生物可吸收性骨固定裝置應用之臨床效果評估

The Evaluation of Clinical Effects for Bioresorbable Bone Fixation Devices

中文摘要

基於生物可吸收性(poly lactic acid, PLA)骨釘/骨板在先期的體外降解實驗（in vitro test）、生物相容性(biocompatibility)與動物實驗中都獲得不錯的結果，爲更深一步的瞭解可吸收性聚乳酸高分子與金屬骨釘/骨板(bone plates / screws)，在臨床使用上及術後癒合的差異，本研究與台北醫學大學 萬芳醫院神經外科（neurosurgery）合作，從 2003-2004 年開始進行手術結果收集，合計 8 位病患，每組 4 位並隨機分組（實驗組 A：可吸收性固定系統(博納力系統)，Bonamates®，對照組 B：鈦金屬骨釘骨板，Titanium bone screws / plates），採用非盲試驗，術後追蹤至少六個月。

實驗結果在 A 組中，患者使用生物可吸收骨釘骨板，於 CT 或 MRI 的影像上並未留下任何植入物之影像。因此，當接受生物可吸收內固定手術後，在施行放射療法時並無需調整劑量。在術後 6 個月後，使用生物可吸收內固定手術患者的頭皮高度看來平坦且光滑，即使生物可吸收骨釘骨板還未完全的被吸收降解，而且病患頭皮輪廓的平滑及等高性也使外科醫師受到病患家屬的高度讚賞。在 B 組中，其中一位患者必須接受放射性療法，而因爲金屬人工植入物的遮蔽，必須重調輻射劑量以避免輻射射線直接投射鈦金屬上。在手術 6 個月以後，病患仍然有某一部分的頭皮高度凸出在手術區域附近。

數據統計結果顯示在 A 組中，術後癒合的成功率爲 100%， B 組（鈦金屬）中，術後癒合的成功率爲 75%。沒有統計分析能應用於小樣本數中。關於術後的併發症（傳染; 軟組織開裂; 植入物相關的組織反應），則無統計學上的差異。這樣的結果可能的原因在於母群的樣本數太小，以至於其統計分析並無重大差異。

英文摘要

Our team devotes bioresorbable polymer (poly-lactic acid, PLA) series in a long time, including the in vitro test, biocompatiblity, and aninal study have good results in our preliminary studys. The aim of this trial was to compare the clinical outcomes of bone flap fixation using a new bioresorbable system (Bonamates®) and a traditional titanium plate/screw system. Bioresorbable devices are particularly useful for skull bone reconstruction. Different systems are now commercially available. Patients diagnosed with a head injury, brain tumor, or cerebral vascular stroke and who received a craniotomy in our hospital in 2003 and 2004 were randomly allocated to 2 treatment groups for skull flap fixation (study group A: Bonamates®: n=4; control group B: titanium plate: n=4). Treatment outcomes and complication rates were compared between these 2 groups. In total, 8 patients (study groups A and B) were followed-up for at least 6 months after surgery. All patients in the study group A

whose bone flap was fixed with bioresorbable plates/screws were reviewed postoperatively. Uneventful healing occurred during the entire follow-up period for all 4 patients (100%) in group A but for only 3 of 4 patients (75%) in group B. None of the patients developed postoperative complications (i.e., infection, soft tissue dehiscence, bone flap sink, or implant-related tissue reactions). After the operation, all patients in group B had severe artifacts on the imaging study (especially the computed tomographic scan), but none was seen in group A. For patients who received radiotherapy (1 from each group), the one fixed with the titanium plate had some dosimetry considerations and complications, but the one using Bonamates® fixation had none. There were no significant differences between the bioresorbable device and titanium fixation with respect to fracture healing, bone flap sink, or postoperative complications. But the fusion rate appeared to be higher in the Bonamates® group. If patients are going to receive radiotherapy (especially brain tumor patients), the Bonamates® system seems to be an ideal choice for bone flap fixation.