

Nanohydroxyapatite promotes the healing process in open-wedge high tibial osteotomy: A CT study



F. Conteduca, P. Di Sette^{*}, R. Iorio, L. Caperna, G. Argento, D. Mazza, A. Ferretti

Orthopaedic Unit and Kirk Kilgour Sports Injury Centre, S. Andrea Hospital, University of Rome Sapienza, Italy

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ABSTRACT

Background: The aim of this prospective and randomized study was to evaluate the effectiveness of adding nanohydroxyapatite (NHA) to heterologous bone graft in open wedge high tibial osteotomy (OWHTO) by measuring the bone density of the tibial osteotomy gap.

Methods: Twenty-seven patients (26 knees) were operated by OWHTO and randomly divided into two groups: pure graft group, in which the osteotomy gap was filled with only heterologous bone graft; nanohydroxyapatite group, in which the osteotomy gap was filled with heterologous bone graft and NHA. All patients underwent computed tomography (CT) examination within one week after operation (Time 0), and after two months (Time 1) and 12 months (Time 2). CT volume acquired Hounsfield Units (HU) were calculated and the mean value of bone density on three planes was measured.

Results: At Time 0, the mineral density of the nanohydroxyapatite group appeared significantly higher compared with the pure graft group, due to the presence of NHA. At Time 1, the mineral density of the nanohydroxyapatite group had decreased relative to Time 0, while in the pure graft group it remained unchanged. At Time 2, the mineral density in the nanohydroxyapatite group had further decreased, reaching values close to the mineral density of normal bone. In contrast, in the pure graft group the mineral density had increased, probably due to the lack of reabsorption of the graft and the development of sclerosis in the osteotomy borders.

Conclusions: The results of the present study show better osseointegration of the heterologous graft when nanohydroxyapatite is added.

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1. Introduction

Open-wedge high tibial osteotomy (OWHTO) is a common procedure for the treatment of symptomatic varus malaligned knees [1–3]. Correcting the lower limb axis creates a gap on the tibia that can be filled with bone graft. Healing of that graft is an important issue, since its delay or nonunion may result in loss of correction. In OWHTO, the gap can be left or filled with autologous, homologous, heterologous, or synthetic grafts [4,5,6]. An autogenous bone graft is considered to be the surgical gold standard because of its good biocompatibility [7,8]. There are, however, major drawbacks involved in this procedure: in particular, the considerably high morbidity and complication rate at the cancellous bone extraction site on the iliac crest.

Alternatively, a large variety of artificial bone substitutes, which can be used as void fillers after reduction, are now available [8,9,10,11,12,13]. In

particular, in recent years, the development of newer nano-molecular technologies has led to the creation of biocompatible compounds that can be used as bone substitutes [14,15,16]. There is general agreement that artificial bone substitutes should meet the following standards: the application of bone replacement materials should be a straightforward procedure; the material should be tolerated by the surrounding tissue; there should be rapid integration of the solid bone substitutes into the bone; and there should be rapid ingrowth of bone tissue into reabsorbable bone substitutes. It has been shown that nanohydroxyapatite (NHA), in its various application forms, fulfills the criteria mentioned above [17,18,19,20]. It has also been suggested that these bone substitutes can accelerate growth and bone remodeling, thus allowing the patient early full weight bearing after OWHTO [6,19]. There are several studies that have reported results using NHA, mostly in dental surgery but also in orthopedic and maxillofacial surgery [21,22,23,24].

The aim of the present study was to evaluate the effectiveness of adding nanohydroxyapatite (NHA) to heterologous bone graft by measuring the bone density via multislice CT of the tibial osteotomy gap. The hypothesis of this study was that the addition of nanohydroxyapatite results in better graft integration.

^{*} Corresponding author at: Orthopaedic Unit and Kirk Kilgour Sports Injury Centre, S. Andrea Hospital, Via Flaminia 656, CAP 00191, Rome, Italy. Tel.: +39 3397644667; fax: +39 0633775887.

E-mail address: priscilladisette@gmail.com (P. Di Sette).

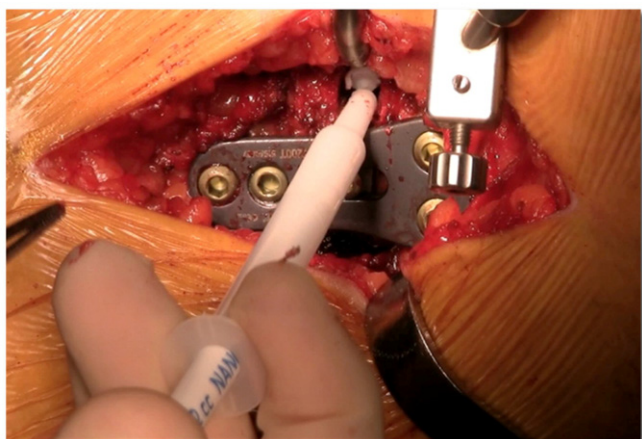


Figure 1. Application of Nanostim using a special preloaded syringe.

2. Materials and methods

In the present study, 26 patients (26 knees) (13 men and 13 women, mean age 57 ± 6.2) who were treated by open-wedge high tibial osteotomy (OWHTO) were prospectively followed up. Patients were randomly divided into two groups: a pure graft group, in which the osteotomy gap was filled with only heterologous bone graft; and a nanohydroxyapatite (NHA) group, in which the osteotomy gap was filled with heterologous bone graft and NHA.

Inclusion criteria for surgical treatment reflected the directions outlined in the literature for this procedure: (1) being aged <65 years; (2) Grade III or lower X-ray Kellgren symptomatic isolated medial knee compartment osteoarthritis; (3) failed conservative treatment; (4) absence of additional cartilaginous procedures (autologous chondrocyte transplantation, microfractures) [3,20].

The OWHTO was performed using an open-wedge medial high tibial osteotomy with a dehydrated equine wedge (Osteoplast, Bioteck, Italy) and a Puddu-like plate (B. Braun Aesculap, Tuttlingen, Germany) for fixation. In the NHA group (13 patients, 13 knees), NHA (Nanostim, Medtronic) was also used in the form of a paste (Figure 1), which, upon examination under an electron microscope, was found to contain needle-like particles of hydroxyapatite with a length varying from 20 to 180 nm.

The surgical technique that was used was the same for all patients. All patients gave written, informed consent prior to participation in the study, which conformed to the ethical guidelines outlined in the 1996 Declaration of Helsinki. It was also approved by the present institution's Internal Review Board (Protocol no. 169/2013). All patients

underwent multislice computed tomography (CT) examination to assess the degree of integration of bone grafts within one week of the operation (Time 0), after two months (Time 1), and at 12 months (Time 2). All CT examinations were performed with one type of CT equipment (GE LIGHTSPEED® Helical CT-16). For all CT examinations, the following acquisition parameters were used:

- Pitch: 0.562
- Slice thickness: 0.625 mm
- mAs: 150
- KVp: 120
- sFOV: 250
- Reconstruction in axial scanning with standard convolution filter
- High spatial frequency convolution filter with enhancement of edge pixels (bone window).

During post-processing, multiplane reformation (MPR) was elaborated with planes on the proximal tibia, oriented along the oblique axial, oblique sagittal, and oblique coronal, in order to obtain a reconstructed set of selected images that would avoid metallic materials of osteosynthesis in the chosen sampling area. In fact, areas for bone density sampling were selected in slices in which the bone graft, NHA, and surrounding trabecular bone would be alone at the center of the region of interest (ROI), without any superimposed disturbance from high-density metallic osteosynthetic materials. The selected ROI were also standardized to avoid cortical bone being inside the areas of density measurement (Figure 2). In order to standardize the density values as much as possible, and to reduce the dependence of the results on the spatial orientation of ROIs, three different standard planes of orientation were chosen: oblique axial, sagittal oblique, and coronal oblique. On each of them, a standard ROI was selected; all ROIs were apt to being repeated in all measurements. The density measurements in the three planes were then summed and divided by three to obtain an additional average sample bone density value for each patient, further reducing the influence of the spatial orientation of the reconstruction planes.

The bone density was recorded in Hounsfield units (HU). Normal bone density was calculated in the same planes on the proximal tibia, oriented along the oblique axial, oblique sagittal, and oblique coronal of both limbs in all patients. A decreasing mineral density on CT indicated better healing of the affected limb, as the values were closer to that of the contralateral limb. Values of tomodensitometry were then compared between the two groups of patients with or without NHA supplementation. A single independent blinded expert radiologist evaluated the relative density of the two sets of patients.

The Bioethics Council of the present institution approved this study, all phases of the study were in accordance with Ethical Guidelines with respect to patients' rights, and all participants gave their informed consent prior to inclusion in the study.

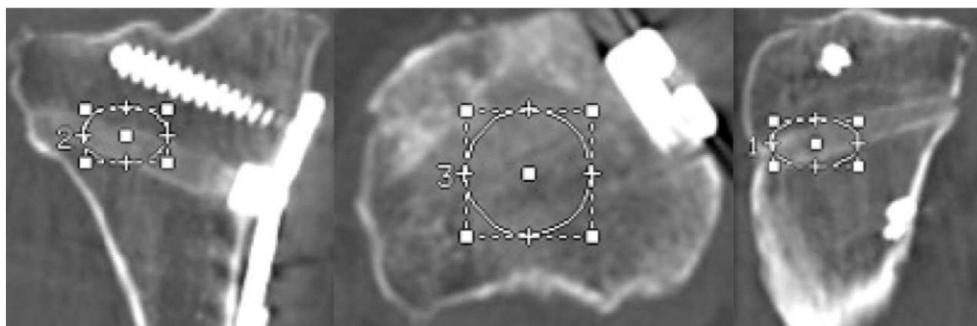


Figure 2. CT scan showing the three different standard planes of orientation (oblique axial, sagittal oblique and coronal oblique) to select a standard ROI (one, two, three dots resemble the measurement spots).

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