scores, fusion rates, and maintenance of the anteriorization either were better or similar for the TTA using the tantalum implant depending on the respective parameter. The operative technique was easier and shorter with the tantalum device. Complication and failure rates were greater using bone graft. Patient satisfaction was greater using the tantalum implant.

Conclusions Porous tantalum provided a reasonable alternative to bone graft in TTA.

Level of Evidence Level I, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

TTA inserting an autologous iliac crest bone graft to reduce the patellofemoral reaction force and contact stresses was proposed by Maquet [30] for treating degenerative chondral lesions and osteoarthritis of the patellofemoral joint. The mechanical efficacy of the procedure has been shown experimentally [3, 5, 10, 11, 14, 35, 37, 40, 52]. As much as 80% to 90% of patients achieve consistent or complete pain relief and substantial improvement or normal knee function at mean followups of 30 months to 16 years in different series [29–31, 43, 50]. However, the literature contains differing opinions regarding the magnitude of optimal advancement [2, 14, 37, 40, 50] and predictability and reliability of clinical results [5, 8, 21, 29, 40, 43, 50]. Some of the studies are limited by cohort size [3, 5, 19], cohort heterogeneity [5, 9, 10, 15, 17, 19, 55], short followup [3, 10, 20, 29, 55], or inadequate scoring systems [10, 17, 20, 26, 50]. Nonetheless, the consensus suggests that with proper indications and accurate technique, TTA still plays a role

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Each author certifies that his or her institution has approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent was obtained.

This work was performed at Instituto de Cirugía Ortopédica y Traumatología de Barcelona.

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in treating patellofemoral cartilage degeneration [9, 21, 31, 50].

The current gold standard for TTA is implantation of either iliac or tibial autograft [3, 8, 29–31, 43, 50, 55] with its inherent potential donor-site morbidity [31, 54] or allograft. Either method has substantial complication and failure rates; partial or complete resorption is reportedly as much as 12% [51], delayed union or nonunion at the osteotomy site was reported in 5% to 10% of cases [3, 31, 43], graft displacement was reported in 3.7% [31], and subsidence was reported in 3.5% of cases [55]. However, modifications of the osteotomies for TTA without the need for bone graft [9, 15, 42, 49] are technically demanding and not recommended for general use [49].

To avoid these drawbacks of the conventionally used technique, in January 2000 we began to use the porous tantalum block to elevate the tibial tuberosity. This bio-material seems very promising as a bone graft substitute because of its excellent mechanical properties [28, 58], the high friction between porous tantalum and cancellous bone optimizing the primary stability of the construct, and the fast and complete osseointegration of implant [4, 12, 13]. Numerous studies have described the clinical use of tantalum in revision arthroplasties [28, 32, 38, 44, 53] or in spinal surgery [13, 57], but none mention the application we propose.

We therefore asked whether graft and porous tantalum would produce similar (1) clinical outcomes [Knee Injury and Osteoarthritis Score (KOOS), Knee Society Score (KSS), a pain VAS, and Activities of Daily Living Scale of the Knee Outcome Survey (ADLS-KOS)]; (2) fusion rates and achievement and maintenance of TTA; (3) operative times, blood loss, and hospital stay; (4) complication and failure rates; and (5) patient satisfaction.

Materials and Methods

Between January 2000 and November 2003, all 124 patients who presented with anterior knee pain secondary to degenerative changes of patellofemoral cartilage at the outpatient department of the Instituto de Cirugía Ortopédica y Traumatología de Barcelona and met the inclusion criteria were asked to participate in this prospective, randomized controlled trial (Fig. 1). During this time, 23 patients expressed unwillingness to participate or anticipated difficulty to return for followups and therefore were not included. The 101 remaining patients, all of whom lived in the Barcelona area (44 men and 57 women with a total of 108 diseased knees), were randomized to either autograft or tantalum implant TTA surgery. All patients were informed of the nature of the study, and after accepting the study protocol, provided informed consent.

Fig. 1 A CONSORT (Consolidated Standards of Reporting Trials) flow diagram is shown.

The criteria for inclusion in this study were as follows: (1) patellofemoral pain for more than 6 months not responding to nonoperative treatment; (2) patellar and/or trochlear degenerative chondral lesions as the only single detectable lesion in an otherwise normal knee; and (3) patella centered in the femoral trochlea with normal tracking. We excluded patients with (1) anterior knee pain without a demonstrable basis on the patellofemoral cartilage; (2) advanced patellofemoral osteoarthritis (Grade 3 of Nagaosa [36]); (3) abnormal trochlear or patellar morphology according to Wiberg's criteria [56]; (4) increased Q angle greater than 20° and/or tubercle-sulcus distance greater than 13 mm [1]; (5) patellar instability or chronic subluxation; (6) patella infera or patella alta (Insall-Salvati index less than 0.8 or greater than 1.2, respectively [23]); (7) traumatic lesions; (8) inflammatory or metabolic diseases; and (9) previous surgery or knee arthroscopy. Following our primary research question, sample size calculation was based on data on the KOOS by Roos et al. [48]. An effect size of 0.6 is regarded as clinically relevant with this score. Following the data presented by Roos et al. [47, 48], with an alpha of 0.05 and a power of 0.8 in a two-tailed test, this results in a required sample size of 46 per group. The mean age of patients at the time of surgery was 43 years (range, 22–65 years) (Table 1). The minimum duration of symptoms was 6 months (range, 6 months–5 years). There was no difference in demographic data

Table 1. Patient demographics and pathologic findings

Data	Group 1	Group 2	95% confidence interval	p Value
Number of knees	51	57		
Male:female	22:26	22:31		0.66
Age (years)*	43.9 (± 10; 27–62)	43.6 (± 12; 22–65)	–4.00 to 4.51	0.90
Body mass index* (kg/m ²)	24.68 (± 4.22; 18.7–35.6)	24.96 (± 5.29; 17.2–37.3)	–2.12 to 1.56	0.92
Duration of symptoms* (months)	13 (± 12.14; 6–60)	14 (± 11.17; 6–52)	–5.24 to 3.65	0.72
Duration of previous conservative treatments* (months)	9.8 (± 3.6; 6–22)	9.9 (± 3.7; 6–19)	–1.45 to 1.35	0.88
Preoperative pain* VAS	7.31 (± 0.78; 6–9)	7.35 (± 0.79; 5–9)	–0.33 to 0.26	0.8
Preoperative KSS*	146.3 (± 11.17; 128–170)	148.26 (± 10.61; 123–169)	–6.10 to 2.20	0.35
Preoperative ADLS-KOS*	41.01 (± 12.46; 15–68)	42.05 (± 9.88; 16–67)	–5.30 to 3.23	0.63
Preoperative KOOS*	42.09 (± 11.27; 22–67)	42.80 (± 9.78; 20–66)	–4.72 to 3.30	0.72
Chondral lesion [†] (Outerbridge grade)				0.34
1	8 (16%)	5 (9%)		
2	9 (17%)	13 (23%)		
3	29 (57%)	37 (65%)		
4	5 (10%)	2 (3%)		
Location of chondral lesion [†] (Pidorian type)				0.55
I	7 (14%)	5 (9%)		
II	20 (39%)	28 (49%)		
III	9 (18%)	12 (21%)		
IV	15 (29%)	12 (21%)		
Grade of osteoarthritis [†] (Nagaosa grade)				0.31
0	16 (31%)	11 (19%)		
1	21 (41%)	30 (53%)		
2	14 (28%)	16 (28%)		

* Data are expressed as mean with standard deviation and range in parentheses; 95% confidence interval for the difference between means; [†]data are expressed as frequency; VAS = Visual Analog Scale; KSS = Knee Society score; ADLS-KOS = activities of daily living scale–Knee Outcome Survey; KOOS = Knee Injury and Osteoarthritis Score.

between the groups (Table 1). The minimum followup was 5 years (mean, 6.2 years; range, 5–8 years). No patient was lost to followup.

Patients were randomized blinded to one of the two groups via a computer-generated random list (Randlist Software; DataInf GmbH, Tübingen, Germany) drawn up by the statistician (ML). Sealed, sequentially numbered envelopes containing assignment to one of the two treatment groups were prepared and given to the assisting nurse (NG), who was blinded to the content and who opened the envelopes in numerical order after the diagnostic arthroscopy was finished. This information then was given to the treating surgeon. Clinical staff involved in the clinical outcome assessments and rehabilitation was blinded to the surgical procedure; radiologists involved in image assessment also did not know about the patients' clinical outcome and vice versa. Patients were informed about the implant they had received only after the study was completed, as was established at the time they gave informed consent.

Diagnostic arthroscopy was performed before the operation to assess the degree and location of chondral lesions, patellar tilt, and tracking [3, 16, 43]. The treating surgeon (MF-F) graded the cartilage changes according to the Outerbridge criteria [39]: Grade 1, softening and swelling of cartilage; Grade 2, fragmentation and fissuring in an area half an inch or less in diameter; Grade 3, the same as Grade 2 but in an area more than half an inch in diameter; and Grade 4, erosion of cartilage down to bone. The location of chondral alterations was mapped following the classification proposed by Pidorian et al. [41].

The same experienced surgeon (MF-F) performed all surgeries. The perioperative regime and surgical technique were identical except for bone harvest and choice of implant in both groups. All patients underwent a 1.5-cm straight TTA, carefully assessed with a caliper, shingling up a 7-cm cortical tibial tongue from its attached distal end. The 51 knees in Group 1 received an autologous corticocancellous tibial bone graft to elevate the tuberosity (Fig. 2), and the 57 knees in Group 2 received a

Fig. 2A–B A good result of tibial tuberosity advancement using autologous local bone graft is shown. (A) Complete fusion of the tuberosity has been achieved, and the initial 1.5-cm height of advancement was completely maintained at the 6-month followup. (B) The skyline view reveals a normal patellofemoral joint space width and good patellofemoral congruence.

porous tantalum device (Hedrocel® cervical spacer; Implex, Allendale, NJ; TM-100 Device; Zimmer Spine, Minneapolis, MN) as a spacer (Fig. 3). No complementary procedure was performed. The construct was secured with one AO standard screw. The wound was closed over suction drainage maintained in place 24 hours postoperatively. An immediate postoperative radiograph was taken. Operation time, blood loss, and length of hospital stay were recorded.

Fig. 3A–C In this case, a tantalum implant was used to elevate the tibial tuberosity. (A) An intraoperative view shows the straight TTA with a porous tantalum spacer in place and the screw securing the construct. (B) A postoperative radiographic control shows a correct TTA. (C) At the 6-month followup, fusion was achieved and the TTA height was maintained.

Full weightbearing assisted with crutches on request and unrestricted motion were permitted from the first postoperative day. Exercises were followed at home, supervised by a physical therapist, twice every week. All patients achieved 90° knee flexion during the first week postoperatively and achieved full ROM during the next several weeks. Isometric quadriceps exercises in 0° knee flexion and straight leg raises were started the 21st day after surgery. Patients added short arc knee extensions, from 30° to 0° knee flexion, 1 month after surgery. In the sixth week postoperatively, seated knee extension concentric and eccentric exercises, from 90° to 0° and to 0° to 90° knee flexion, were permitted. Each of these exercises was performed doing three sets of 10 repetitions per day, maintaining muscle contraction for 5 seconds. Progressive resistance was exerted by increasing 0.5-kg weight on the ankle as soon as patients were able to perform three sets of 10 repetitions of the exercise easily. Eight weeks after the operation, patients started 10 to 15 minutes of exercise on a

stationary bike with the seat elevated and with moderate resistance, fast stepping, lunges, and squatting. Full activity, including sports, was permitted after 3 months.

All patients were seen at 15 days, 3 months, 6 months, and each year after surgery. Outcome questionnaires were completed and radiographic and CT studies were done at the 6-month and 5-year followups. All patients, assisted by a trained interviewer, filled out a questionnaire of the KOOS [48] and the ADLS-KOS [25]. We chose these tools because they have good validity and reliability in the evaluation of patellofemoral disorders [17], are fast and easy to complete, and have high effect sizes, requiring fewer subjects to yield significant differences. In addition, we used the KSS [24] to determine the knee status and a 0 to 10 VAS to estimate pain “right now.” Clinical outcomes were assessed by two independent investigators not involved in surgery (AM, JB) with each observer blinded to the other observer. Interobserver agreement had kappa values > 0.81 for all parameters assessed.

We obtained standardized AP weightbearing long radiographs and a lateral view in extension, lateral view in 30° knee flexion, comparative axial views in 20° and 45° flexion, and CT (16-row multislice CT; 0.5-mm slice width, 0.5-mm reconstruction interval) at 15°, 30°, and 45° knee flexion, as proposed by Fulkerson [16]. A Telos device (Telos GmbH, Marburg, Germany) was used to take reproducible axial views. The radiographic study included both knees from each subject in all cases.

All radiographs and CTs were evaluated by two independent experienced radiologists (AM, NL) with each observer blinded to the results of the other, and to the patients' clinical status and timing of their followup. Agreement among the evaluators was measured by calculating the simple kappa coefficient (κ). The femoral, tibial, and patellar alignment was estimated in the three planes. The patellar shape according to Wiberg [56] on the axial view and trochlear morphology following the criteria of Grelsamer and Tedder [18] on the lateral knee radiograph were assessed. The position and congruence of the patella in relation to the trochlea and tracking were evaluated measuring the sulcus angle, congruence angle, tilt angle, and patellofemoral index. We considered a sulcus angle of $138^\circ \pm 7^\circ$ and congruence angle of $-6^\circ \pm 6^\circ$ [33, 34], lateral patellar tilt angle of $15^\circ \pm 5^\circ$, and patellofemoral index of 1.6 [1] as normal. The patellofemoral joint space was measured in its minimum width, from the bright radiodense band of the subchondral cortex on the patella to the articular margin of the femoral cortex [27], and was rated using a 0 to 3 atlas-based scale [36]. Interobserver agreement had kappa values > 0.7 for all parameters assessed.

All complications were recorded. Loss greater than 0.5 cm of the initial 1.5-cm TTA, as a result of spacer

dislodgement, subsidence, resorption, fracture, or fragmentation, was considered failure of the procedure. Cases were graded according to the maintenance of the TTA: Grade 1 corresponded to greater than 1 cm TTA, Grade 2 was 0.5 to 1 cm, and Grade 3 was less than 0.5 cm advancement. Deterioration, based on the Nagaosa scale [36], of one grade or more was considered radiographic osteoarthritis progression.

At the 5-year postoperative visit, all patients were interviewed for subjective satisfaction and rated with the four-point scale (1 = very satisfied; 2 = satisfied; 3 = uncertain; 4 = unsatisfied) used by Robertson et al. [45] and validated by Robertson and Dunbar [46] against general health (Nottingham Health Profile, SF-36, SF-12) and disease/site-specific (Oxford-12, and WOMAC) outcome questionnaires.

The primary analysis was intention-to-treat and involved all patients who were randomly assigned to each of the two groups (48 of 48 patients in Group 1 and 53 of 53 patients in Group 2). Descriptive analysis of variables was performed using univariate statistics. Data were tested for normality using the standardized kurtosis, standardized skewness, and Shapiro-Wilks test. Kolmogorov-Smirnov test was performed to compare the distribution between the samples. To analyze our primary question, we determined differences in KOOS, ADLS-KOS, and pain score between the treatment groups using the Student's *t* test and differences in KSS using the Mann-Whitney *U* test. Differences in preoperative clinical scores between the two groups and between preoperative and postoperative values in the respective group were determined using the Student's *t* test for KOOS, ADLS-KOS, and pain score. For KSS data, the Mann-Whitney *U* test and Wilcoxon signed rank test were performed. Correlation among age, body mass index, and duration of symptoms with these scores was determined using the Spearman rank correlation coefficient (r_s). Correlation between preoperative and postoperative scores was determined using the Pearson product-moment correlation (*r*). Impact of initial grade and location of chondral lesion, preoperative and at followup grade of osteoarthritis, and complications on these scores was determined using MANOVA. Differences in postoperative scores in relation to the grade of preoperative chondral lesion and osteoarthritis were determined using multiple range tests and the Kruskal-Wallis test. Differences in the amount of achieved advancement with the respective technique were determined using the Mann-Whitney *U* test. Correlation between magnitude of TTA and postoperative scores was determined using the Spearman rank correlation coefficient. To determine differences in scores among grades of loss of advancement, we applied multiple range tests and the Kruskal-Wallis test. To evaluate differences regarding perioperative parameters, the Student's *t*-test was used for

duration of surgery and the Mann-Whitney U test was performed for blood loss and duration of hospital stay. To analyze differences in complication rates, grade of loss of TTA, and deterioration in the Nagaosa scale, the chi square test was used. The probability of patellofemoral deterioration according to the grade of TTA loss was determined by calculation of odds ratio and relative risk (RR). Differences in patients' satisfaction were determined using the chi square test. The contribution of residual pain, magnitude of advancement, complications, and patellofemoral deterioration to grade of satisfaction was determined using a MANOVA. We calculated all variable and modeling statistics using 95% confidence intervals (CIs). Statistical analysis was performed using Statgraphics Centurion XV.I (StatPoint Inc, Herndon, VA).

Results

Results generally were better in Group 2 with tantalum implants than in Group 1 with the autografts. The KOOS, ADLS-KOS, and KSS were greater ($p = 0.003$; $p = 0.014$; $p = 0.01$, respectively) in Group 2. Pain at followup was less ($p = 0.024$) in the tantalum Group (Table 2). Scores improved ($p < 0.0001$) in all cases after surgery and did not deteriorate with time.

The magnitude of achieved TTA was greater ($p < 0.0001$) in Group 2 than in Group 1 (Table 3) and

correlated well with the KOOS ($r_s = 0.49$), the ADLS-KOS ($r_s = 0.59$), and the KSS ($r_s = 0.58$). All patients in Group 2 maintained TTA greater than 1 cm, whereas 13 cases (26%) in Group 1 had tibial advancement less than 1 cm. Patients maintaining a minimum of 1 cm TTA had better KOOS, ADLS-KOS, and KSS outcomes than patients with less than 1 cm remaining (Table 3). Fusion of the osteotomized tuberosity was seen in all patients at the 6-month followup.

Duration of surgery and length of hospital stay were shorter and blood loss was less in Group 2 compared with Group 1 ($p < 0.0001$ for both) (Table 4).

The complication rate was less ($p = 0.044$) in Group 2 (Table 4). Delayed wound healing was reported in two patients in Group 1 and in one patient in Group 2. Two patients in Group 1 needed evacuation of a hematoma. No patients experienced an infection or neurovascular complication. Eight patients in Group 1 and six in Group 2 reported tenderness of the tuberosity, making it uncomfortable for them to kneel after surgery. Removal of the screw relieved these symptoms partially (Fig. 4). None of the patients had additional knee surgery during followup. Loss of TTA was smaller ($p = 0.0003$) in Group 2, with a minimal subsidence of the tantalum, which in no case exceeded 0.5 cm, than in Group 1 with four cases having lost more than 1 cm of TTA. In this group, the graft dislodged in two cases, fragmented and collapsed in two cases, and the tibial shingle fractured in

Table 2. Comparison of clinical outcomes

Variable	Group 1		Group 2		p Value score at last followup Group 1 versus Group 2
	Preoperative	Score at last followup	Preoperative	Score at last followup	
Pain*	7.3 $\pm$ 0.7	2.3 $\pm$ 0.7	7.3 $\pm$ 0.8	2.0 $\pm$ 0.6	0.024
p Value preoperative to postoperative	$p < 0.0001$		$p < 0.0001$		
KOOS*	42.0 $\pm$ 11.2	80.2 $\pm$ 7.1	42.8 $\pm$ 9.7	83.9 $\pm$ 5.5	0.003
p Value preoperative to postoperative	$p < 0.0001$		$p < 0.0001$		
ADLS-KOOS*	41.0 $\pm$ 12.4	78.4 $\pm$ 7.5	42.0 $\pm$ 9.8	81.7 $\pm$ 6.1	0.014
p Value preoperative to postoperative	$p < 0.0001$		$p < 0.0001$		
KSS*	146.3 $\pm$ 11.1	177 $\pm$ 8.5	148.2 $\pm$ 10.6	181.4 $\pm$ 7.4	0.01
p Value preoperative to postoperative	$p < 0.0001$		$p < 0.0001$		
Grade of satisfaction [†]					
1		23 (45%)		40 (70%)	0.032
2		16 (31%)		11 (19%)	
3		9 (18%)		6 (11%)	
4		3 (6%)			

* Data are expressed as mean $\pm$ standard deviation; p value between preoperative and postoperative scores in both groups using paired t test; p value between postoperative scores in Groups 1 and 2 using unpaired t test for pain, KOOS, and ADLS-KOS scores, and Mann-Whitney U test for KSS score; [†]data are expressed as frequency; p value between postoperative score in both groups using chi square test; KOOS = Knee injury and the Osteoarthritis Outcome Score; ADLS-KOS = activities of daily living scale-Knee Outcome Survey; KSS = Knee Society score.

Table 3. Correlation, impact of distinct factors on scores, and differences in score between grades of factors

Factor	KOOS at last followup	ADLS-KOS at last followup	KSS at last followup
Age (r_s)	-0.08	-0.11	-0.18
Duration of symptoms (r_s)	0.17	0.17	0.18
Body mass index (r_s)	-0.14	-0.08	-0.22
Scores preoperatively (r)	0.53*	0.61*	0.52*
Impact of grade of chondral lesion [†]	$p = 0.012^*$	$p = 0.0000^*$	$p = 0.0000^*$
Outerbridge grade [‡]			
1/2	2.02	3.17	1.78
1/3	7.65*	10.72*	10.61*
1/4	17.09*	20.62*	20.54*
2/3	5.63*	7.54*	8.83*
2/4	15.07*	17.44*	18.76*
3/4	9.44*	9.90*	9.93*
Impact of location of chondral lesion (Pidoriano) [†]	$p = 0.148$	$p = 0.392$	$p = 0.276$
Impact of grade of OA (Nagaosa) [†]	$p = 0.092$	$p = 0.408$	$p = 0.675$
OA grade [‡]			
0/1	5.21*	5.16*	6.03*
0/2	11.14*	11.58*	12.17*
1/2	5.92*	6.42*	6.13*
Advancement at last followup (r_s)	0.49*	0.59*	0.58*
Grade of loss of TTA at last followup [‡]			
1/2	7.92*	10.76*	11.0*
1/3	14.11*	14.15*	15.5*
2/3	6.19	3.38	4.5

Data are expressed as Spearman rank correlation coefficient (r_s); Pearson product-moment correlation (r); *statistically significant; [†]p value of effect of factor on scores at the last followup using multivariate analysis of variance; [‡]difference in score between grades of factor using one-way analysis of variance; KOOS = Knee injury and the Osteoarthritis Outcome Score; ADLS-KOS = activities of daily living scale-Knee Outcome Survey; KSS = Knee Society score; OA = osteoarthritis; TTA = tibial tuberosity advancement.

Table 4. Data and complications related to surgical procedure

Variable	Group 1	Group 2	p Value
Duration of surgery* (minutes)	57 ± 6.0	51 ± 4.7	< 0.0001
Blood loss* (mL)	232 ± 38.7	155 ± 50.3	< 0.0001
Hospital stay (days)*	3.1 ± 0.9	2 ± 0.2	< 0.0001
TTA (cm) at last followup*	1.27 ± 0.31	1.48 ± 0.06	< 0.0001
Grade of loss of TTA at last followup [†]		57 (100%)	0.0003
1 (≤ 0.5 cm)	38 (74%)		
2 (0.5-1 cm)	9 (18%)		
3 (≥ 1 cm)	4 (8%)		
Cases with one or more complication [†]	14 (27 %)	6 (11%)	0.044
Progression of osteoarthritis [†]	12 (24%)	4 (7%)	0.032

* Data are expressed as mean ± standard deviation; p value between data in Groups 1 and 2 using unpaired t-test for duration of surgery, and Mann-Whitney U test for blood loss, duration of hospital stay, and amount of TTA remaining, in centimeters, at last followup; [†]data are expressed as frequency; p value between data in both groups using chi square test for TTA remaining at last followup expressed in thirds of initial elevation, and using chi square test with the Yates correction for cases with complications and for progression of osteoarthritis; TTA = advancement of tibial tuberosity.

one case (Fig. 5). The RR of suffering complication was 2.6 (95% CI, 1.08-6.27) greater in Group 1 than in Group 2.

Progression of patellofemoral osteoarthritis, defined as deterioration of at least one grade on the scale of Nagaosa et al., was greater ($p = 0.032$) in Group 1 (Table 3) and was

Fig. 4A–B (A) Complete fusion of the tuberosity is seen on this radiograph of a TTA with a tantalum implant at the 6-month followup. (B) In this AP radiograph, both knees are shown, operated on using the same procedure, and using a tantalum spacer. In the left knee, the screw has been removed.

Fig. 5A–C (A) Fracture of the graft occurred in this case. (B) An example of failed TTA with local bone graft is shown in this other case. The immediate postoperative radiograph shows a 1.5-cm TTA

using a corticocancellous local bone graft. (C) The procedure failed by fragmentation and subsidence of the graft with loss of greater than half of the initial advancement.

associated with ($p = 0.0001$) loss of TTA height. The probability of radiographic patellofemoral deterioration was approximately 12 times greater for knees with a TTA loss greater than 0.5 cm than for knees maintaining TTA between 1 and 1.5 cm (RR of osteoarthritis progression among grades of TTA loss: $\frac{1}{2} = 12.31$ [95% CI, 5.26–28.79]; $\frac{1}{3} = 11.87$ [95% CI, 4.55–10.98]; $\frac{2}{3} = 0.96$ [95% CI, 0.49–1.87]).

Patient satisfaction was greater ($p = 0.032$) in Group 2 than in Group 1. The loss of TTA and the occurrence of complications had a negative effect ($p = 0.0126$ and $p = 0.0025$, respectively) on patient satisfaction.

Discussion

Reduction of patellofemoral load by means of TTA seems to be a rational approach to treat symptomatic degenerative chondral lesions of this joint [6, 7, 22, 30]. Moreover, the

porous tantalum has shown good performance as a substitute for structural bone grafts in several applications [13, 28, 32, 38, 44, 53, 57]. To achieve high and sustainable clinical scores and fusion rates while maintaining the anteriorization, we have used a tantalum block as a spacer to perform TTA. Therefore, we asked whether clinical scores, the achieved elevation and the fusion rate of the tuberosity, duration of surgery, blood loss, length of hospital stay, complication and failure rates, and patient satisfaction would be similar between a tantalum device and autologous local bone graft.

Our study has some limitations. First, patients needed assistance of a trained interviewer to complete the KOOS and ADLS-KOS questionnaires because no validated Spanish translations of these documents were available at the time. Second, variations in the preoperative treatment regimens could not be avoided because patients had been referred to us from different centers. Third, considering our outcome parameters are linked intrinsically to further

degeneration of the patellofemoral joint, the mean followup of 6.2 years may seem relatively short. Fourth, is the lack of an arthroscopic second view to directly check the state of articular surfaces. However, strict patient selection, exact adherence to the experimental protocol, and the prospective, randomized, and blinded study design enhance the validity of our data.

The substantial improvement in clinical scores with respect to pain and function of the patellofemoral joint, daily activities, knee-related quality of life, and patient's subjective perception of knee function after surgery confirms improvements described in published studies [19, 29, 31]. We suspect our finding of better improvement in all scores improved when the tantalum device was used is related to better maintenance of the advancement. Our experience, like that of other authors [10, 20, 30, 31, 43, 50], has confirmed that appropriate indication and accurate surgical technique facilitate good clinical results in the treatment of degenerative patellofemoral chondral lesions (Table 5). However, direct comparison of our results with published results is limited by the heterogeneity of cohorts [3, 10, 15, 19, 55], the exact procedures used, and the outcome instruments used [8, 10, 20, 26, 50]. Consistent with the findings of others [3, 26], we found age, gender, body mass index, duration of symptoms, preoperative patellofemoral narrowing, or location of chondral lesion did not influence the clinical outcome scores. However, we found outcomes correlated with preoperative clinical status and grade of chondral lesion (Table 3). Heatley et al. [19] reported 12.5% of poor results (Larson score ≤ 80) when the preoperative score had been greater than 60 points and 66.6% of poor results in cases with lower preoperative scoring.

Our results suggest maintenance of the desired and achieved level of TTA is crucial for clinical performance. Some authors [2, 10, 14, 37, 49] have suggested that TTA between 1 and 1.5 cm is great enough to decrease contact pressures by 25% to 80%. TTA greater than 1.5 cm reportedly reduces the contact area [5, 30, 31, 43, 50] and congruity of the patellofemoral joint [37] with a paradoxical increase of joint stresses on the medial facet and proximal portion of the patella [2, 14, 49]. Such advancement also produces substantial changes in knee mechanics (2-cm posterior translation and 20% increase on tibiofemoral contact forces [52]), causes a higher rate of complications [8, 19, 31] and cosmetically worse appearance [8], and does not yield better results than 1 cm TTA [20]. Conversely, an advancement less than 1 cm reportedly fails to substantially increase the patellar tendon lever arm [40]. None of the patients reported by Engebreetsen et al. [8] with advancement less than 1.5 cm improved according to the Lysholm functional score and the Tegner activity score. Tantalum implant has enabled us to achieve sustained

1.5 cm TTA without later loss of anteriorization. Subsidence of the tantalum block was negligible and seemingly did not influence the clinical scores. None of our patients experienced delayed union or nonunion of TTA, as was reported by others when using autologous grafts [3, 31, 43].

The incision, dissection, and elevation of soft tissues attached to the tibial metaphysis were reduced using a tantalum implant. Probably for this reason and by avoiding graft harvest, the operative time, blood loss, and duration of hospitalization were lower using the tantalum implant than when using local graft. The fact that the complexity of the procedure correlates with the length of hospital stay is manifest when comparing the mean hospital stay of 4.1 days reported by Hejgaard et al. [20] after TTA with local bone graft combined with shaving of the patella with the 3.1 days of our Group 1 undergoing TTA with local bone graft and 2 days with a tantalum implant. Harvesting autologous iliac graft may even increase the numbers for perioperative parameters to means of as much as 2 hours 20 minutes surgery duration (range, 1.5–4 hours), 820 mL blood loss (range, 520–1350 mL), and 27 days hospitalization (range, 14–73 days), as reported by Mendes et al. [31].

Complications and failures of the procedure compromised our patients' outcome, as reported previously [3, 19, 29]. The use of a tantalum block has reduced the rate of failures and complications. Avoiding graft harvesting is one of the reasons. Moreover, we have never observed fragmentation or displacement of a tantalum implant, and fusion was achieved in all cases. The high friction between porous tantalum and cancellous bone in the osteotomy site enhances the stability of construct, allowing early mobilization and rehabilitation. We no longer use screws in this application. Sudmann and Salkowitsch [55] believed the rate of complications could be lessened by improving the surgical technique and avoiding immobilization and the delayed rehabilitation recommended by some authors [10, 19, 20, 29]. Bessette and Hunter [3] reported a complication rate of 67% associated with the use of screws compared with a 27% incidence in patients in whom no screw was used. Furthermore, 67% of screws required later removal [3]. Tenderness on the prominent tibial tuberosity resulting in discomfort when kneeling is the most frequent complaint of patients after TTA, in some series affecting as much as 75% to 90% of cases [19, 20, 29]. The incidence in our series was 10.5% using the tantalum implant and 15.6% using local bone graft, comparable to the 20% reported by Lund and Nilsson [29]. Problems with wound healing and cosmetic appearance also are related to the magnitude of advancement, reported as being less for TTA of 1.5 cm, or less as performed in our study [10, 26, 29]. Progression of osteoarthritis has been only briefly assessed in other studies. Only Schmid [50] reported progression of

Table 5. Results of TTA for degenerative chondral lesions of patellofemoral joint in published studies

Study and year	Number of cases/control subjects	Age range (years)	Followup (years)	Etiology of PF pain	Graft type (cm)	TTA	Associated procedures	Result (score)	Complications (cases with at least one)	Progression of OA (percent of cases)
Besette et al. [3], 1980	20/none	15–61	2.4	18 PF cartilage degeneration. 2 postpatellectomy	Autologous iliac 1.5	None	None	45/100 points (Besette)	40%	Not evaluated
Engelbrekt et al. [8], 1989	38/none	23–55	5.4	Chondromalacia	Autologous iliac ≥ 1.5	None	None	30% (Lysholm, Tegner)	$\geq 90\%$	Not evaluated
Ferguson [10], 1982	184/none	15–76	2–4	Various	Local tibial 1.25	Medialization if required	Medialization if required	85% satisfactory (Ferguson)	16.2%	Not evaluated
Heatley et al. [19], 1986	29/none	18–71	7.2	Various	Local tibial ≥ 1.5	Medialization if required	Medialization if required	68% success rate (Larson)	$\geq 75\%$	Not Evaluated
Hejgaard et al. [20], 1982	20/22	18–50	12	Chondromalacia	Local tibial 1 (0.8–1.4)	Shaving	Shaving	70% very good + good (Hejgaard)	$\geq 90\%$	Not evaluated
Jenny et al. [26], 1996	65/none	17–64	11	Chronic PF pain	Local graft 1–1.5	Local treatment	Local treatment chondral lesion	62% success rate (Bandi)	13.8%	7.7%
Lund et al. [29], 1980	68/none	12–58	2.5	PF cartilage degeneration	Autologous iliac 0.98 ± 0.25	Shaving	Shaving	80% improvement (Lund)	28%	Not evaluated
Maquet [30], 1976	39/none	19–81	4.7	PF cartilage degeneration	Autologous iliac 2–3	Medialization if required	Medialization if required	95% improvement (Maquet)	10.2%	Not evaluated
Mendes et al. [31], 1987	27/none	35–76	5.5	24 PF cartilage degeneration 3 postpatellectomy	Autologous iliac 2.5	Various	Various	80% very good + good (modified HSS)	63%	Not evaluated
Radin et al. [43], 1993	42/none	16–49	6.1	Various	Autologous iliac 1.5–2.5	Medialization if required	Medialization if required	79% (Radin)	28%	Not evaluated
Schmid [50], 1993	35/none	20–66	16	PF OA	Autologous iliac 2–2.5	Shaving	Shaving	80% very good + good (Schmid)	11.5%	20%
Sudmann et al. [55], 1980	32/none	17–57	1.8	Chondromalacia	Autologous iliac 1–2.3	Shaving	Shaving	90% good pain relief	18%	Not evaluated
Fernandez-Fairen et al., 2009	51/57	22–65	6.2	PF cartilage degeneration	Local graft/Ta 1.5	None	None	Post > pre $p < 0.0001$ Ta > graft $p < 0.05$ KOOS, ADLS-KOS, KSS, VAS for pain	Local graft 27% Ta 11% 24% Ta 7%	Local graft

TTA = tibial tuberosity advancement; PF = patellofemoral; OA = osteoarthritis; HSS = Hospital for Special Surgery; KOOS = Knee Society score; VAS = Visual Analog Scale.

patellofemoral osteoarthritis after a mean followup of 16 years in 20% of cases with a TTA of 2 to 2.5 cm using autologous iliac bone graft. This rate is similar to that observed for TTA with local bone graft and three times greater than with tantalum implant.

Finally, the ultimate goal of treatment must be the satisfaction of patients [45]. Patients were satisfied or very satisfied with the procedure using local bone graft in 76% of cases, similar to that reported by Mendes et al. [31]. In our tantalum group, 89% achieved this grade of satisfaction. The grade of patient satisfaction correlated with maintenance of TTA and the absence of complications. We believe, in accordance with Robertson et al. [45], that patient satisfaction is indicative for treatment quality and a very important question to be addressed in this kind of study.

Our data suggest that a porous tantalum device is a good bone graft substitute in TTA for treating degenerative chondral lesions of the patellofemoral joint. Given enhanced clinical scores, achieving and maintaining an adequate 1.5 cm TTA, with a fusion rate of 100%, through an easy and safe technique, avoiding complications and progression of patellofemoral osteoarthritis, with a high level of patient satisfaction, we recommend using porous tantalum implants rather than bone graft as a spacer for TTA.

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