國立臺灣大學技術行銷表

台大案號：98 工 988

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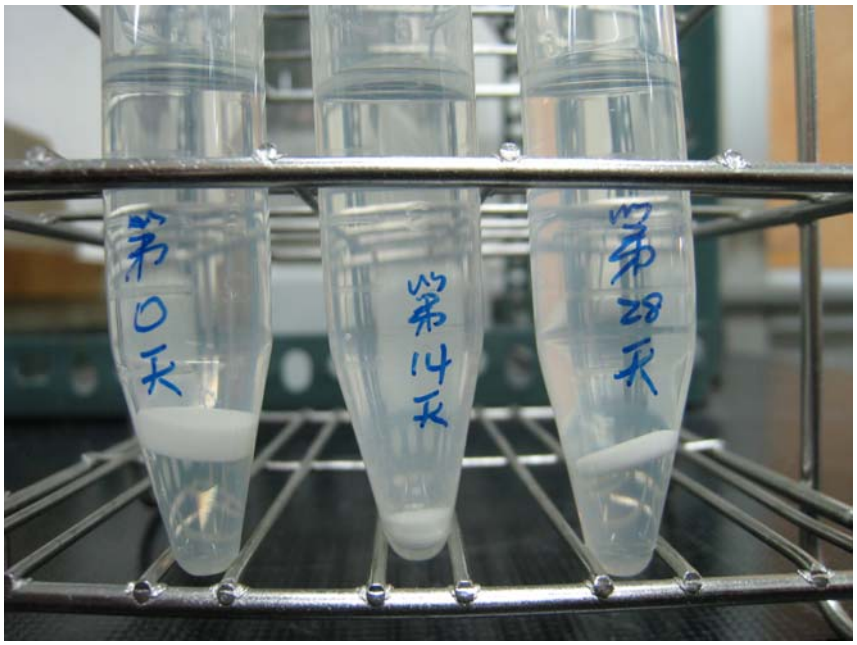
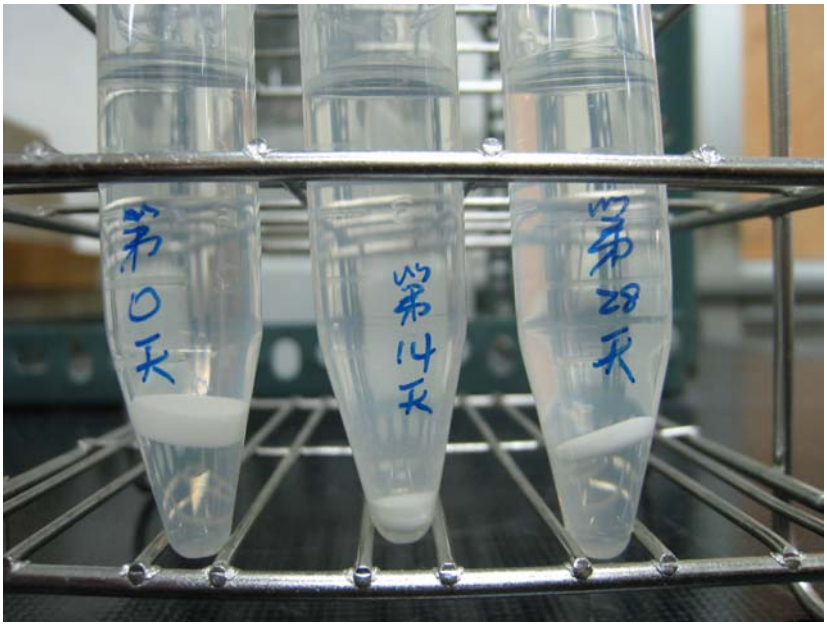
<table>
<tr><td>產品/技術名稱</td><td>可控制分解速率的生物陶瓷及其製法</td></tr>
<tr><td>發明人/單位</td><td>段維新教授及其研究團隊
國立台灣大學材料系</td></tr>
<tr><td>產品/技術說明</td><td>每年全球約有二百萬的病患經歷骨移植手術來醫治其骨頭缺損的問題。本發明揭露出一種控制生物陶瓷的分解行爲的方法，此種方法是將生物用之硫酸鈣材料藉由添加含不同價數之元素及其化合物及玻璃起始材料，經由混練、成型後，再施以熱處理。如此，可使生物用之硫酸鈣材料於熱處理時具有可燒結性，而此燒結後之生物用的硫酸鈣材料具有理想之強度與生物相容性。</td></tr>
<tr><td>應用範圍</td><td>生醫材料-骨替代物(bone graft substitutes): block or pre-form（即，塊材或多孔材料）。</td></tr>
<tr><td>產品/技術優勢</td><td>本計畫研發之骨科陶瓷材料與市售品牌之骨水泥填充物功能比較如下：
<table>
<tr><th>材質</th><th>生物相容性</th><th>生物降解性</th></tr>
<tr><td>自體骨</td><td>良好</td><td>潛行時間長</td></tr>
<tr><td>異體骨</td><td>普通</td><td>潛行時間長</td></tr>
<tr><td>PMMA (Howmedica)</td><td>差</td><td>不可生物降解</td></tr>
<tr><td>金屬(不鏽鋼)</td><td>差</td><td>不可生物降解</td></tr>
<tr><td>氫氧基磷灰石(HA)</td><td>普通</td><td>不可生物降解</td></tr>
<tr><td>Vitoss (Orthovita)</td><td>良好</td><td>潛行時間長</td></tr>
<tr><td>Osteoset BVF Kit (WMT)</td><td>良好</td><td>良好/時間不可控制</td></tr>
<tr><td>本技術所開發之骨科陶瓷材料</td><td>良好</td><td>良好/時間可控制</td></tr>
</table>
本計畫研發之骨科陶瓷材料具備下列特點：
(1) 抗壓強度: 150 MPa
(2) 在生理食鹽水中崩散速率: < 3 %/day (可調控)
(3) 毒性測試結果（根據ISO 10993-5:2009）
Cell line：ATCC (American Type Culture Collection)　L929 (fibrous blast cell)
(a) MTT assay所測得之細胞存活率 ~ >80% (Noncytotoxic level)
(b) Cell life line method 所測得之細胞存活率 ~ 95%
(4) 生理食鹽水中量測一個月後之 pH 值: 6.6~7.1</td></tr>
</table>

市場潛力	根據『*US markets for orthopedic biomaterials* 報導』指出，每年人工骨替代物所產生營業額可達 10 億美金，且其在商業市場上，每年以 10%成長。 1999 年全球產品的銷售將近 120 億美元，與 1998 年相比成長了 10%，其中重建元件佔 45 億美元（美國佔 22 億），骨折固定方面佔 14 億美元（美國佔 7 億），脊椎植入物及器械佔 13 億美元（美國佔 9 億），關節內視鏡及軟組織修復佔 11 億美元（美國佔 7 億），生物製品佔 6 億（美國佔 5 億），其他產品佔 27 億美元，總計 116 億美元。其中，生物製品包括『人工骨骼替代物』、『自體異體移植骨』及『軟組織置換產品』。
產品/技術 智財權保護方式	已申請中華民國與美國專利
圖片 (已公開之成果可提供圖片)	 第 0 天：試樣剛浸泡時 第 14 天：所開發之材料中的一種，在浸泡第 14 天時，完全崩散。 第 28 天：所開發之材料中的另一種，在浸泡第 28 天時，仍未崩散。

Marketing Abstract of NTU's Invention Disclosure

CIAC contact：蘇祈烈　　Tel：02-33669949　　e-mail：such@ntu.edu.tw

<table>
<tr><td>Title</td><td>Controllable biodegrading bioceramics and method of manufacturing the same</td></tr>
<tr><td>Inventor (s)</td><td>Wei-Hsing Tuan / Department of Materials Science and Engineering, NTU</td></tr>
<tr><td>Brief Description</td><td>Every year, around 2 million patients in the world sustain a bone grafting procedure to repair bone defects. The present invention discloses a method that can improve the degradation rates of calcium sulfate. The material can be used as a bio-material. This method is prepared by mixing calcium sulfate different valence elements and/or chemical compounds and/or glass starting materials as sintering aids. By adding the sintering aids, the densification of calcium sulfate is possible. The strength and biocompatibility of the specimens after sintering is satisfactory.</td></tr>
<tr><td>Fields of Application</td><td>Biomaterials - bone graft substitutes: block or pre-form</td></tr>
<tr><td>Advantages</td><td>Comparing with the commercial products:
<table>
<tr><th>Materials</th><th>Biocompatibility</th><th>Biodegradation</th></tr>
<tr><td>Autograft</td><td>well</td><td>long time</td></tr>
<tr><td>Allograft</td><td>moderate</td><td>long time</td></tr>
<tr><td>PMMA (Howmedica)</td><td>poor</td><td>no resorption</td></tr>
<tr><td>Metal (stainless steel)</td><td>poor</td><td>no resorption</td></tr>
<tr><td>Hydroxyapatite (HA)</td><td>moderate</td><td>no resorption</td></tr>
<tr><td>Vitoss (Orthovita)</td><td>well</td><td>long time</td></tr>
<tr><td>Osteoset BVF Kit (WMT)</td><td>well</td><td>Well (Degradation behavior cannot be controlled.)</td></tr>
<tr><td>Bone graft substitutes developed by using this technology</td><td>well</td><td>Well (Degradation behavior can be controlled.)</td></tr>
</table>
Characteristics of bone graft substitutes developing in this project are:
(1) compressive strength: 150 MPa
(2) disintegration rate in normal saline: < 3 %/day (controlable)
(3) cytotoxicity test (according to ISO 10993-5:2009)
Cell line : ATCC (American Type Culture Collection)　L929 (fibrous blast cell)
(a) MTT assay - cells viability ~ >80% (Noncytotoxic level)
(b) Cell life line method - cells viability ~ 95%
(4) pH (incubate in normal saline for 1 month): 6.6~7.1</td></tr>
</table>

Market Potential	According to"*US markets for orthopedic biomaterials*", the turnover generated by bone graft substitutes is about 1 billion US dollars a year, with a yearly market growth close to 10%. Compared with in 1998, the bone graft products for global sale were about 12 billion, growing up 10%, in 1999. Among the bone graft products, the rebuilding components were 4.5 billion dollars (accounted for 2.2 billion dollars in USA). Components for bone fracture fixing were 1.4 billion dollars (accounted for 700 million dollars in USA). The items for implanting into vertebra and relative apparatus were about 1.3 billion dollars (accounted for 900 million dollars in USA). The products for observing joints and soft tissue repairing accounted for 1.1 billion dollars (accounted for 700 million dollars in USA). The biological products were around 600 million dollars (accounted for 500 million dollars in USA); other related products accounted for 2.7 billion dollars. The sum of them was 11.6 billion dollars. In the biological products, the bone graft substitutes, autograft/xenograft and items for replacing soft tissues were including.
IP Right(s)	Applications of US and ROC patents are in progress.
Picture	 0 day: The sample immersed in the normal saline. The 14th day: one of samples immersed in the normal saline. It disintegrated completely at the 14th day. The 28th day: one of samples immersed in the normal saline. It still held the shape after immersing at the 28th day.