

Opening-wedge High Tibial Osteotomy with a Tricalcium Phosphate Wedge

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Purpose. To assess the effectiveness of a variety of high tibial osteotomy with internal fixation that consists in the placement of reabsorbable synthetic tricalcium phosphate wedges.

Materials and methods. Between September 1996 and March 2003, 42 patients were subjected to 43 high tibial osteotomies with implantation of tricalcium phosphate wedges. Primary osteoarthritis was the predominant etiology (41 cases); 2 cases corresponded to Ahlbäck's Grade I, 28 cases were Grade II and 11 cases were Grade III.

Results. Preoperative pain was 19.88 ± 5.39 points and currently 27.20 ± 5.37 points ($p < 0.00005$); preoperative walking capability was 17.30 ± 1.50 points and 19.53 ± 2.55 at present ($p < 0.00005$), pre-op mean flexion was $128.8^\circ \pm 6.2^\circ$ and $132.3^\circ \pm 4.2^\circ$ at the last examination ($p < 0.00005$). In all cases radiological incorporation was observed. The size of the mean tibiofemoral angle as measures preoperatively was $184.7^\circ \pm 2.6^\circ$ and currently $175.58^\circ \pm 2.07^\circ$ ($p < 0.00005$).

Conclusions. The use of tricalcium phosphate wedges in high tibial osteotomies has shown satisfactory results. Radiological incorporation was achieved in all osteotomies performed; no complications were observed that could be attributable to the tricalcium phosphate wedges.

Key words: knee, osteoarthritis, high tibial osteotomy, bone substitutes, knee.

Osteotomía tibial de valguización con cuñas de fosfato tricálcico

Objetivo. Valorar una variante en las osteotomías valguizantes de adición interna, consistente en la colocación de cuñas de fosfato tricálcico sintético reabsorbible.

Material y método. Entre septiembre de 1996 y marzo de 2003 fueron intervenidos 42 pacientes en los que se efectuaron 43 osteotomías de valguización implantando cuñas de fosfato tricálcico. La artrosis primaria fue la causa etiológica predominante (41 casos), 2 casos correspondían al Grado I de Ahlbäck, 28 casos al Grado II y 11 casos al Grado III.

Resultados. El dolor preoperatorio fue de $19,88 \pm 5,39$ puntos y en la revisión actual $27,20 \pm 5,37$ puntos ($p < 0,00005$); la capacidad de marcha en el preoperatorio fue de $17,30 \pm 1,50$ puntos y $19,53 \pm 2,55$ puntos en la actualidad ($p < 0,00005$), la flexión media del preoperatorio fue de $128,8^\circ \pm 6,2^\circ$ y $132,3^\circ \pm 4,2^\circ$ en la última revisión ($p < 0,00005$). En todos los casos se observó la consolidación radiológica. La medición del ángulo fémoro tibial medio obtenido en el preoperatorio fue de $184,7^\circ \pm 2,6^\circ$ y en la revisión actual de $175,58^\circ \pm 2,07^\circ$ ($p < 0,00005$).

Conclusiones. La utilización de cuñas de fosfato tricálcico en las osteotomías de valguización ha demostrado unos resultados satisfactorios, consiguiéndose la consolidación radiológica en todas las osteotomías y no observándose complicaciones inherentes a la cuña de fosfato tricálcico.

Palabras clave: rodilla, artrosis, osteotomía tibial, sustitutos óseos, rodilla.

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Numerous techniques have been used to treat valgus gonarthrosis since Jackson¹ described the high tibial osteotomy to eradicate or alleviate the pain caused by medial compartment overload. Since then, different types of osteotomies have been described: closing wedge osteotomy²⁻⁵, opening wedge osteotomy⁶⁻⁸ and dome osteotomy⁹⁻¹¹. Although authors seem to agree that the benefit brought about by an osteotomy is purely mechanical, i.e. the tibiofemoral

axis is corrected and the medial compartment is offloaded, the excellent results obtained in suboptimally corrected knees would seem to indicate a beneficial effect in the local blood flow.

Tricalcium phosphate (TCP) wedges are biocompatible synthesis materials, devoid of an organic phase and osteoconductive, i.e. their porosity promotes cell penetration and enhances graft ingrowth into the bone tissue. They are also bioactive, since they generate a genuine chemical bond with the bone without fibrous interposition, and resorbable through a cell process that is simultaneous to that of the bone mineral.

The purpose of this study is to assess a variant of additive high tibial osteotomies whereby a wedge is inserted medially; specifically, a resorbable synthetic tricalcium phosphate wedge was implanted with a minimally invasive technique in order to improve on the results obtained with other techniques and minimize complications.

MATERIALS AND METHODS

A total of 42 patients were included. They were subjected to 43 osteotomies at the Orthopedic and Trauma Surgery department of the Morales Meseguer University Hospital of Murcia and at the Valladolid University Hospital, between September 1996 and March 2003.

A medial addition high tibial osteotomy was performed, using tricalcium phosphate wedges (BIOSORB®) as a bone substitute, with a porosity of 250 to 400 µm. The surgical technique used involved a medial oblique metaphyseal approach with a 5-7 cm incision. The medial tibial plateau was exposed sparing the medial lateral ligament and the attachment of the pes anserine tendons. A partial oblique high tibial osteotomy was carried out, introducing a TCP wedge that had previously been planned for; special care was taken not to damage the lateral cortex. The osteosynthesis was performed by means of staples in 40 cases (2 staples were used in 5 cases and one in the rest). In one case, plating and screws were used. Osteosynthesis was not used in 2 cases. A compressive postoperative bandage was used.

Knee mobilization started 48 hours after surgery. Weight-bearing was deferred until the osteotomy had healed. A preventive anticoagulation protocol and antibiotic prophylaxis were used in all operated patients.

A total of 46 wedges were used with a mean height of 9 mm (range: 6-13 mm) (Table 1). In 3 cases, a double wedge was used.

Of the 42 patients, 20 (47.6%) were male and 22 (52.4%) female. The mean age at surgery was 55 ± 8 years (range: 23-67); 34 knees were operated before the age of 60 (79%); 26 knees (60.5%) were on the left side and 17 (39.5%) on the right side; there was one bilateral case. Patient weight was between 60 and 100 kg, with a mean value

of 78.76 ± 8.87. Mean follow-up was 49 months ± 15 (range: 78- 31); 23 cases had a mean follow up of 6 years (53.48%).

Regarding etiology, the main cause was primary osteoarthritis with the following distribution: 41 cases of primary osteoarthritis, one case of pseudoarthrosis further to osteotomy and one case of post-traumatic osteoarthritis.

Twenty-three knees had been subjected to a previous surgery, 21 cases had undergone either diagnostic or therapeutic arthroscopy prior to osteotomy (in 6 cases a meniscectomy and/or joint lavage was performed with perforations into the involved areas on the articular cartilage). One case had had a previous osteotomy and another had sustained a tibial plateau fracture treated by means of osteosynthesis. In 19 cases risk factors (intercurrent pathologies) were present: obesity, diabetes, hypertension, hypothyroidism, chronic obstructive pulmonary disease (COPD), depression, hyperlipemia and varicose syndrome.

Patients were clinically assessed preoperatively, one year post-op and at the time of performing the study (two years after the last case in the series was operated), following the criteria laid down by the American Knee Society¹². An assessment was made of pain, function, motion, muscular force, flexion deformity and instability using a 0-100 point scale. Scores ranging between 85-100 points were considered excellent; those between 70-84 were considered good; those between 60-69 fair and those below 60 points were ranked as poor.

From the radiographical point of view, the followed the classification by Ahlbäck¹³ to distinguish between the different degrees of tibiofemoral osteoarthritis: 2 cases (4.7%) were grade I; 28 cases (65.1%) were grade II and 11 cases (25.6%) were grade III; no grade IV or V knees were operated. One case was a pseudoarthrosis secondary to a prior osteotomy and another was a post-traumatic arthritis sequela (tibial plateau fracture).

A radiographic assessment was made of the tibiofemoral angle, following the anatomical axes of both

Table 1. Sizes of the TCP wedges and number of cases where they were used

Wedges (mm)	Number of cases
6	2
7	5
8	7
9	10
10	11
11	5
12	5
13	1

A statistical analysis was performed by means of a Student's paired «t» test with statistical significance defined at an-level of 0.05 (p <0.05). A variance analysis with repeated measures was also conducted taking follow-up time as a covariable. TCP: tricalcium phosphate.

bones, preoperatively, postoperatively, at one year and at the time of performing the present study. We considered those knees with a tibiofemoral angle ranging between 4-7° valgus (range: 176-173°) had been satisfactorily corrected, those with an angle smaller than 4 degrees hypocorrected and those with an angle above 7° hypercorrected.

RESULTS

Mean hospital stay was 4 days (range: 1-9), 26 patients (60.46%) were hospitalized less than 4 days.

Complications

Intraoperatively, we had two lateral tibial plateau fractures. In the early post-op period we had one case of reflex sympathetic algodystrophy, one case of phlebitis and 2 cases of superficial surgical wound infection that resolved with medical treatment. We found no evidence of intolerance to the TCP wedges.

During the follow-up period we carried out two reoperations: one of them was a revision with a total knee arthroplasty (TKA) and the other was an instance of loss of correction caused by the patient's osteoarthritis 5 years after the osteotomy had been performed.

Clinical results

Pain scores improved during the first year in all patients; ability to walk on a flat surface also improved during this period in 39 of the 43 cases operated.

In our post-op analysis, we found 3 cases that presented with symptoms similar to those in the pre-op period (Fig. 1). The pre-op pain score was 19.88 ± 5.39 points and postoperatively 27.20 ± 5.37 points ($p < 0.00005$). Ability to walk was rated at 17.30 ± 1.5 points preoperatively and 19.53 ± 2.55 points postoperatively ($p < 0.00005$). The overall pain/function ratio was 37.18 ± 6.11 points (range: 21-45 points) preoperatively and 46.51 ± 6.8 points (range: 21-52 points) at present ($p < 0.00005$).

All patients recovered their pre-op ROM; mean flexion was $128.8^\circ \pm 6.2^\circ$ (range 115° - 135°) preoperatively and $132.3^\circ \pm 4.2^\circ$ (range: 120° - 138°) at present ($p < 0.00005$). All cases recovered their muscular force at one year and only 2 cases presented with instability of the medial compartment caused by a recurrence of the varus deformity.

Radiographic results

Radiographic healing was achieved in all cases with an effective filling up of the metaphyseal space between the 10th and 14th week, except for one case in which the filling up did not occur until the 27th week. The TCP wedges grew into the bone and presented with a variable thickness as

compared to their original size (Fig. 2). Most of them showed up as a radiographic line postoperatively. The fastest area to fill up was the lateral side of the osteotomy.

The mean tibiofemoral angle under load was $184.7^\circ \pm 2.6^\circ$ preoperatively and $175.06^\circ \pm 1.8^\circ$ ($p < 0.00005$) post-op. The mean angle at the time of the present study was $175.58^\circ \pm 2.07^\circ$ ($p < 0.00005$). Postoperatively, 9 knees had an angle between 178- 177°, 31 were between 176-173° and 3 were below 173°. In the last follow-up, one knee had a varus deformity of 179°, 13 were between 178-177°, 27 between 176 and 173° and 2 were less than 173° (Fig. 3).

At 6 and a half years; follow-up, 37 cases had excellent clinical results with a preservation of the alignment of the operated limb.

Cell invasion of the TCP wedges and their osteointegration were histologically confirmed by a case that had to be rescued with a total prosthesis (Fig. 4).

In our series we found no significant differences between the correction obtained preoperatively, 1 year after surgery and at the time of the study, and that afforded by the use of staples.

DISCUSSION

TCP wedges can be used as bone substitutes¹⁴⁻²¹ since the interaction between the ceramics and the bone tissue permits specific chemical and biological changes. Mean porosity of ceramics, normally between 250-400 μm , has osteoconductive ability and permits cell and tissue invasion. We have not found signs of intolerance to TCP wedges in any of the cases in our series. Radiographic osteointegration has been constant. Although in some cases angular correction of our osteotomies was lost in the long term, the bone substitutes used were not related to this. All three criteria laid down by Lascart et al¹⁷: clinical tolerance, radiologic osteointegration and preservation of the correction are fulfilled in our series. Bone colonization starts between the second and third week¹⁸, but healing does not occur until the third month.

Mechanical resistance (average rupture under compression is 10-20 Mpa¹⁸) is what moderates our enthusiasm for TCP wedges. But their advantages over iliac grafting are undeniable²²⁻²⁴ since they require less OR time, they do not entail local morbidity at the donor site and achieve a better angular correction given the shape of the wedges, which come in different sizes. In order to overcome the problems related to iliac grafts^{8,22,23,25}, other materials, such as porous alumina ceramics, cement and hydroxyapatite have been used to manufacture these wedges; the results have been satisfactory.

Medial additive HTO is frequently used^{6,23,26,27}. One of the advantages of using TCP wedges lies in the fact that they permit an easy conversion into a total knee arthroplasty

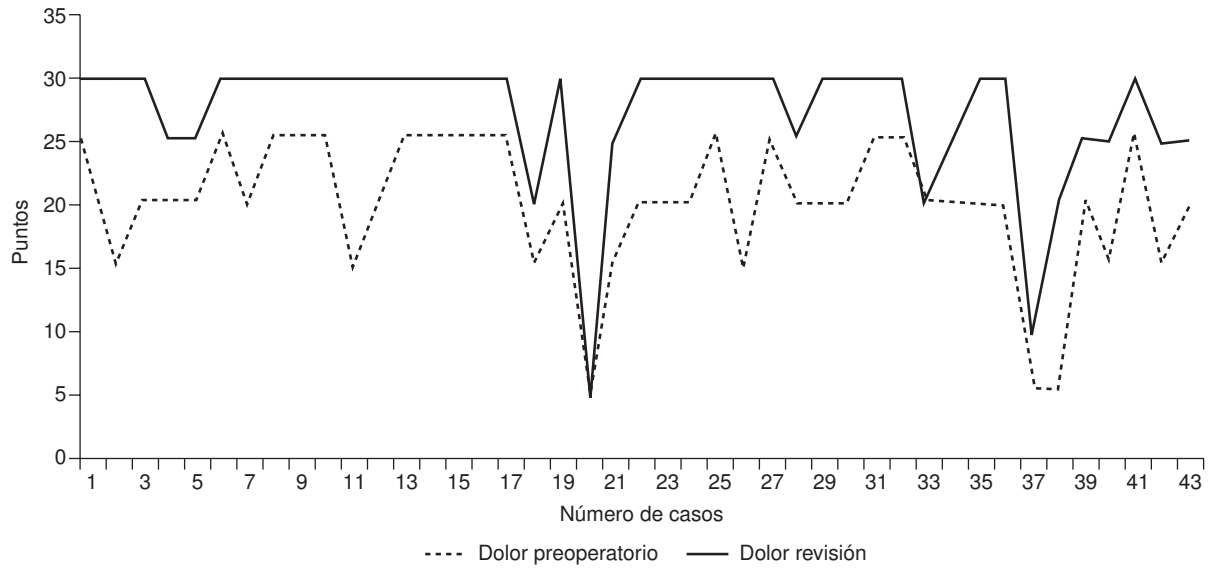


Figure 1. Assessment of pain, preoperatively and postoperatively.



Figure 2. 53 year-old patient with gonarthrosis. (A) A/P x-ray. (B) Lateral x-ray. High tibial osteotomy with a TCP wedge and staple-based osteosynthesis. Radiological healing at 4 months. (C) A/P x-ray. (D) Lateral x-ray. Operated knee at 6 years. (E) A/P x-ray. (F) Lateral x-ray.

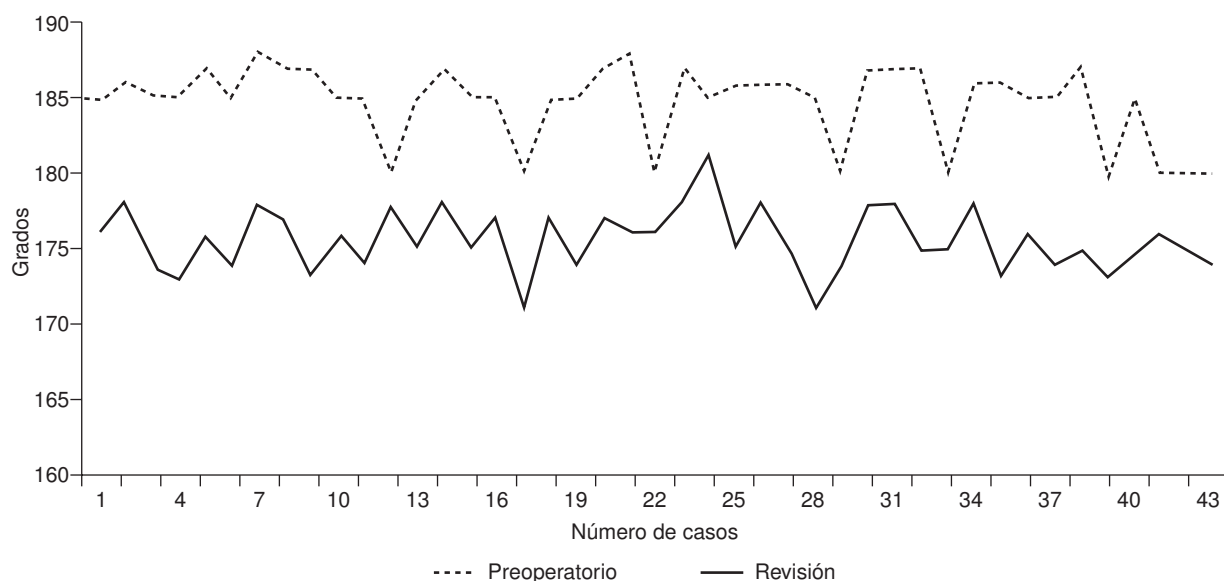


Figure 3. Assessment of the tibiofemoral angle: pre- and post-operatively.

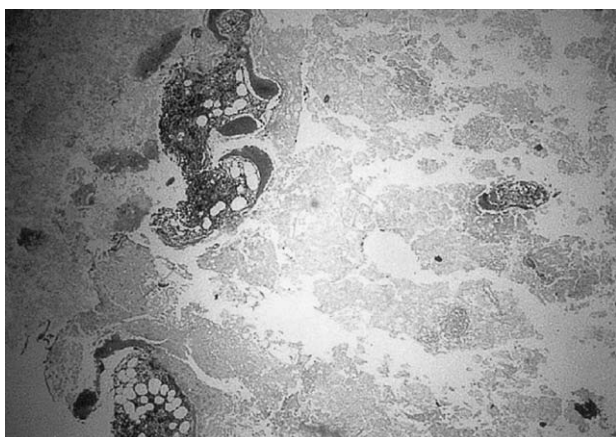


Figure 4. Microscopically normal cancellous bone areas that have histologically integrated into the eosinophilic granular material of a bio-prosthetic origin (H-E; 40 X).

by means of a small skin incision that does not interfere with the posterior approach, causes a slight descent of the patella and a limited amount of bony callus, does not compromise the patient's bone stock and requires little hardware^{22,28,29}.

As regards the angular correction afforded by a medial additive tibial osteotomy, in their study of 188 knees with a mean follow-up of 5 years, Debeyre and Artigou⁷ report 55% normal corrections (170-175°), 30.7% hypocorrections and 14.2% de hypercorrections. Hernigou³⁰ holds that only one-third of the knees operated by him, followed-up over 20 years, achieved satisfactory results. This same author²⁴ mentions the difficulty inherent in obtaining an accurate osteotomy correction angle and presents a review of 101 medial tibiofemoral gonarthroses, over 25% of which having a

post-operative correction below 3-6° valgus. He establishes a mathematical calculation model, both for the frontal and sagittal planes. Angular correction is a key factor to obtain good results. We have obtained less satisfactory medium-term results in hypocorrected knees than in hypercorrected ones.

The efficacy of tibial osteotomy is limited in time. Even knees that achieve optimal angular correction may be exposed to recurrence throughout their evolution, both regarding symptoms and varus deformity^{4,5,7,30,31}. One of the factors to be taken into account when assessing the results of a tibial osteotomy is the follow-up time of each series – there are few published medium and long-term papers^{4-6,26,30-33}. Debeyre and Artigou⁶ state that the laxer and hypercorrected a knee, the worse results are obtained. In our series, with a mean follow-up of 4 years, we obtained 86% good results, although it cannot be compared with other series with a longer follow-up, which tend to show a clear worsening of results after 7 years' follow-up^{4,30-33}.

Offloading the operated limb for 2 or 3 months permits the healing of staple-based osteotomies. When we intraoperatively observe that the assembly containing the TCP wedge is stable we do not carry out an osteosynthesis. We have not had significant complications or losses of correction. Unlike some authors who advocate^{6,8,22} stabilization with a screwed-in plate, we believe that such a procedure compromises a subsequent TKR.

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