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EXPERT'S OPINION • KNEE - BIOMATERIALS

Minimally invasive opening wedge tibia outpatient osteotomy, using screw-to-plate locking technique and a calcium phosphate cement

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Abstract

Medial knee osteoarthritis on angular varus deformity of a lower limb is very common. Open-wedge high tibial osteotomy is a treatment of choice if cartilage is not excessively worn (Allback 1 or 2). The technique based on a plate fixation and the bone defect filled with calcium phosphate cement is thoroughly described. Data at 1, 3, 6 months and 1 year of a 19 cases continuous and prospective series are collected and analysed. Mean age at the time of operation was 55 years. The average preoperative varus deformity was 5° and corrected to an average postoperative valgus of 4° (range 3°–6°). Each control includes the collection of eventual complications, the measurement of health status (quality of life and functional scores) and antero-posterior and lateral X-rays. All osteotomies were considered healed at 6 weeks without any correction loss except one, probably result of a technical error. There was no difference in clinical and functional results between the group and the literature, but the final result occurred earlier in the treatment when the bone defect was filled with either calcium phosphate cement. Faster recovery involved no specific complication and enabled outpatient treatment in a majority of patients.

Keywords Knee · Osteoarthrosis · Osteotomy · Calcium phosphates · Bone cement

Introduction

Medial unicompartmental knee osteoarthritis is a common degenerative condition that most often arises as a primary condition at the site of an angular deformity of a varus lower limb, but can also be secondary to a medial meniscectomy that was performed several years prior. The aetiological treatment of this mechanical condition caused by overloading is logical to surgically modify the axis by an osteotomy, when the discomfort caused becomes significant and the medical treatment is insufficient [1–7].

Clinical diagnosis is based on the existence of medial knee pain that is mechanical and modulated by activity, with frequent radiation towards the popliteal fossa and/or towards the lower part of the tibia. This pain becomes excruciating by tapping a finger against the medial intercondylar tubercle. It may or may not be accompanied by permanent, or more commonly intermittent, hydrarthrosis. Instability or a sensation of the joint locking-up should lead to a search for an associated meniscal pathology. Flexion deformity as pain relief (flexum) only sets in very slowly over the course of years.

Radiological diagnosis is based on posterior–anterior and lateral X-rays that show a variable degree of impingement which can be scored using the Ahlbäck classification [8]. This classification is taken into account when deciding on a treatment, but less so than the patient's age and desired activity level. If the patient is young and active, and perhaps enjoys playing sports (and wishes to continue), the indication will more likely be for osteotomy rather than arthroplasty, which should be reserved for older or more sedentary patients. An axial X-ray is taken with 30° of flexion in order to study patellar involvement. Teleradiography of the entire lower limb will provide the angle of deviation formed by the three points: the centre of the femoral head, the centre of the intercondylar eminence and the centre of the tibio-talar mortise [9].

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Operative technique

The degree of correction is based on the measurement of the HKA angle [9]. Conventional knowledge suggests that a hypercorrection of 3°–5° is ideal in the light of the many publications that have validated this statement in large studies with long-term follow-up [1–10].

The incision is made vertically at 2 cm on the inside of the anterior tibial tubercle, along a height of 5–6 cm (Fig. 1).

It includes the skin, the subcutaneous tissue and goes directly to the bone. There is nothing between the epidermis and the tibia at this location. The pes anserinus is at the back and is not affected (Fig. 2).

The periosteum is detached towards the inside and the outside, upwards and downwards, to subperiosteal approach of the anterior external surface of the tibia in the metaphyseal and epiphyseal zone from the tibial crest towards the front, which remains covered by the periosteum, up to the posterior edge of this anterior external surface towards the back (Fig. 3).

The periosteum is gradually detached towards the top until arriving beneath the patellar tendon and towards the back going around the posterior medial edge of the tibia in order to introduce here in both places a small double-ended Merle d'Aubigné type retractor.

The periosteum is also detached upwards until 1 cm below the interline and downwards for several centimetres so as to be able to place the chosen osteosynthesis plate there (5 cm for a screw-to-plate locking plate).

Detachment is easy if a well-sharpened elevator, or better still a chisel, is carefully used.

Fig. 1 Skin incision

Fig. 2 Incision in red: the pes anserinus is at the back and is not affected (colour figure online)

A 15/10e pin is put in place in the middle of this surface, both the middle of the anterior–posterior plane and of the vertical plane (the latter point is located at the edge of the slope between the metaphysis and epiphysis and is easily identifiable). The surgeon directs it obliquely towards the outside and in a proximal direction as though aiming for the head of the fibula: it is advisable to use fluoroscopy at this stage in order to verify this pathway, which will be the same for the osteotomy (Fig. 4).

The anterior external cortex of the tibia is then cut with a narrow-bladed saw, under visual control (Fig. 5).

The surgeon uses his or her judgement and perception when cutting the anterior external cortex with this narrow-bladed saw, taking care not to cut too deeply once the bone has been cut.

A chisel is introduced into the saw cut and is pushed in with a hammer to a depth of several millimetres in the

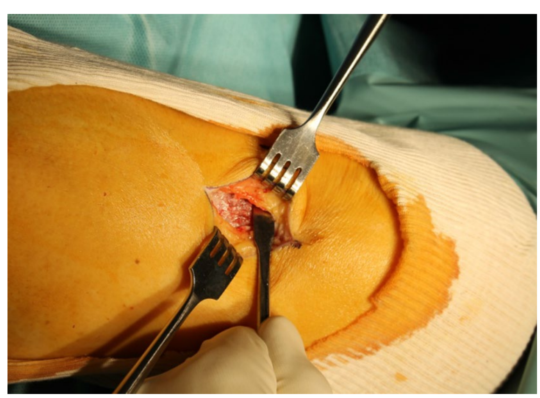


Fig. 3 Subperiosteal approach of the anterior external surface of the tibia

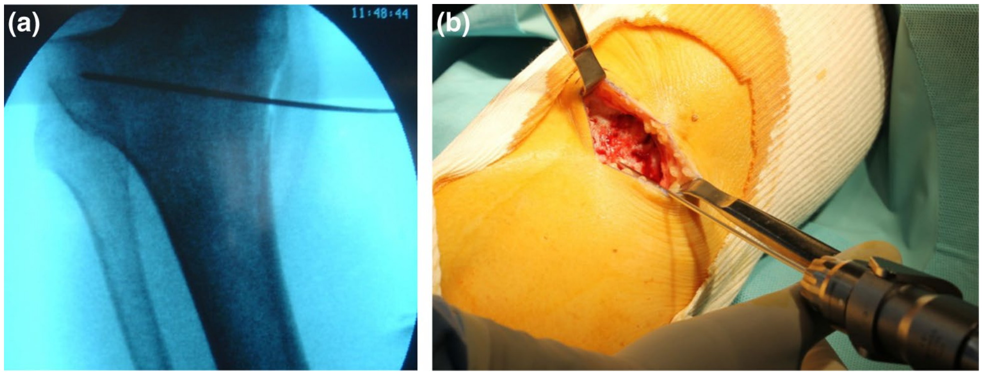


Fig. 4 A 15/10e pin is put obliquely in a direction as though aiming for the head of the fibula

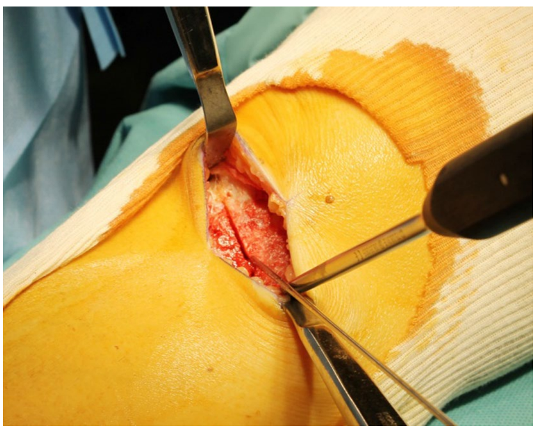


Fig. 5 Anterior external cortex of the tibia cut with a narrow-bladed saw

posterior half of the path of the saw cut, where the cortex is thickest. This opens up the saw cut from 1 to 2 mm (a second chisel may be introduced ahead of the other if necessary, which is rarely the case). This gap in the saw cut is necessary for the following step, which is the perforation, in the form of a dotted line, with a 1-mm-diameter drill bit, all along the posterior cortex with necessary care so as not to go beyond the cortex towards the back more than 1–2 mm. The result is that the posterior cortex is perforated like a postage stamp (Fig. 6).

The dotted line is completed, if necessary (a young patient having a thick, solid cortex) with a few very restrained taps with the chisel.

The surgeon then uses a light hammer to drive in wedges of which the angulation increases degree by degree within the osteotomy section with the help of the assistant facing opposite who cups the patient's ankle with one hand and pushes his or her fist against the lateral, external surface of the knee with the other hand in order to make the osteotomy cut gape open. It is not always easy, and it is sometimes necessary for the surgeon to adjust the preparation of the

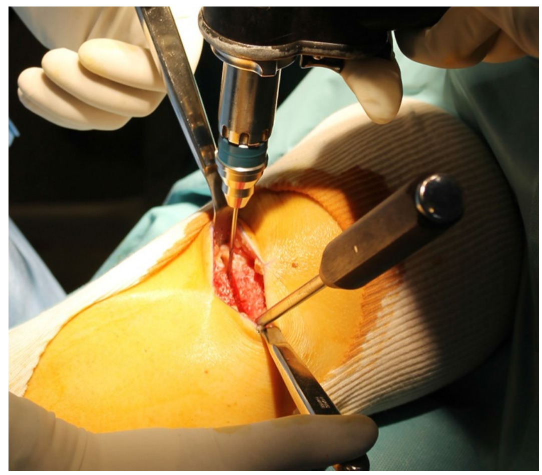


Fig. 6 Perforation in the form of a dotted line with a 1-mm-diameter drill bit of the posterior cortex

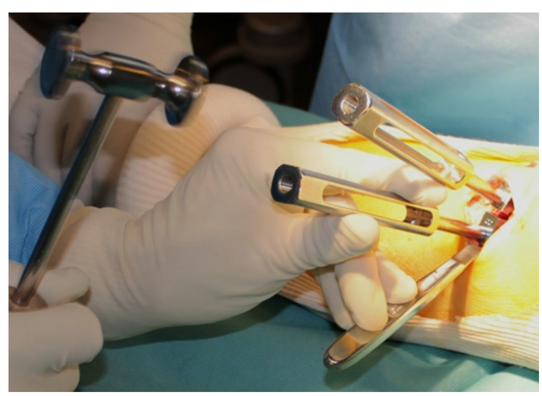


Fig. 7 Wedges of which the angulation increases degree by degree are driven within the osteotomy

posterior surface. This must be progressive and controlled so as to reshape without breaking (Fig. 7).

A breakage would destabilise the continuity of the posterior cortex, which must be preserved. The corners are inserted alternately in the posterior half, then in the anterior half within the osteotomy cut, which is gaping open, but without using force to pass them through, as this would crush the sides and would make it difficult to assess the degree of correction. Another risk to be aware of is insufficient cutting of the bone beneath the lateral tibial plateau (the saw must cut until it is going through the external cortex, carefully, but it must be going through), which may lead to a vertical fracture of the lateral plateau, particularly in the case of very hard bone. If this happens, additional osteosynthesis using a long transverse screw and with compression at about 1 cm beneath the joint interline will be necessary. This is not grave, but it does complicate the procedure and changes the follow-up somewhat.

The surgeon finishes with a corner going towards the back, while carefully ensuring that the opening has parallel edges and thus avoiding any flexum or recurvatum. If need be, the surgeon may leave two corners going towards the front and towards the back while the plate is being put in place. The opening is chosen by surgeon and is, as previously stated, between 3° and 5° more than the varus correction measured during preoperative telemetry.

The chosen screw-to-plate locking plate (which is shaped, but can still be reshaped) is placed anterior on the tibia straddling the osteotomy site and is fixed in place with two proximal cancellous bone screws, whose tips should touch the lateral cortex, and two bicortical screws that are placed distally in relation to the opening (Fig. 8).

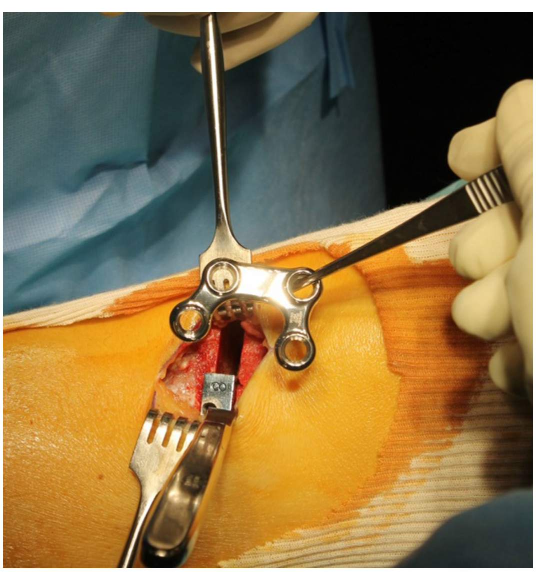


Fig. 8 A shaped plate is placed on the tibia

The holes are drilled with the drill bit diameter of 3.5 mm proximally and 4.5 mm distally, without reaming. The lodging of the distal screw heads in the tibial cortex is prepared with the screwdriver provided for this purpose. Proximally, they go into the epiphysis cancellous bone on their own. Video control makes it possible to see if the screws are correctly placed, then the locking nuts are placed in the plate on the screw heads (Fig. 9).

Roughly 2–3 cm^3 of cancellous bone is removed with a curette at a distance of 5 mm from the screws, in the centre of the osteotomy of the tibia. A part is positioned ahead of the plate and behind it within the gap of the osteotomy cut in order to accelerate consolidation and create a semi-closed cavity that can receive the calcium phosphate cement while avoiding leakage towards the back, particularly (Fig. 10).

The calcium phosphate cement (*all patients will be treated with GRAFTYS® Quickset*) is then prepared extemporaneously and injected into the opening of the osteotomy. It is bone void fillers; it is an inorganic product, taking the form of highly porous calcium deficient apatite. It is supplied

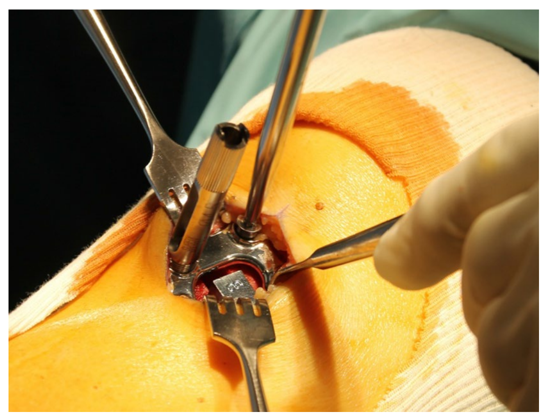


Fig. 9 Screws are placed, then the locking nuts

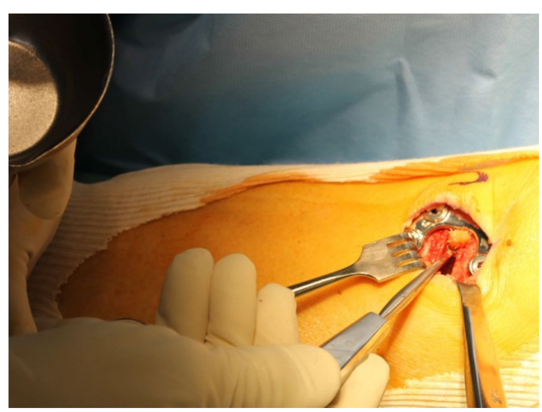


Fig. 10 2–3 cm^3 of cancellous bone are removed with a curette, in the centre of the osteotomy

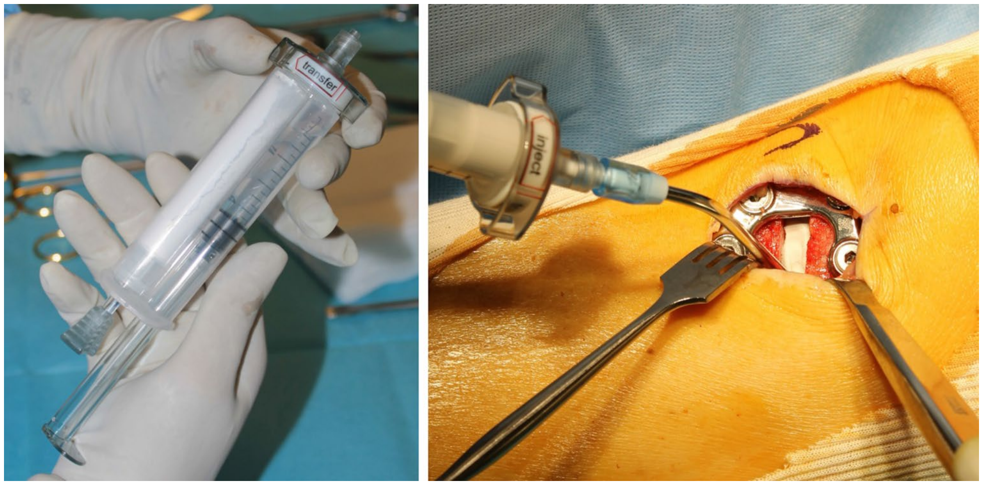


Fig. 11 Preparation and injection of the calcium phosphate cement (colour figure on line)

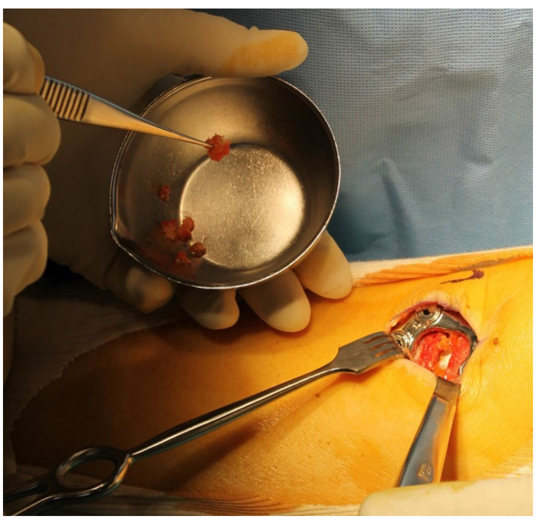


Fig. 12 Remaining bone is positioned onto the cement

sterile, with precursor compounds ready loaded in a sterile syringe or in a sterile vial for the aqueous solution depending on the injection system (Fig. 11).

They provide a framework enabling new bone growth to close the gap resulting from the opening osteotomy. It will have the effect of reinforcing the assembly and allowing immediate mobility with simulated weight-bearing, then true weight-bearing with only two canes for "relief" starting the day after the surgery.

The remaining cancellous bone is positioned onto the calcium phosphate cement (Fig. 12).

Closure is done in three steps: a few stitches of decimal 2 absorbable thread on the periosteum, a few stitches of 00 absorbable thread on the cutaneous tissue and skin closure with 000 nylon or absorbable thread, depending on the surgeon's choice. There is no drainage. However, instilling a few cc of naropin with 1 mg of adrenalin into the wound site before injecting the cement is beneficial (Fig. 13).

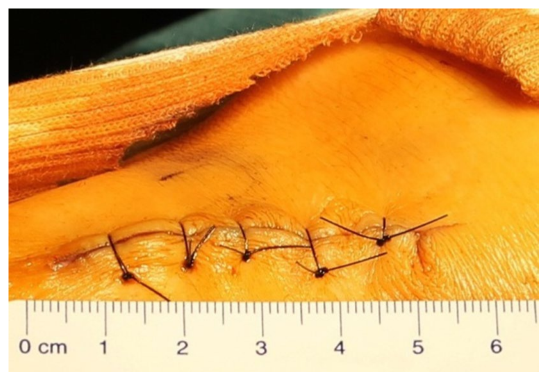


Fig. 13 Skin closure with a fine thread

The procedure is almost always performed in an outpatient setting. The patient is aided to stand immediately and walk with simulated weight-bearing using two canes or a medical walker depending on the terrain. A compressive, cooling splint is a good care practice: it will limit bruising, decrease pain and thus facilitate walking. The splint should be able to be freely removed for flexion/extension movements as early as the evening of the procedure day.

Our experience

Methods

The study was supported by a registry named CPC registry and developed by Graftys SA, 13 854 Aix en Provence, Cedex 3. The aim of the registry was to collect safety and performance data relating to the use of GRAFTYS®HBS/Quickset) in routine clinical practice.

- Inclusion criteria:

  1. Age ≥ 18 years
  2. Patient information and signed informed consent form
  3. Exclusively medial gonarthrosis up to Allback III.

- Exclusion criteria:

  1. Patients with inflammatory articulation disease
  2. Patients with a calcium or severe metabolic disease, immunological deficiencies
  3. Inability to understand the consent and objectives of the study.

All the patients were seen before and just after surgery, then at 1, 3, 6 months and 1 year if appropriate. Each visit or phone call includes the collection of eventual complications, the measurement of health status (quality of life and functional scores) and antero-posterior and lateral X-rays results.

Quality of life measures have become a vital and often required part of health and outcomes appraisal. Here, this health status information was collected before and after a procedure and provides an indication of the clinical outcomes or quality of care delivered to patients (paper self-completed or telephone interview).

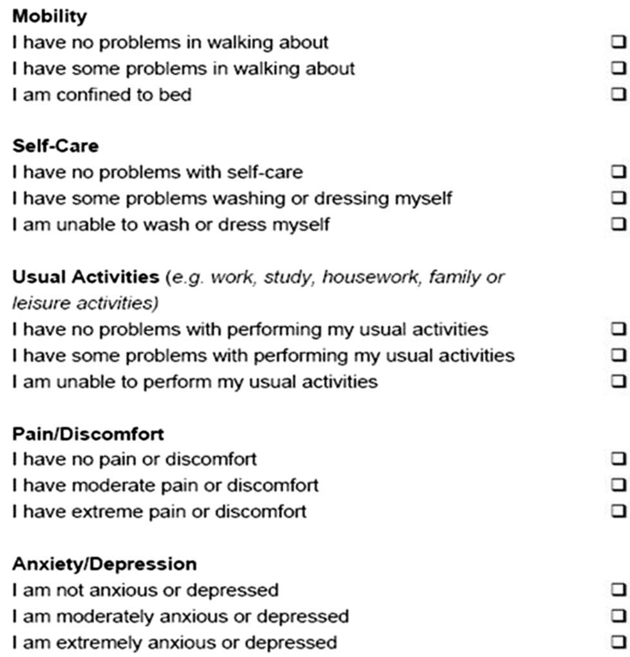
It was collected preoperative, at 6 months and 1 year by the EQ-5D (Fig. 14) and the EQ-VAS (Fig. 15) as quality of life scores and especially by the KOS, which reflects the functional result and quality of life, and therefore the patients' satisfaction with the results of the procedure.

The KOOS-PS (Fig. 16) is a seven-item measure of physical function derived from the items of the function (daily living, sports and recreational activity), subscales of the KOOS. As with the KOOS, it is intended to elicit people's opinions about the difficulties they experience with activity due to problems with their knee. As EQ-D5 and EQ-VAS, the measure is intended to be self-completed and can be completed as a mailed survey or in the waiting room. Each question must have a response.

Radiological follow-up comprised of an anterior–posterior and lateral X-ray study of the knee, supplemented by teleradiography to measure the axis and an axial radiography to see the patellofemoral joint.

Series

Nineteen patients were operated on between 28 September 2015 and 19 June 2017. There were 11 women and eight men. Ages ranged from 47 to 73 years, with an average age of 55.5 years. There were no differences for either side (Table 1).


Mobility
I have no problems in walking about ❑
I have some problems in walking about ❑
I am confined to bed ❑

Self-Care
I have no problems with self-care ❑
I have some problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*
I have no problems with performing my usual activities ❑
I have some problems with performing my usual activities ❑
I am unable to perform my usual activities ❑

Pain/Discomfort
I have no pain or discomfort ❑
I have moderate pain or discomfort ❑
I have extreme pain or discomfort ❑

Anxiety/Depression
I am not anxious or depressed ❑
I am moderately anxious or depressed ❑
I am extremely anxious or depressed ❑

Fig. 14 EQ-5D® score descriptive system

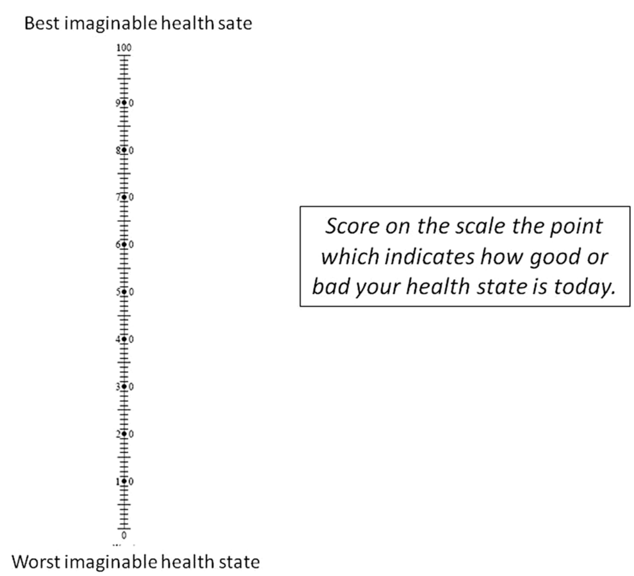
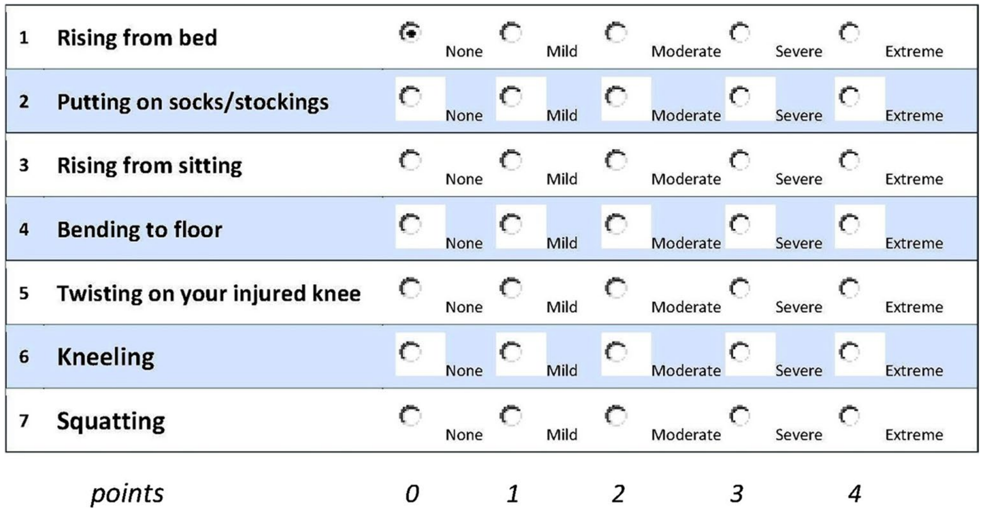


Fig. 15 EQ-VAS scale

The Allback stage was 1 or 2. The preoperative varus angle was between 2 and 11°, with an average of 5°.

Results

Eleven patients (58%) were operated on in an outpatient setting. The others were hospitalised for 1–4 days, with a



1	Rising from bed	None	Mild	Moderate	Severe	Extreme
2	Putting on socks/stockings	None	Mild	Moderate	Severe	Extreme
3	Rising from sitting	None	Mild	Moderate	Severe	Extreme
4	Bending to floor	None	Mild	Moderate	Severe	Extreme
5	Twisting on your injured knee	None	Mild	Moderate	Severe	Extreme
6	Kneeling	None	Mild	Moderate	Severe	Extreme
7	Squatting	None	Mild	Moderate	Severe	Extreme
	points	*0*	*1*	*2*	*3*	*4*

Fig. 16 KOOS-PS score (0 = excellent to 28 = the worst)

Table 1 Series

Case	Gender	Op date	Age	Varus pre-op	Correction	Valgus post-op	Nights in clinic
1	M	28/09/2015	66	7	10	3	4
2	F	19/10/2015	51	6	10	4	5
3	F	07/12/2015	52	2	7	5	4
4	M	26/10/2015	49	3	6	3	3
5	F	26/10/2015	49	3	7	4	4
6	M	15/02/2016	60	2	6	4	0
7	M	23/05/2016	59	5	8	3	0
8	F	13/06/2016	47	4	8	4	0
9	F	20/06/2016	53	9	12	3	0
10	F	29/08/2016	54	11	14	3	0
11	F	27/06/2016	57	5	9	4	0
12	M	19/09/2016	59	9	12	3	1
13	F	12/12/2016	47	5	9	4	0
14	M	02/01/2017	52	2	7	5	0
15	M	24/07/2017	54	3	7	4	0
16	M	20/02/2017	50	5	8	3	1
17	F	13/02/2017	54	3	7	4	2
18	F	29/05/2017	70	3	8	5	0
19	F	19/06/2017	73	8	11	Varus 5°	0
Average			55.5	5°	9°		1.25

global average for the 19 cases of 1.25 days. The correction performed ranged from 6° to 14°, with an average of 9°.

The mobility was the same before and after surgery at 3 months aside a slide improvement in flexion deformity as pain relief.

We had no infection and no algodystrophy.

In three cases, plate was removed because of local discomfort in skinny people.

The health status measurement questionnaire EQ-5D was filled out incompletely and cannot be used.

The EQ-VAS scores were filled out preoperatively for 19 of the 19 cases. Sixteen of the 19 were filled out at 6 months, and only five out of the 12 cases for which there was 1 year of follow-up. It goes from an average of 75 preoperatively to 89 at 6 months (*the worst score is equal to* 0 *and the ideal score to* 100); we did not retain the 1 year's data, insufficient in number. The scores of all the patients increased, by a range of 1–25 points, with an average of 15 points (Fig. 17).

The KOOS-PS score, collected in 13 cases with a follow-up period of 1 year, went from 17 before the procedure to 4 during the examination around 6 months, and finally 5 at 1 year of follow-up (Fig. 18).

All of the patients would undergo the procedure again, except two:

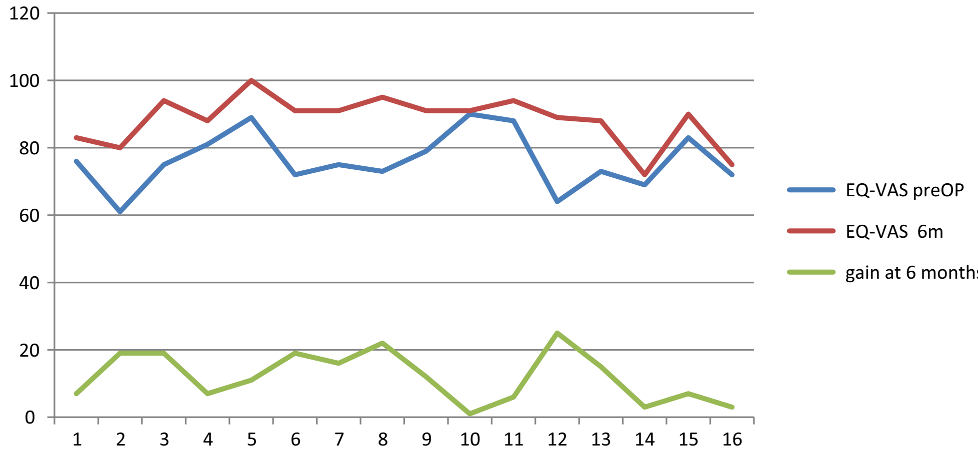


Fig. 17 EQ-VAS at 6 months

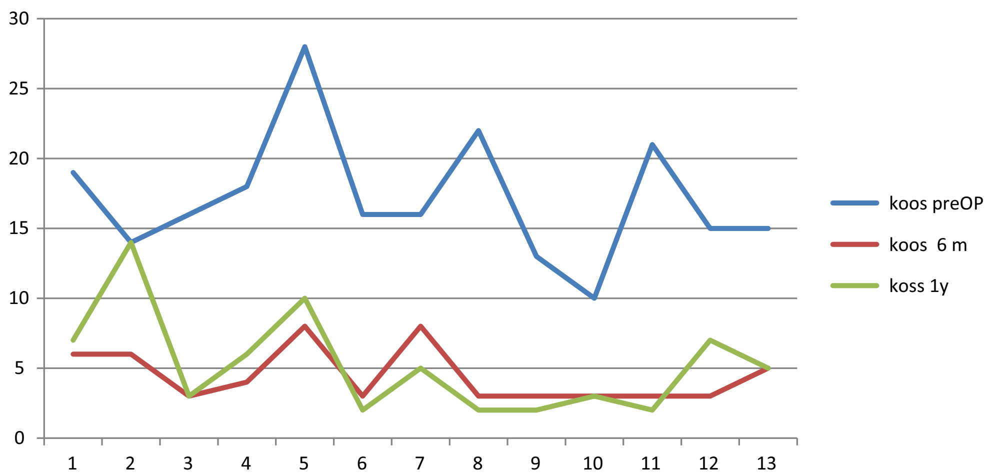


Fig. 18 KOOS-PS score preoperative, at—6 months and 1 year

- one female patient (case 2) who did not receive the desired outcome, with a KOOS-PS that went from 14 preoperatively to 6 at 6 months before returning to 14 at 1 year. However, this 51-year-old woman will not consider arthroplasty at this time. She did not benefit from the procedure and returned to her prior state without any worsening.
- one female patient (case 19) who had the complication cited above: the vertical fracture of the lateral plateau with a partial recurrence of the varus position(preoperative at 8°; to the consolidation at 5°). She states that she was able to walk without canes at 20 days, but there was an onset of sudden pain a few days later. A vertical fracture that occurred peroperative and was not detected on the postoperative X-rays is more likely than a stress fracture. This very active woman is 73 years old and very active; she does not wish to undergo arthroplasty in the near future not having enough pain.

All the osteotomies consolidated within 2 months (Figs. 19, 20), except one with a fracture of lateral plateau and recurrence of the varus position (Fig. 21).

More often than not, the X-ray images showed a border around the cement zone during the examination at 3 months. However, the border around the calcium phosphate cement was not observed at 6 and 12 months (Fig. 22). This was probably caused by a zone of osteoid bone that was still not calcified at this stage of healing (Fig. 23).

Discussion

In order to facilitate a more complete and faster bone healing, many surgeons use bone replacement to fill any bone defect. These are usually categorised as autografts, allografts or synthetic materials (calcium carbonates; calcium sulphates; calcium phosphates). The gold-standard bone filler is autologous bone harvested from the patient's iliac

Fig. 19 An example: preoperative, postoperative and at 1 year

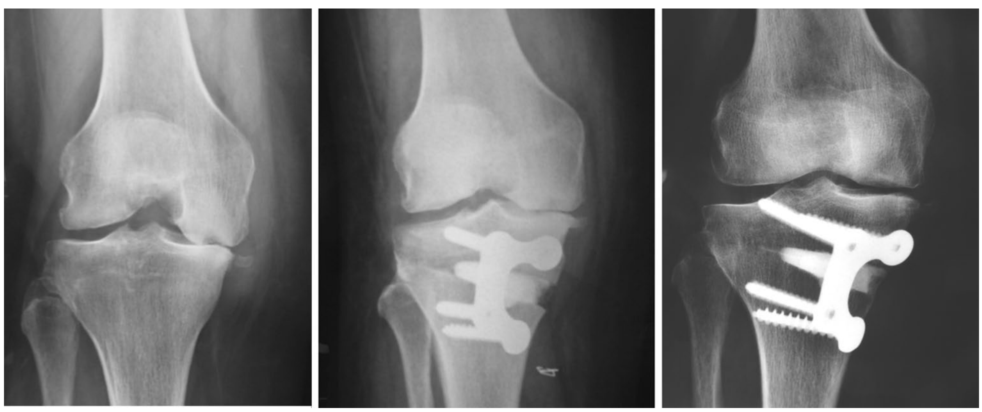


Fig. 20 Another example: preoperative, postoperative and at 1 year

crest. However, many people suffer from problems at the harvest site.

Calcium phosphate synthetics in forms such as granules, paste and various geometric shapes are increasingly used as an alternative for filling bone void defects. Recently, advances in calcium phosphate cement formulations, in modelable or injectable forms, offer improved osteoconductivity and enhanced ability of synthetic bone substitutes to restore natural bone. Many studies demonstrate the successful use of these injectable cements to treat bone-grafting indications (various fractures [11–13] and cysts [14]).

The literature review covers a range of calcium phosphate bone fillers and concludes that these products offer a viable alternative to autologous grafts, avoiding the problems associated with harvest-site morbidity.

There are two controlled clinical trials using injectable bone cements to treat fractures, both with control groups with no use of bone filler. In one case Mattson et al. [15], using Norian SRS® in 118 cases, final outcomes were the same for the two groups, and the test group required more re-operations. Complications include: discharges from wounds, vein thromboses, infections, reduction loss, avascular necrosis, lysis around screws, aseptic flow of fluid. All these complications are typical of any bone-grafting procedure. These disappointing findings contrast with a trial conducted by Johal et al. [16] with 47 calcaneal fractures in which patients treated with αBSM (Biobon®) bone filler showed markedly better final outcomes and low complication rates.

In all cases, follow-up [17–21] conducted at least a year after surgery, in order to assess long-term results new bone growth was reported. No evidence of complications specifically relating to the use of injectable calcium phosphate was reported.

Histological observations on the incorporation of calcium phosphate cements in human bone were published [22–24].

Currently, there was no publication about the use of calcium phosphate cement in tibial osteotomies.

Fig. 21 Vertical fracture of the lateral plateau with a partial recurrence of the varus position

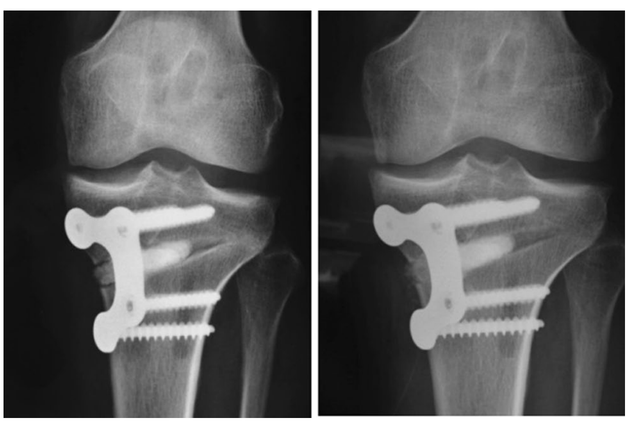


Fig. 22 Border around the calcium phosphate cement observed at 3 months and disappeared at 1 year

Conclusion

High tibial valgus osteotomy for isolated medial knee osteoarthritis secondary to genu varum remains a good surgical treatment if the osteoarthritis is unicompartmental and is not too advanced (up to Ahlbäck score 2 on X-rays in young patients).

Osteosynthesis, using a plate with locked screws and the mechanical benefits without iatrogenesis of using phosphocalcic cement, enables immediate weight-bearing with two canes for 1 month without any remarkable complications and shortens hospitalisation time by 1 or 2 days and may even allow this surgery to be done in an ambulatory setting for about 60% of patients.

Fig. 23 After 1 year, the cement is entirely embedded in the hosting bone. An example after plate removing at 9 months postoperative

Compliance with ethical standards

Conflict of interest The author has a contract as medical advisor to Graftys SA, 13 854 Aix en Provence.

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