Effects of the Use of Polyetheretherketone (PEEK) Bone Fixation Devices After Completion of Craniotomy on Experimental Animals: A Histopathological Study
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Introduction
Polyetheretherketone (PEEK) is a non-absorbable biopolymer widely used in the manufacture of various medical devices. Since the 1980s, PEEK has been increasingly employed as biomaterial for trauma, orthopedic, and spinal implants. It has been shown that PEEK devices are biocompatible, radiolucent, and are characterized by a modulus of elasticity similar to bone. The good results obtained in the setting of the spine with the use of PEEK cages, and lower complications compared to the use of iliac crest, make these PEEK devices an attractive platform upon which to develop novel bioactive materials. Currently, work is being carried on to design a new bone-fixative device for closing craniotomies using PEEK. This device has a clamping force similar to other standard systems based on metallic structures, which require additional instrumentation. The aim of this work was to study the effects caused by these devices on the meningeal membranes and the process of bone regeneration when used as bone fixative devices after completion of craniotomy in an experimental model in vivo.

Material and Methods:
As experimental animal we used New Zealand white rabbits (n = 6) weighing between 3.500-4.000 kg (3.850±0.273 kg). After being anesthetized, the animals underwent a craniotomy of 1.5 cm². The removed bone fragment was again placed in its anatomical site and fixed by a PEEK device (FC05, NEOS surgery SL) consisting in an intracranial part in direct contact with the dura, and one subcutaneous over the dome. We performed a histopathologic study of the effect of the device on the dura and monitored the bone healing to 30d (n=3) and 60d (n=3). Conventional histological staining techniques (hematoxylin-eosin, Mason trichrome), specific staining techniques (PAS=Periodic Acid-Schiff) and immunohistochemical techniques to study the presence of macrophagic reaction (antibody anti rabbit macrophage RAM-11) were performed.

Results:
The morbidity and mortality rates were 16.67%. All animals reached the end of the study (mortality = 0%), while only 1 of 6 animals studied presented a subcutaneous infection, being attributable to surgical procedure. The histopathological examination showed a good behaviour of PEEK, both at 30 and 60 days of study, showing a normal morphology and dura without significant histopathological changes. The device also allowed a good bone healing process, as evidenced by the appearance of normal trabecular bone in the defect area at 30 days surrounded by a connective tissue from the subcutaneous area. Osteoid substance and new bone formation were observed and this osteogenic increase was much more evident at 60 days. Both at 30 and 60 days, we noticed the presence of PAS positive cells compatible with histiocytic cells. Immunohistochemical study confirmed the presence of RAM-11 positive cells compatible with the presence of macrophages in areas around the biomaterial.

Conclusions:
- The use of PEEK as bone fixing devices after craniotomy maintains normal morphology of the meninges.
- PEEK devices allow good bone healing after craniotomy.
- Due to its unique design and properties, PEEK device may be a good alternative to the classical metallic bone fixative devices after craniotomy.

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