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Opening wedge high tibial osteotomy: navigation system compared to the conventional technique in a controlled clinical study

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Abstract
Purpose This study aimed to verify if the navigation system used in high tibial osteotomy (HTO) adds precision to the procedure regarding mechanical axis correction and prevention of tibial slope increases.
Methods In this historically controlled study, patients with medial osteoarthrosis and genuvarum underwent HTO between 2004 and 2012; the first 20 were operated with the conventional technique, using pre-planning correction by the Dugdale method and 18 further patients were operated with the navigation system introduced in our hospital.
Results The two groups were similar for pre-operative mechanical axis (mean 8.10±3.14 for the control and 6.60±2.50 for the navigated group), pre-operative tibial slope (mean 8.95±3.47 versus 8.17±3.11, respectively) and Lyshom score (40.85±15.46 and 44.83±16.86). After surgery, the control group presented mean mechanical axis of 3.35±3.27, tibial slope of 13.75±3.75 and Lyshom score of 87.60±11.12. The navigated group showed a postoperative mechanical axis mean of 3.06±1.70, tibial slope of 10.11±0.18 and Lyshom score of 91.94±11.61.
Conclusions The navigation system allowed a significantly better control of tibial slope. Patients operated with the navigation system had significantly better Lysholm scores.

Keywords Osteotomy · Knee osteoarthritis · Genu varum · Computer-assisted surgery · Tibia

Introduction

High tibial osteotomy (HTO) has been an established treatment option for young and active patients with unicompartmental osteoarthritis (OA) of the knee since the 1960s [1–4]. The mechanical leg axis is one important factor influencing the mechanical load distribution in the knee joint. According to the biomechanical studies of Hsu et al. [5], in a varus deformity of 1°, 75 % of the knee joint load passes through the medial tibial plateau, but this load increases to over 90 % in a 6° varus deformity. An effective method to decrease the load of the medial tibial plateau is a "valgisation" of the leg. It has been also demonstrated that malalignment increases the risk of progression of OA [6].

Inadequate preoperative planning of the desired correction has primarily caused failures of high tibial valgus osteotomy [7]. Other reasons for failure include inaccurate correction during surgery. Furthermore, undercorrection [8] leads to progression of medial joint arthritis [9] and patient dissatisfaction [10]. On the other side, overcorrection leads to patellar subluxation, *patella baja* [9], medial joint opening [7] and rapid degeneration of the lateral cartilage [11].

Computer navigation systems for total knee arthroplasty (TKA) have facilitated better correction of alignment and orientation of components compared with conventional

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techniques [12]. The accuracy and reliability of navigated opening wedge HTO have been shown in cadaveric studies [13–15].

Clinical results using a computed tomography (CT)-free computer navigation system for opening wedge HTO have recently been presented [16], describing a reliable procedure using the same navigation system used in our institute. With this study, we aimed to verify if the navigation system used in HTO adds precision to the procedure regarding mechanical axis correction, prevention of tibial slope increases and clinical response.

Patients and methods

Study design, allocation and ethics

Between 2004 and 2012, all consecutive patients with medial osteoarthrosis and varus deformity and with an indication of surgical correction by high tibial osteotomy (HTO) were recruited for this historically controlled clinical study. The study protocol was approved by our service ethical review board, and all patients signed informed consent forms for the procedures. All patients were operated by the same surgeon in the same public, university hospital.

Patients were included in the study if the presence of idiopathic unicompartmental medial osteoarthritis of the knee was verified, with 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 for this study were as follows: previous knee surgery, osteoarthritis degrees IV and V, patellofemoral pain and a diagnosis of rheumatoid arthritis.

Data from patients treated with the conventional opening wedge HTO, and allocated in a control group, were compared with data from patients who were treated with navigated opening wedge HTO after the navigation system was introduced in our public service. During the study period, 38 patients were included in the study, 20 in the control group, therefore operated first, and than 18 individuals who underwent the navigated opening wedge HTO.

All patients underwent clinical, subjective (by the Lysholm score) and radiographic evaluation preoperatively, as described in detail below, and 12 months after surgery. Within three months after surgery, anteroposterior and lateral X-rays of the knee were used to evaluate healing. Paley's criteria were used to allow weight bearing.

Radiographic evaluation and pre-operative planning

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 the pre-operative planning for the control group. The opening wedge necessary to correct the deformity in all cases in the control group was calculated using Dugdale's method [7]. The measurement of the posterior tibial slope was performed using the method developed by Oswald et al. [17], pre and postoperatively in both groups.

Surgical techniques

After spinal anaesthesia, the surgical procedure was initiated by performing arthroscopy to treat the meniscal lesions, debride the cartilaginous regions, and remove free bodies. After the arthroscopy in the navigated osteotomy group, the sensors were located in distal femur, proximal tibia, and distal tibia. Anatomic parameters of the hip, knee and ankle were marked for the navigation data collection.

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. Two more Kirschner wires were inserted, parallel with each other, oriented medially to laterally towards the head of the fibula. Afterwards, the osteotomy was 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 spreader.

In the control group, the osteotomy was fixed with Anthony® plate (France Bloc S.A, CE n0499, ISO 9001, EN46001), positioned on the medial border of the tibia, next to the posterior cortical bone; the opening applied was that calculated during the preplanning. A tricortical 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 was placed on the knee.

In the navigated group, a HTO version 1.5 OrthoPilot® system (Aesculap, Germany) with continuous visualization of the mechanical alignment was used to determine the correction angle in the coronal and sagittal planes intraoperatively. After the initial navigation reading, a wedge was opened searching for a mechanical axis of 30 %–40 % of the lateral tibial surface, to set the axis in 3°–6° of valgus [18]. Fixation was made with HTO® plate (Aesculap, Germany), and the wedge was filled with Biosorb® (β Tricalcium phosphate wedge, Otis, France).

Postoperative care

Prophylaxis with intravenous antibiotics was initiated in the anaesthetic induction, and maintained for 48 hours. 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 crutch training, 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 allowed 120 days after surgery, following radiographic control.

Statistical analysis

Preoperative profiles, clinical and radiographic data were compared between groups. Postoperative, clinical and radiographic data 12 months after surgery were likewise compared between groups. Data were collected in a Microsoft Excel table (Microsoft Office 2010) and converted for input to the Statistical Package for Social Sciences (SPSS) software, version 15.0. Descriptive variables were evaluated using summarized measurements and groups compared using Mann-Whitney tests. Values of $p<0.05$ were considered statistically significant.

Results

The two groups were compared regarding baseline demographic data, and no significant differences were found for age or rate of the affected side. Though the group operated with the navigated system had a higher proportion of men (17 men, one woman; $p=0.01$); while in the control group genders were more equally distributed with eight women and 12 men (Table 1).

No significant differences between groups were found in pre-operative mechanical axis, tibial slope and Lysholm score ($p>0.07$ for all comparisons, as shown in Table 2).

Table 1 Patients' data. Pre-operative profiles

Variables	Conventional group	Navigated group	p-value
Patients	20	18	
Age (years)	48,4	46,6	n.s.
Gender (male/female)	12/8	17/1	0.01
Knees	20	18	n.s.
Side (right/left)	11/9	9/9	n.s.

n.s. not significant

Table 2 Data sets for the group of patients treated with the conventional technique (control) and with the navigated system group

Variable		# Observations	Mean	Std deviation	Coef variation	Minimum	Quantile 1 Q1	Quantile 2 Q2	Quantile 3 Q3	Maximum	Interquartile	Range	p-value
Initial mechanical axis	Control group	20	8.10	3.14	0.39	2.00	6.00	8.00	10.00	16.00	4.00	14.00	0.073
	Navigated group	18	6.50	2.50	0.39	3.00	4.83	6.00	7.75	12.00	2.93	9.00	
Final mechanical axis	Control group	20	3.35	3.27	0.97	−4.00	2.25	3.00	5.00	10.00	2.75	14.00	0.733
	Navigated group	18	3.06	1.76	0.58	0.00	1.83	3.50	4.75	5.00	2.93	5.00	
Initial slope	Control group	20	8.95	3.47	0.39	2.00	6.00	9.50	11.25	14.00	5.25	12.00	0.497
	Navigated group	18	8.17	3.11	0.38	4.00	4.83	9.00	10.00	12.00	5.18	8.00	
Final slope	Control group	20	13.35	3.75	0.28	7.00	10.75	14.00	15.25	20.00	4.50	13.00	0.014
	Navigated group	18	10.11	3.18	0.31	3.00	8.83	10.50	12.00	15.00	3.18	12.00	
Initial Lysholm score	Control group	20	40.85	15.46	0.38	16.00	30.50	44.50	50.50	69.00	20.00	53.00	0.357
	Navigated group	18	46.83	16.86	0.36	19.00	31.00	47.50	58.50	72.00	27.50	53.00	
Final Lysholm score	Control group	20	87.60	11.12	0.13	52.00	84.00	89.00	95.50	99.00	11.50	47.00	0.033
	Navigated group	18	91.94	11.67	0.13	55.00	91.00	95.00	99.00	100.00	8.00	45.00	

After surgery, two variables showed significant differences between groups: tibial slope (p=0.014) and Lysholm score (p=0.033). The group undergoing surgery with the navigation system had a significantly lower tibial slope than patients in the control group. The Lysholm score was statistically greater in the navigated group than in the control group, as shown in Table 2.

Discussion

Recently, the computer-assisted surgery system has significantly advanced in orthopaedic surgery. It can avoid intra-operative technical errors seen in the conventional surgery and improves reproducibility. In high tibial osteotomies (HTO), the computer-assisted surgery system was introduced to decrease variations in surgeons' experiences with regard to pre-operative planning and intra-operative correction.

In the conventional method, the desired mechanical axis is calculated pre-operatively with weight-bearing X-rays, which could be confirmed by the cable method or alignment observation intra-operatively [19]. Several unintended errors can occur when calculating the desired correction angle pre-operatively, as well as when confirming the corrected mechanical axis intra-operatively [20].

In our study, the navigation system did not improve the precision in the correction of the mechanical axis (p=0.733), as previously shown in the literature; Lützner et al. [15], in their experiment with 19 cadavers, obtained better correction of the line of load with navigation, and Akamatsu et al. [21] also concluded that navigation can reduce the risk of hypocorrection, allowing better intra-operative control of the mechanical axis and tibial slope as compared with the traditional technique. In our clinical study, despite the lack of significant differences between groups regarding the mean mechanical axis, we did observe that the dispersion was higher in the control group; the coefficient of variation of the mechanical axis was 58 % around the mean for the navigation system and 97 % around the mean for the control group, operated with the traditional open wedge HTO.

A careful pre-operative planning allows adequate correction in the coronal plane, which could explain why we did not find a significant difference between groups regarding mechanical axis. However, this pre-operative planning does not offer control in the sagittal plane, which is possible with the navigation system. The tridimensional control during the deformity correction results in a better clinical response from the patient, as seen by the Lysholm score results in our study (p=0.033). Probably, these better clinical results are related to maintain the tibial slope, which was significantly lower in the group operated with the navigation system (p=0.014), since changes in the tibial slope lead to extension loss and knee instability in patients with anterior cruciate ligament lesion [22]. Although all patients in our study had stable knees, the loss of extension can result in mechanical overload in the patellar-femoral joint and consequentely pain, which interferes with Lysholm score results [23]. Kim et al. [16] also observed a superior result with navigation both in the clinical and radiographic evaluations, and concluded that the navigation-guided high tibial osteotomy is a reproducible and reliable procedure.

In a recent systematic review about the navigation technique, Picardo et al. [24] found only two studies comparing the conventional and the navigation techniques, evaluating the mechanical axes, tibial slope and the clinical results, both very similar to our study. The mechanical axis was better controlled, but the tibial slope and the clinical evaluation were different. In the study by the Kim group [16], the clinical outcome was better with the navigation system, but not the control of the tibial slope; on the other hand, Akamatsu et al. [21] obtained better slope control but this was not reflected in improvement of the clinical aspects. In both studies the mean follow-up time was 12 months, like in ours, and follow-up is indeed one of the limitations of our study. Although it is known that after a few years there is a tendency to progressive loss of the correction obtained and consequently deterioration of the clinical improvements, the use of the navigation adds precision to the amount of correction needed and maybe represents a gain of time to the treatment of the affected knees. Still, a long-term follow-up is necessary.

Another limitation of the present study is the fact that we used different types of implants. However, despite the differences in biomechanical properties, both implants were stable and maintained the correction of the osteotomy until the present time.

Conclusion

According to this study, navigated open wedge high tibial osteotomy is preferred to the conventional technique regarding radiographic results, especially to control the tibial slope. The clinical response of the patients operated by the navigation system is improved compared with the traditional technique.

Conflict of interest No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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