ARTICLE IN PRESS

THEKNE-02451; No of Pages 10

The Knee xxx (2017) xxx-xxx



Contents lists available at ScienceDirect

The Knee



Three dimensional-printed patient-specific cutting guides for femoral varization osteotomy: Do it yourself

Juan Arnal-Burró*, Rubén Pérez-Mañanes, Eudaldo Gallo-del-Valle, Cristina Igualada-Blazquez, Manuel Cuervas-Mons, Javier Vaquero-Martín

Department of Orthopaedic and Trauma Surgery, General University Hospital Gregorio Marañón, Madrid, Spain

ARTICLE INFO

Article history: Received 24 July 2016 Received in revised form 10 November 2016 Accepted 26 April 2017 Available online xxxx

Keywords: Cutting guides Femoral varization osteotomy 3D-printed Patient-specific Valgus knee

ABSTRACT

Introduction: In valgus knees of young patients, opening-wedge distal femoral osteotomy is a valid treatment option for axial corrections. It allows the surgeon to achieve accurate correction, which is directly related to the functional outcome and survivorship of the osteotomy. This study presents a new technique based on three-dimensional (3D)-printed cutting guides for opening-wedge distal femoral osteotomies, in which pre-operative planning and intraoperative executional accuracy play a major role.

Material and methods: Pursuing axial correction accuracy, 3D-printed patient-specific positioning guides and wedge spacers were both created and used by the surgeon to implement the femoral osteotomy. The proposed technique was performed in 12 consecutive patients (cases). The results were compared with 20 patients (controls) in which opening-wedge distal femoral osteotomies were performed following the traditional technique. Accuracy of the axial correction, surgical time, fluoroscopic time and costs were measured.

Results: More accurate axial correction with reduced surgical time (32 min less), intraoperative fluoroscopic images (59 images less) and costs (estimated €412 less) were achieved with the use of the customized guides when compared with the traditional technique.

Discussion: Accurate correction of the axial alignment of the limb is a critical step in survivorship of the osteotomy. Improving the technique to enhance accuracy focused on this issue. Conclusions: The use of patient-customized cutting guides minimised human error; therefore, surgical time was reduced and accurate axial correction was achieved. The surgeon mastered all steps in a do-it-yourself philosophy style.

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1. Introduction

Lateral compartment osteoarthritis (OA) of the knee represents a challenge for orthopaedic surgeons, especially when coupled with valgus malalignment in young patients [1]. In elderly patients, partial or total knee arthroplasty (TKA) achieves pain relief and long-term implant survival. However, less favourable results have been reported in younger, more active patients undergoing a knee replacement procedure [2]. A three- to five-fold higher risk of revision surgery has been found in patients aged <55 years [3].

Realignment varus osteotomy is a successful treatment option for lateral unicompartmental knee OA with associated valgus malalignment in young or middle-aged patients [4]. It results in a weight-bearing transfer to unload the damaged lateral compartment [5]. While valgus osteotomies are usually performed on the tibial side, varus osteotomies are most common in the femur

https://doi.org/10.1016/j.knee.2017.04.016

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Please cite this article as: Arnal-Burró J, et al, Three dimensional-printed patient-specific cutting guides for femoral varization osteotomy: Do it yourself, Knee (2017), https://doi.org/10.1016/j.knee.2017.04.016

^{*} Corresponding author at: Avenida la Gavia 11, portal F, 4b, 28051 Madrid, Spain. E-mail address: juanarnal@hotmail.com (J. Arnal-Burró).

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[4,6]. However, high tibial osteotomy (HTO) may also be performed in a valgus knee when a small varus correction is required [7]. In greater deformities (i.e. valgus malalignment $>10-12^{\circ}$) an osteotomy performed on the femoral side is preferred, as HTO may lead to joint instability due to iatrogenic joint line obliquity [8,9]. Although distal femur varus osteotomy (DFVO) is not a common procedure, even in major orthopaedic centres, recent literature reported it achieving good results with 10-year survival rates ranging 74–94% [4,10–12].

Traditionally, closing-wedge techniques have been most commonly used for DFVO, but the good results achieved in studies with opening-wedge high tibial osteotomy (HTO) performed for correcting varus deformities have led surgeons to pursue the advantages of opening-wedge procedures in the distal femur [13]. Opening-wedge DFVO allows for more accurate correction of alignment compared with closing-wedge techniques, with a narrower range of final tibiofemoral angles [1,14]. Achievement of optimal mechanical alignment is crucial in perigenicular osteotomies [1,15], and is directly related to the longevity of the native knee function [16]. Moreover, opening-wedge DFVO is considered technically easier than closing-wedge procedures, as the latter may lead to a less accurate axis correction because removal of a precise bone wedge is technically difficult and inaccurate [17].

Appropriate predictive surgical planning is essential to achieve the ideal correction angle that will ensure a good functional result, because selection of the osteotomy site and wedge position and size are the key points in performing an accurate correction that avoids joint line obliquity or creation of a new deformity [18]. In order to improve accuracy in axis correction, navigation techniques have recently been used with good results [19].

The purpose of this study was to describe a new surgical procedure based on patient-specific three-dimensional (3D)-printed cutting guides, with intraoperative positioning of an opening-wedge DFVO, in order to achieve the maximum accuracy and surgical time efficiency, and to analyse clinical experience with this procedure.

2. Material and methods

A case–control study was conducted on patients undergoing DFVO for lateral OA of the knee that was performed by orthopaedic surgeons at the present hospital from 01/01/2014 to 31/12/2015 using mainly open available software. The authors contributed to pre-operative planning (ABJ, PMR), data collection, outcome assessment, and figure preparation (GDVE, IBC, CMCM, VMI). Institutional review board approval was obtained for this study (IRB number CEIC 476/14).

2.1. Patient population

Patients were enrolled consecutively. Inclusion criteria were recent onset of pain (within one year), being aged <60 years, and low-grade lateral joint OA [20]. Exclusion criteria were range of motion $<90^{\circ}$ and radiographic Kellgren/Lawrence grade III or IV knee OA [15]. The group consisted of 12 patients consecutively recruited and operated on using the new procedure. The control group consisted of patients who received a standard DFVO procedure for lateral OA of the knee by surgeons experienced in DFVO between 01/01/12 and 31/12/15, and who had met the same inclusion and exclusion criteria. Twenty control patients were enrolled. Specific written informed consent for this study was obtained from all patients that were recruited.

2.2. Independent variables and outcomes

The primary outcome measure was accuracy of the osteotomy, defined as final axis-limb correction and execution accuracy. Final axis correction was defined as the deviation in degrees in the final mechanical axis of the operated limb (three degree slope as compared to that of the vertical axis) [21]. Execution accuracy was defined as the difference between the planned wedge (lateral opening gap) and the lateral cortex opening performed [17]. The difference was considered excellent if <1 mm, good if ranging from one to 1.5 mm, fair if ranging from 1.5 to two millimetres, and poor if >2 mm.

Differences in operating times, need for fluoroscopy, and estimated costs between both procedures were considered as secondary variables. They were measured as: (1) tourniquet time in minutes, (2) number of intraoperative fluoroscopic images, and (3) estimated costs. Cost analysis included the potential economic differences between both procedures during surgery planning and performance (pre-operative investment and operating time savings); a cost-effectiveness analysis was not conducted.

Data and variables were prospectively collected and evaluated by two independent assessors (GDVE, IBC); the new and classical procedures were compared. Demographic data were collected (age, sex, height, weight, etc.), and primary and secondary variables were recorded in all patients.

2.3. Intervention

The 3D-guided technique consisted of two phases: (1) a pre-operative planning phase where the opening gap was calculated and guides were designed by the surgeon himself; and (2) an intraoperative phase, which was simplified thanks to a 3D-printed patient-specific guide as a surgical aid.

2.3.1. Pre-operative planning

Calibration was performed in each case with the help of a 28-mm sphere radiolabel as a magnification marker for weight-bearing long-leg alignment radiographs. The calibrated long-leg alignment images were loaded to Orthoview® software

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