Dr Torsten Gerich

Abstract

Implementation of phase 1 studies in trauma surgery and neurosurgery in Luxembourg - collaboration CHL-LIH

Fracture complications, and particularly long bone non-union and/or pseudarthrosis, are a challenge for orthopaedic surgeons. NVD-003 is an autologous 3-dimensional osteogenic implant derived from adipose stem cells that had demonstrated to induce bone formation and support bone healing in severe pathophysiological conditions in preclinical settings.

The purpose of this first-in-human study was to evaluate the safety and preliminary efficacy of NVD-003 in patients with recalcitrant lower limb non-union.

Adult patients with recalcitrant lower limb non-union underwent in situ implantation of NVD-003, processed from adipose tissue that was collected via liposuction, followed by fixation of the fracture with classical fixation material.

After the implant surgery, patients' safety was followed-up for 24 months, including recording of all adverse events, abnormalities in vital signs, physical examinations and safety laboratories. Additionally, efficacy was assessed based on clinical symptoms and radiological scoring of bone healing parameters by independent central readers.

Nine patients underwent NVD-003 grafting surgery and completed the two-year follow-up. None of the 48 documented AEs was considered by the investigators related to NVD-003. Eighteen events were assessed as related to the adipose tissue collection or the implant surgery.

After a follow-up of 24 months, 8 out of 9 patients were considered clinically healed. The median and mean time to clinical healing were 6 months and 9 months, respectively.

Six weeks after the implant surgery, 7 out of 9 patients showed radiologically confirmed bone formation on plain X-ray. Between 3- and 12-months post-implant, 100% bone formation was recorded for all patients. At 24 months, the observed positive clinical progress for 8 out of 9 patients was reinforced radiologically, indicated by high bone union scores.

These results support the safety and clinical efficacy of the NVD-003 implant in the treatment of recalcitrant lower limb non-union.

This was followed by A single arm, single-center study in adult patients, suffering from a distal radius fracture: “A first-in-human proof-of-concept study with NVDX3, an osteogenic bone void filler of human allogenic origin, in the treatment of distal radius fractures in adults.”

NVDX3 is an osteogenic bone void filler of human allogenic origin. This lyophilized and gamma-irradiated tissue engineered product is composed of hydroxyapatite/beta-tricalcium phosphate (HA/βTCP) particles embedded in an extracellular matrix, various biologically active growth factors (including but not limited to OPG, IGF1, VEGF, CTNNB1, OB and COLX), and non-viable osteogenic cells.

Ten patients have been operated in 2023 and are currently followed.

Dr Anas Dyab

Abstract

A proof-of-concept study with NVDX3, an osteogenic implant of human allogenic origin, in the treatment of low grade degenerative lumbar spondylolisthesis by interbody fusion in adults.

Introduction: Advances in biomaterials offer new opportunities to improve outcomes in spinal fusion procedures by enhancing bone healing and stability. This proof-of-concept study investigates the application of **NVDX3**, a bioactive, osteoconductive stem cells material, in Transforaminal Lumbar Interbody Fusion (TLIF) to promote faster and more robust fusion. TLIF is a widely used technique for treating degenerative lumbar disc disease, but achieving consistent and timely fusion remains a clinical challenge, particularly in patients with risk factors such as osteoporosis, smoking, or diabetes.

Methods: Five patients, all presenting with symptomatic lumbar disc degeneration and varying degrees of spinal instability, underwent TLIF procedures augmented with **NVDX3**. The material was applied during the interbody fusion process to the surgical site between the vertebral endplates, with the goal of enhancing osteogenesis and promoting faster fusion. Clinical outcomes will be assessed at regular intervals over 24 months using a combination of physical examinations, Oswestry Disability Index (ODI) scores, and Visual Analog Scale (VAS) for pain. Radiographic fusion will be evaluated using X-rays and CT scans at 3, 6, and 12 months postoperatively to monitor the progression of bone growth and stability of the implants.

Results: showed that all five patients demonstrated early signs of bone formation at the 3-month follow-up. The radiographic evidence confirmed continuous bone growth across the interbody space, with no signs of pseudoarthrosis or hardware

loosening. Clinical outcomes were also favorable, with significant improvements in pain relief and functional recovery.