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A new fixation material for open-wedge tibial osteotomy for genu varum

Cristiano Hossri Ribeiro *, Nilson Roberto Severino, Ricardo de Paula Leite Cury, Victor Marques de Oliveira, Roger Avakian, Tatsuo Ayhara, Osmar Pedro Arbix de Camargo

Knee Surgery Division, Department of Orthopaedics and Traumatology, Faculdade de Ciências Médicas, Irmandade da Santa Casa de Misericórdia de São Paulo (FCMSCSP), Brazil

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ABSTRACT

Varus deformity of the knee is a determining factor in the development of osteoarthrosis of the medial compartment. Open wedge osteotomy corrects the deformity and has quickly become popular due to the fact that the surgical technique can be easily reproduced, it spares loss of bone tissue in the metaphysiary region, and it does not require muscle dissection, reducing the risk of lesion of the fibular nerve. The objective of this study was to evaluate the characteristics of a new fixation implant (Anthony-K plate - France Bloc S.A, CE n0499, ISO 9001, EN 46001), in terms of its clinical improvement, correction of the deformity, and slope alteration. Twenty adult patients with varus deformity were evaluated, and submitted to open wedge high tibial osteotomy using the Anthony plate, between October 2004 and November 2006. The varus deformity was corrected in all cases, and there was a significant increase in the Lysholm score. Correlation analysis has shown that the greater the preoperative varus deformity, the larger the opening wedge used. Also, the greater the initial posterior tibial slope, the larger the final posterior tibial slope (p=0.0168). There were no complications. The Anthony plate can be considered an alternative in the treatment of medial osteoarthrosis of the varus knee, enabling the correction of the deformity and improvement of the clinical picture. It occurs an increase in posterior tibial slope, similar to that observed with other fixation materials. More studies with the Anthony plate are necessary, after these encouraging results.

1. Introduction

Open wedge valgus tibial osteotomy with medial wedge plate fixation is a well-established method for the treatment of medial unicompartmental osteoarthrosis associated with varus knee alignment, particularly in young or very active individuals [1,2].

The first publication of relevance on osteotomy for the treatment of osteoarthrosis of the knee was that of Jackson, in 1958 [3]. In the nineteen seventies, with the studies of Coventry and Insall's staff, closed wedge osteotomy of the metaphysiary region of the tibia became a popular technique for the correction of varus deformity [4]. At the start of the 1990s, with the presentation of the Puddu plate, the open wedge technique gained prominence in valgus osteotomy, as it provided a stable fixation of the osteotomy and earlier joint mobility. (Puddu plate, Arthrex plate) [5,6]. Since then, new plates have been developed for medial fixation of the osteotomy, all based on the same open wedge, rather than the closed wedge principle. In 2003, the Anthony plate was developed by France Bloc S.A, and it differed from the others used up until then in that it had a coupling system which was marked in millimeters, manufactured in predetermined sizes. The new plate therefore enabled the correction in the valgus tibial osteotomy to be adjusted millimeter by millimeter, as required for each patient.

The objective of this study was to evaluate the characteristics of a new fixation implant, in terms of clinical improvement, correction of the deformity, and slope alteration.

2. Materials and methods

This prospective study evaluated all adult patients, aged up to 60 years, with medial osteoarthrosis of the knee with varus deformity consecutively submitted to open wedge high tibial osteotomy with an Anthony plate (Anthony-K plate - France Bloc S.A, CE n0499, ISO 9001, EN 46001), between October 2004 and November 2006. All the patients signed an informed consent form and the study was approved by the ethics committee of the medical service.

All the patients were submitted to radiological evaluations of slope and mechanical axis pre-surgery, and 12 months post-surgery. Three months after treatment, healing was evaluated radiologically according to Paley's criteria [7]. Subjective evaluation, by means of the Lysholm score [8], was also performed before the treatment, and 12 months after treatment.

A diagnosis of osteoarthritis was obtained according to the clinical and radiological profile of the patient. Pain in the medial compartment of the knee for more than one year was established as a clinical criterion. The radiographic criteria used were those described by

* Corresponding author. Av. Nove de Julho, 1017, Vila Icaraí- CEP 12243-690, São José dos Campos, SP, Brazil. Tel./fax: +55 12 3946 4966; +55 11 8383-7156 (Mobile).
E-mail address: alelorenti@yahoo.com.br (C.H. Ribeiro).

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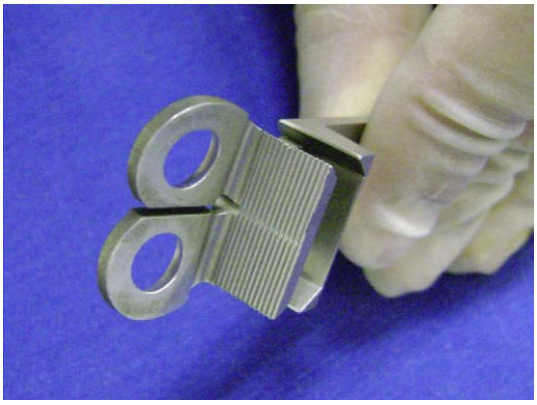

Fig. 1. Jagged surface of the Anthony plate.

Ahlbäck [9]. The radiographic evaluation of the patients included anteroposterior bilateral incidences, profiles in 30° orthostatic flexion, and axial patella profiles in 30°, as well as panoramic radiography with bipodal load. These incidences enabled evaluation of the osteoarthritis degree, as well as the mechanical axis, knee slope, and measurement of the opening wedge necessary to correct the deformity.

The inclusion criteria for the study were: presence of idiopathic unicompartmental medial osteoarthritis of the knee, genu varum deformity of up to 20°, preserved range of movement (less than 90° flexion and less than 15° flexion contracture), and stable knee. The exclusion criteria were as follows: previous knee surgery, osteoarthritis degrees IV and V, patellofemoral pain and a diagnosis of rheumatoid arthritis. In the study period, 20 knees of 20 patients were included (12 men, 8 women; a mean age of 48 years; ranging from 24 to 60 years).

The calculation of the mechanical axis was performed by drawing a line, on the X-rays, from the center of the head of the femur to the center of the knee, and another from the center of the knee to the center of the ankle. The acute angle formed by the intersection of the two lines in the center of the knee denotes the mechanical axis.

The measurement of the posterior tibial slope was performed using the method developed by Oswald et al. [10]. The opening wedge was calculated by the method described by Dugdale et al. [11]. The aim of this surgical method is to transfer the load sideways from the leg to the lateral plateau, in a position corresponding to 62% of the tibial articular surface. All the osteotomies were fixed with Anthony plates (Figs. 1–3) by the same medical team, and a tricortical graft was used.

Fig. 2. Precisely adjustable opening in the Anthony plate, which can be modified at all stages of the operation.

Fig. 3. Joined components of the Anthony plate.

The descriptive variables were analyzed as means and standard deviations. The mechanical axis was considered as a continuous variable and the pre- and post-operative periods were compared by the Student's t test. The Lysholm score was considered as a categorical and continuous variable. In order to identify correlations between the study variables, the Pearson's linear correlation method was used.

2.1. The plate

The Anthony-K plate (France Bloc S.A, CE n0499, ISO 9001, EN 46001) is modular, i.e. it has two components. The proximal component is comprised of the wedge which supports the proximal tibial metaphysis region, and is fixed proximal to the osteotomy site by two parallel screws. The distal component is formed by the wedge, which is supported on the distal plane of the opening of the osteotomy, and can be fixed by up to three screws (Fig. 2). These components fit together by means of millimeter-marked teeth which prevent the parts from sliding against each other. These teeth enable

Fig. 4. The guide of the Anthony plate indicates the precise position of the osteotomy.

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Table 1
Results from the mechanical axis, Slope, and Lysholm

	Start				End				Average difference	p
	Avg.	Std. Dev.	Max.	Min.	Avg.	Std. Dev.	Max.	Min.		
Mechanical axis	−8.1	3.1	−2	−16	3.4	3.3	10	−4	11.5	<0.001
Posterior Tibial slope	9	3.5	14	2	13.4	3.7	20	10	4.4	<0.001
Lysholm	40.85	15.46	69	16	87.60	11.11	99	52	46.75	<0.001

the distance between the wedges to be adjusted, millimeter by millimeter (Fig. 3).

2.2. Surgical technique

After rachianesthesia, the surgical procedure was initiated by performing an arthroscopy. Its purpose was to treat the meniscal lesions, debride the cartilaginous regions, and remove free bodies. For the osteotomy, a longitudinal incision of 8–10 cm was made on the anteromedial border of the tibia. The pes anserinus tendons and superficial medial collateral ligament were dissected from the bone at the site of the osteotomy. Using a fluoroscope, a Kirshner guide wire was inserted, oriented medially to laterally, 1 cm from the articular surface of the tibia.

The guide [mold] of the plate was then positioned on the medial border of the tibia, supported on the previously positioned Kirschner wire (Fig. 4). Two more Kirschner wires were inserted, parallel with each other, via the plate guide, oriented medially to laterally towards the head of the fibula. Afterwards, the guide was removed from the tibia, and the osteotomy performed in the medial, anterior and posterior cortical bones, immediately below the Kirschner wires, using an oscillating saw. The osteotomy was completed using a chisel, under direct fluoroscopic visualization. The osteotomy cut was interrupted 1 cm from the lateral cortical bone and opened using a millimeter-marked diapason, until the previously calculated opening was obtained. The two parts of the plate were coupled together with millimeter precision, according to the open wedge. The Anthony plate was then positioned on the medial border of the tibia, next to the posterior cortical bone, and the diapason was removed. Proximally, the plate was fixated with two cancellous bone screws of 6.5 mm and distally, by two cortical screws of 4.5 mm (distally the plate enables up to three screws). A tricortal bone graft was taken from the ipsilateral iliac crest, to fill the osteotomy opening. Finally, a drain was inserted, the incision sutured in layers, and a dressing placed on the knee.

2.3. Postoperative care

Prophylaxia with endovenous antibiotic was initiated in the anesthetic induction, and maintained for 48 h. The drain was removed on the first day post-surgery. The knee was not immobilized, and on the second day post-surgery, the patients were encouraged to perform exercises to increase the range of movement. After training in the use of crutches, without bearing weight on the operated leg, the patients were discharged from hospital. Two months post-surgery, walking was initiated, with the gradual introduction of weight bearing on the operated leg. Full weight bearing was permitted 120 days after surgery, following radiographic control.

3. Results

In the pre-surgical period, the patients presented an average mechanical axis of 8.1° varum (−8.1), with a standard deviation of 3.1°. In the post-operative period, the average was 3.4° of valgus (+3.4), with a standard deviation of 3.3° ($p<0.001$). The average correction of the mechanical axis was 11.5°, with a standard deviation of 4.6°.

The average posterior tibial slope was 9.0°, with a standard deviation of 3.5 in the surgical evaluation; and post-surgery, the average value was 13.4°, with a standard deviation of 3.7° ($p<0.001$). The average increase in posterior tibial slope was 4.4°. It affected 90% of the patients that underwent surgery, and showed a effect of loss of knee extension in 9 (45%) patients, which varied from 3 to 5° in 7 patients, and from 6 to 10° in two patients.

The initial clinical evaluation, according to the Lysholm score, obtained an average score of 40.85 points; 19 patients were classified as poor, and only one as moderate. There was a post-operative average increase of 46.75 points, with an average final value of 87.60 points ($p<0.001$). All the patients presented an increase in the score, and only one remained with a classification of poor. Three patients were classified as moderate, nine moved to a classification of good, and seven achieved a score of excellent (Table 1).

The average obtained from the open wedges performed was 10.8°, with a standard deviation of 2.3°.

The analysis showed a correlation (Pearson's linear correlation) between the mechanical axis and the opening wedge ($p<0.0001$), such that the greater the pre-operative varus deformity, the larger the opening wedge used. Also, the greater the initial posterior tibial slope, the larger the final posterior tibial slope ($p=0.0168$).

No correlation was found between the initial varus deformity and the final posterior tibial slope, or between the opening wedge performed and the final posterior tibial slope. Neither was there any correlation between the final posterior tibial slope and the final Lysholm score (Table 2).

All the cases were consolidated by the third postoperative month. These include the appearance of trabecular formation, bridging of bone ends, and corticalization of three of the four sides, as shown on the anteroposterior and lateral radiographs.

In this study, no complications were seen, such as lateral cortical fractures, intra-articular fractures, pseudoarthrosis, plate breakage, infection, or deep venous thrombosis, for a period of one year post-surgery.

4. Discussion

The results described in our study show that the new plate tested as a fixation implant is able to correct valgus deformity: we obtained a final mechanical average of 3.4° valgus. We also observed an average correction of the deformity in our study, of 11.5°, similar to that mentioned by Hart et al. [12], with 11.1°. This shows that the use of the Anthony plate reproduces the satisfactory results reported in the literature with the use of other plates, in terms of the correction of the deformity. The literature has shown a satisfactory correction through the use of other plates, i.e., with a mechanical axis between 3 and 6°

Table 2
Correlation between the mechanical axis, slope, and Lysholm

	Lysholm post	Lysholm pre	Pre-EM	Post-EM	Opening wedge	Start slope	End slope
Opening wedge	−0.39444	−0.08967	0.77128	−0.07995	1.00000	0.21223	0.07899
P	0.0853	0.7070	<0.0001	0.7376		0.3690	0.7406
Start slope	−0.39055	0.35384	0.16927	−0.02624	0.21223	1.00000	0.52766
P	0.0887	0.1259	0.4756	0.9126	0.3690		0.0168
End slope	0.10464	0.39173	0.03263	0.13578	0.07899	0.52766	1.00000
P	0.6606	0.876	0.8914	0.5681	0.7406	0.0168	

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valgus [10,12,13]. Marti et al. [13] in 2004, obtained 5.9° valgus, Esenkaya et al. [14], in 2006 obtained 5.6° valgus, and Hart et al. [12], in 2007, obtained 4° valgus.

Varus deformity of the knee is a determining factor in the development of osteoarthrosis of the medial compartment. This deformity can be caused by a lateral capsular-ligament avulsion, however, the main cause is the presence of a bone deformity [15]. Osteotomy has been used for many years, with the aim of correcting the bone deformity, seeking to decrease pain in the medial compartment. The main effect of osteotomy is mechanical, causing a transfer of load from the medial to the lateral compartment. This, in turn, decreases the impact on the subcortical bone, decreasing the intraosseous venous hypertension and hypertension of the microfractures of the subchondral bone, alleviating the pain and giving a functional improvement [15,16].

Today, we have various osteotomy techniques which seek, besides correcting the deformity, to alleviate the pain and preserve a good range of movement [17]. Open wedge osteotomy quickly became popular due to the ease with which the surgical technique can be reproduced [18]. Furthermore, it spares loss of bone tissue in the metaphysiary region, facilitating future arthroplasty; it does not require muscular dissection; and it presents lower risk of lesion of the fibular nerve, as it does not require a lateral approach, enabling a more accurate correction [16,19]. The success of the osteotomy does not depend exclusively on the appropriate selection of patients, but also on the use of a good surgical technique. The use of a stable osteotomy fixation material greatly influences the results of this technique [16,19]. Seeking to provide a stable fixation of the open wedge osteotomy, various plates were developed, such as the Puddu plate (Arthrex Inc., Naples, Florida, USA), the TomoFix plate (Mathys Inc., Bettlach, Switzerland) and more recently, the Anthony plate (France Bloc S.A, CE n0499, ISO 9001, EN 46001). The latter presents some unique characteristics which differentiate it from other existing plates. However, to date there have been no studies on its performance.

The mechanical characteristics of the Anthony plate, with two components and millimeter-precision adjustment, enable the deformity to be corrected with greater precision. As with the Puddu plate, the Anthony maintains the opening of the osteotomy by means of a wedge; however, while the wedge of the Puddu plate is a solid, smooth-sided cubic block, the Anthony plate has two parallel wedges, one proximal and the other distal, with a beveled surface which comes into contact with the bone (Fig. 1). We believe that due to its greater wedge surface, it provides better support for the opening of the osteotomy, while the beveled surface of the wedges causes them to adhere more firmly to the bone.

Realigning the limb may alter other characteristics of the joint. For example, in recent years the increase in the posterior tibial slope due to osteotomy is becoming increasingly important, because it impairs extension and stability of the knee [20]. Physiologically, the posterior tibial slope is 10° [21]; in our study, we obtained an average of 9° in pre-surgery, which increased to 13.4° in post-surgery. That average slope increase of 4.4° is statistically significant ($p = 0.001$), as it can also be seen in the literature, as described by Marti et al. [13] and Bombaci et al. [22], who obtained slope increases of 2.7 and 3.5°, respectively.

Recent studies have identified factors correlated to the increase in slope, including the position and the design of the plate [23]. The plate is usually placed in the posterior region of the opening wedge aiming at a previous opening. The normal tibial posterior slope can be maintained if the anterior opening gap is approximately two thirds the size of the posterior opening gap [24].

However, there is another relevant issue regarding the format of the plate. Both Puddu-like plates and the Anthony plate are rectangular-shaped, with parallel bases. However, the open wedge is usually trapezoidal, and this leaves a space which needs to be filled. This is a problem to be resolved in further mechanical and clinical studies. During the positioning of the plate in the previously defined opening wedge, we observed that the posterior region of the plate wedge is easily accommodated, which is not the case with the anterior region of the wedge that always requires a greater opening. This shows that the opening wedge forms a trapezoid shape in the sagittal plane, as opposed to the rectangular shape seen in the Anthony and Puddu plates.

In our study, we were careful to position the plate so that it was juxtaposed with the posterior cortical of the tibia, and to carefully dissect the medial superficial collateral ligament. Despite these precautions, the slope still increased. We have observed that even when positioning the plate as posteriorly as possible during surgery, the radiographic evaluation showed that in some cases, the positioning could have been even more posterior. Thus, based on our data, it is not possible to state that a change in the posterior tibial slope can be avoided with posterior positioning of the plate.

High tibial valgus osteotomy is considered to be a valid therapeutic option for the treatment of medial knee osteoarthritis, relieving pain and improving function in approximately 80–90% of patients during a five-year follow-up period, and 50–65% in a 10-year follow-up period [25,26]. According to the Lysholm evaluations, we observed improvement in 100% of the patients in one year. However, this follow-up may be considered a short period, and further studies with longer follow-up periods are necessary.

Comparing our study with the study by Hart et al. [18], which reports an initial Lysholm score of 55 points and a final score of 82 points, with increments of 27 points after a 2-year follow-up, it can be observed that even with a relatively low initial Lysholm score (40.8), we still managed to obtain a similar final result, due to a greater increase (27 in the Hart study, compared with 46.8 points in ours). The difference in the increases in Lyshom score observed between the two studies might be due to a shorter post-operative follow-up in our study. With a 2-year follow-up, patients would probably present a decrease in Lysholm scores, which would bring that difference down.

5. Conclusion

The Anthony plate can be considered an alternative in the treatment of medial osteoarthrosis of the varus knee, enabling the correction of the deformity and improvement of the clinical picture. It occurs an increase in posterior tibial slope, similar to that observed with other fixation materials. More studies with the Anthony plate are necessary, after these encouraging results.

6. Conflicts of interest

None. No author has received any financial support from any company within the last three years.

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