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SAFETY OF A POROUS HYDROXYAPATITE BONE SUBSTITUTE IN ORTHOPEDICS AND TRAUMATOLOGY: MULTI-CENTRIC CLINICAL STUDY

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Material: ENGIpore bone substitutes are made of biomimetic porous hydroxyapatite, which is very similar in its chemical composition and microstructure to the mineral component of human bones. ENGIpore is a partially resorbable. In addition, HA is acknowledged to provide an intrinsic antibacterial properties, which in turn provides higher resistance to microbial infections.

Intended Use IFU: orthopaedic surgery applications, osteosynthesis and bone reconstruction (calcaneus, talus, femoral, tibia, humerus).

Keywords paper: orthopedics, hydroxyapatite, bone grafts, bone substitute

Background



Although iliac crest bone graft harvesting currently remains the gold standard as an autograft, the properties of hydroxyapatite bone substitutes appear to be valid. The first fundamental step to consider is the safety of using these devices. The purpose of this study is consider all the adverse events observed in our population and assess their relationship with the bone substitute device.

Methods



The population analyzed consisted of patients undergoing trauma osteosynthesis with at least one implanted porous hydroxyapatite device. We have considered a court of 114 patients treated at “Azienda Ospedaliera Universitaria di Ferrara - U.O. di Ortopedia e Traumatologia” in a period from January 2015 to December 2022.

Results



Considering the data obtained from our population and the remaining study groups included, a safety profile is observed in the use of the bioceramic bone substitutes used. In detail, as previously reported, no adverse events were observed in the population coming from our reference center, furthermore the limited percentage (1.23% and 3.92% respectively) of major or minor complications observed in two other centers examined, outlines a clear safety profile.

Conclusions



The safety profile is also supported by the data reported in the scientific literature in similar application area. These conclusions allow the possibility of structuring any further studies regarding effectiveness to optimize the use of the devices and to better understand the interactions between the biomaterial and the surgical intervention.



Take home messages: the morphological characteristics of ENGIpore bone substitutes promote the migration and accumulation of cells specialised in synthesis of the mineral matrix and promote the regenerative processes of the skeletal system. This paper outlines a safety profile in the use of ENGIpore as bone substitute in Trauma Orthopedic Surgery.