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Cyclic Compression Test Procedure for an innovative 3D-Printed Vertebral Filling Device

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This paper presents the development of a dedicated experimental procedure for the mechanical characterization of SPHEREPLAST™, a novel vertebral filling device designed to restore load-bearing capabilities in compromised vertebral bodies. The device consists of porous trabecular spheres with a diameter of 3.3 mm, manufactured via Electron Beam Melting (EBM) additive technology in Ti6Al4V-ELI (grade 23) titanium alloy. These elements are inserted into the damaged vertebral body using a stainless-steel cannula designed for the scope. Due to the absence of specific regulatory standards for such patented devices, a testing protocol is proposed to assess durability and performance under realistic physiological conditions. A custom-designed containment apparatus, with an internal volume comparable to that filled with spheres in real cases, was mounted on a hydraulic testing machine to apply a series of sinusoidal compression cycles to a group of spheres. The test was designed to simulate approximately three months of post-implantation patient activity, i.e., the expected healing period, both in terms of the total number of cycles and the magnitude of the applied loads. A procedure is identified for analyzing the experimental data, obtained through continuous acquisition of load and crosshead displacement during the test, aiming at the identification of the drift in the package height and the cyclic displacement amplitude, delivering useful indicators to evaluate the progressive packing of the spheres, their effective stiffness, and the overall durability of the system. The proposed procedure provides a reliable benchmark for future design variants and quality control.

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