

醫工學會



中華民國生物醫學工程學會

Taiwanese Society of Biomedical Engineering

E-Newsletter

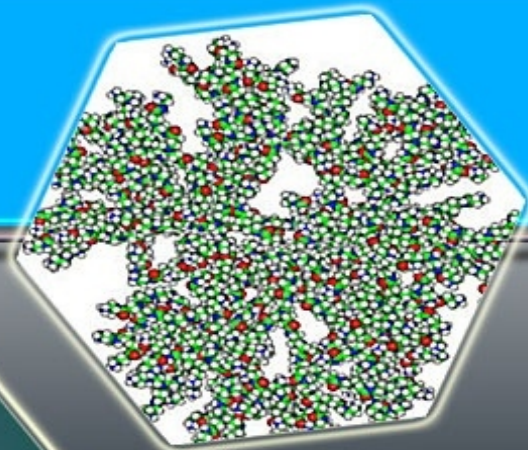
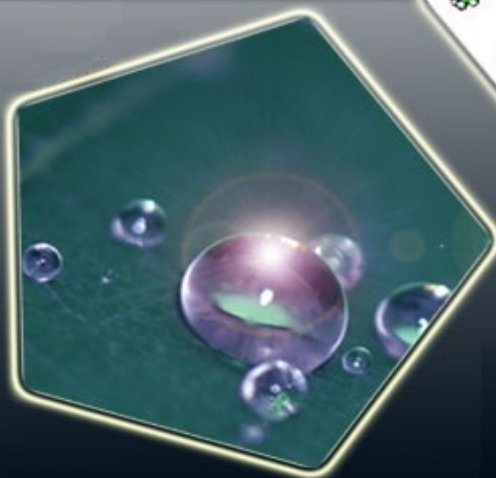
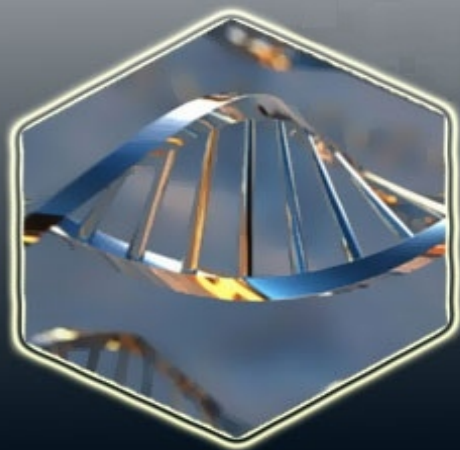


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生醫工程研究所

Graduate Institute of Biomedical Engineering



行政院衛生署食品藥物管理局

Food and Drug Administration, Department of Health, Executive Yuan



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更多醫工動態盡在醫工學會電子報，請即刻閱讀！
學會為了嘉惠醫工大家庭，100年4月回復電子報發行，預計每三個月出刊一期，敬請期待，對於本學會電子報，有任何意見，歡迎來電指教
(06) 2760665

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【成果榮譽】

恭賀本會 JMBE 年度最佳論文「Red Blood Cell Velocity ,Measurement in Rodent Tumor Model : An in vivo Microscopic Study」榮獲中工會工程論文獎，

獲獎者為:林康平教授研究團隊。

詳請請見中工會 102 年度各獎項得獎名單。

http://www.cie.org.tw/news_detail.php?id=75

【成果榮譽】

恭賀本會常務理事林峯輝教授榮獲 102 年度中工會傑出工程教授

詳請請見中工會 102 年度各獎項得獎名單。

http://www.cie.org.tw/news_detail.php?id=75

【2013 張冠諒教授紀念獎學金得獎名單】

博士級：廖書賢(成功大學 醫學工程研究所)

碩士級：李忠翰(台灣大學 醫學工程研究所)

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張吟綺(銘傳大學 生物醫學工程學系)

祁惠商(義守大學 生物醫學工程學系)

以上獲獎同學將於今年度中華民國生物醫學工程學會會員大會(年會)中授獎
(2013/11/15~11/6 於清華大學，另行通知。)

【重要活動訊息】

102 年度「韓偉生物醫學工程服務獎章」推薦開始囉！

今年由於評審會議需提前召開，相關作業程序需較往年提早，今年之收件期間為
即日起至 7 月 20 日截止(以郵戳為憑)，詳請請參閱醫工學會網站

http://www.bmes.org.tw/notice_show.php?id=304，敬請會員踴躍參與，謝謝！

國立中興大學 生醫工程研究所

Graduate Institute of Biomedical Engineering



本所概況

國立中興大學生醫工程所於 96 學年度首度成立碩士班，所規劃的課程和訓練以奈米科技為中心，進而衍生為組織工程與再生醫學和微奈米生醫工程兩大主軸，以期能整合生醫產業上(學界)、中(產界)、下游(醫界)之理論與技術，以培育創新研發及促進商品化所需的跨領域醫療及工程人才的目標。本所課程之多樣化及選課高自由度提供學生獲得生醫學科知識與工程應用之良好連結途徑。鑑於生醫工程所為獨立所師資員額有限，藉由聘請合聘及兼任師資，以及與校內外學術研究單位合作開課，更進一步提供學生多元化課程學習管道。同時，本所教師積極與國內外研究單位進行跨單位與跨國的研究合作計畫，每學期都會邀請外國學者來本所演講，此舉不僅將本所研究能量灌注至國內外科技、技術發展，更提供本所學生與國外學術界之間的聯繫管道與合作交流機會。在產學合作推動上，除了持續推動與華廣生技、亞諾法生技等檢驗與醫材業界指標公司合作外，並與台中榮民總醫院、中山醫學大學、中國醫藥大學等區域教學醫院合作，期整合資源以進行團隊研究。本所的研究設備在這幾年來，藉由本校及國科會等單位之支持下，陸續添購新增，目前尚能滿足師生研究所需。而空間部分，本所計劃於兩年後遷入興建中之應用科技大樓，屆時將能做更多的空間應用以符合本所之發展規劃及師生使用之需求。

本所特色介紹

- 1、 **組織工程與再生醫學**：利用生物技術方法製造人工器官供人類疾病治療使用。此領域涉及細胞學、生理學、分子生物學、臨床醫學、外科、病理學及獸醫學

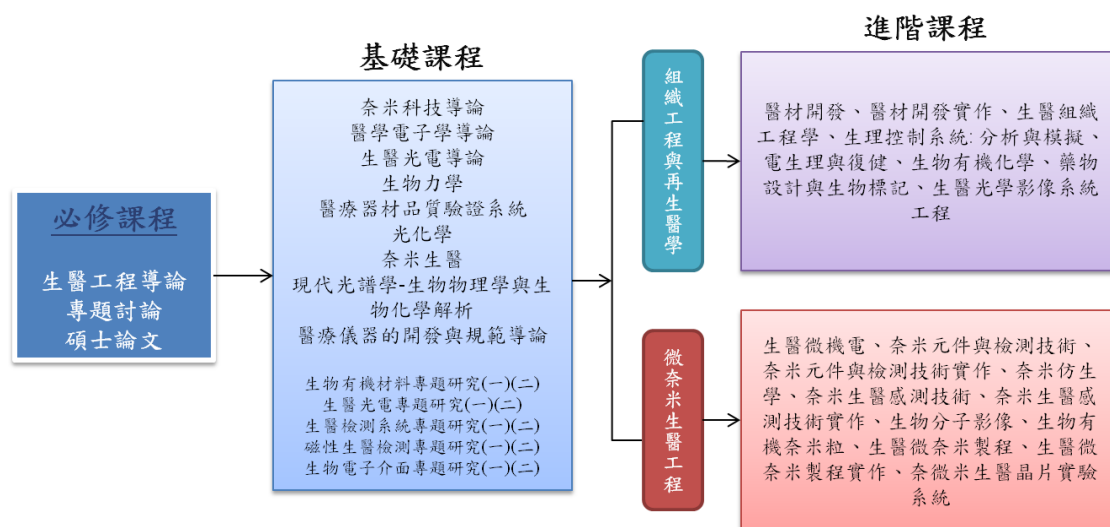
等專業知識，利用發展的生物人工移植體以促進組織重塑來達到修補組織和增進器官功能的目的。

- 2、**微奈米生醫工程**：整合基礎學科、機械、化工、材料與生物醫學等領域之技術，以奈米材料與奈米技術為出發點，使用奈米元件或奈米結構，在分子層次上掌控、修復、建構生物體，進行醫學上之診斷、治療與預防。

課程規劃

依「微奈米生醫工程」與「組織工程與再生醫學」兩大領域規劃必選修科目與30畢業學分要求。基礎課程（12學分）與所訂進階課程（21學分），其中進階課程內容以兩大項分類，分別為組織工程與再生醫學以及奈米生醫工程，學生可以按照其興趣以及未來生涯發展規劃，選擇所需要之課程研修，取得足夠學分通過畢業門檻。在課程地圖宣導方面，本所以網頁、宣導摺頁及每年固定新生座談的方式，幫助本所師生了解課程地圖。必修課程「生醫工程導論」引領來自理工醫農各具不同專業背景的學員，了解其所長在本領域可能的應用模式，並學習其他相關的知識，以團隊的觀點來探討研習在醫學工程上，可能面臨的挑戰與因應之道，為日後職場上的需求踏出跨越領域隔閡的第一步。

- 1、**必修課程**：「專題討論」藉由產、學、醫業界受邀專業人士的經驗分享，使學員對將來生涯規劃，能有更具體的了解，以儘早擬定學習計畫。每學期規劃本所學生聆聽至少一場國際學術演講，藉由國際學術專家與學者的交流活動，增加學生外語能力並培養學生國際視野。
- 2、**選修課程**：分為「基礎課程」和「進階課程」。基礎課程含「奈米科技導論」、「醫學電子學導論」、「生醫光電導論」、「生物力學」、「醫療器材品質驗證系統」、「光化學」、「奈米生醫」、「現代光譜學-生物物理學與生物化學解析」、「醫療儀器開發與規範導論」。
- 3、「**專題研究**」課程內容主要以指導教授之研究團隊為主體，每星期於固定時間進行文獻選讀與報告、實驗進度報告與討論，旨在建立學生獨立進行研究、與同儕或指導教授間的溝通及協調能力。
- 4、**進階課程**：組織工程與再生醫學進階課程含「醫材開發」、「醫材開發實作」、「生醫組織工程學」、「生理控制系統」、「電生理與復健」、「生物有機化學」、「藥物設計與生物標記」、「奈米仿生學」、「生物有機奈米粒」。微奈米生醫工程進階課程含「生醫微機電」、「奈米元件與檢測技術」、「奈米元件與檢測技術實作」、「奈米生醫感測技術」、「奈米生醫感測技術實作」、「生物分子影像」、「生醫微奈米製程」、「生醫微奈米製程實作」、「奈米生醫晶片實驗系統」、「生醫光學影像系統工程」。
- 5、**持續推動與產(聯合骨科器材、3M、全微精密)、官(工研院、國家奈米元件實驗室)、醫(台中榮總、中國醫藥大學、中山醫學大學、澄清醫院、高雄醫學大學)、學(台灣大學、成功大學、海洋大學、長庚大學)合作**，藉由邀請授課、臨床儀器或生產設備參觀及實習觀摩等方式，增進學生之實務經驗。



專兼任教師及研究方向

至 101 年 9 月止，生醫工程所目前擁有 5 位專任教師，其中含 1 位教授、1 位副教授及 3 位助理教授，均具有博士學位。因應教學與研究需要，本所合聘 1 位師資(國立中興大學機械工程學系王國禎教授)、延聘 1 位校外兼任教授(國立台灣大學高分子科學與工程學研究所徐善慧教授)，並且邀請數名來自校內其他系所的支援教師，尚能應付目前本所開課需求。目前本所教師於本所任教前，皆從事一定時間的博士後研究之訓練或者具業界與他校教學經驗，專、兼任教師之學術專長包括材料、元件、組織工程、奈米生醫及醫學影像領域，且所有教師研究主題皆與本所主要發展方向相關，符合本所創立之精神、課程設計與研究方向。在 99 至 101 學年度間，本所專任暨合聘教師一共通過包含國科會(含國家型、跨國雙邊計畫)、衛生署、教育部及台中榮總等教學研究計畫案共 20 件(其中 12 件為多年型)，累計補助金額 44,607,080 元，所發表的 SCI 論文達 35 篇(其中第一或通訊作者為本所教師者 23 篇)。而除了教學研究工作，所上教師也積極參與許多專業相關的社會性服務工作，如計畫、專利評估、論文審查、政府機關顧問、受邀演講、承辦技術教育訓練等。本所規劃了專屬實驗室，由相關專長之教師主持，致力相關領域的研究，每一位研究生入學後均會加入一個研究團隊，每一個專屬實驗室(包含研究生研究室)提供團隊內研究生平時研究所需之設備與空間，讓同學能在適當之環境下，互相討論與學習，致力於相關專業能力的養成與研究進行，並能提升研究的成果。

磁性生醫檢測實驗室

【指導教授：洪振義】



主要研究方向為『磁性生醫』方面相關研究，研究內容包括將磁性奈米粒子進行表面改質，使之成為具生物功能性之磁性奈米粒子，並於最外層接上特定生物探針成為磁性試劑。目前的研究係利用此磁性試劑在生醫方面之應用，含磁性生醫檢測、磁性分離及純化及用來作為目前正進行開發之 DNA 配適體快速篩選平台之載具。

奈微米系統實驗室

【指導教授：王國禎】



主要研究領域以『生醫微機電』與『奈微米生醫』為主軸。研究方向包括：

- 組織工程之人工微血管→以生物相容性材料配合雷射加工技術製作出生物支架。
- 奈微米結構與生物可降解性材料在組織工程上的應用→在生物可降解性材料上製作奈微米結構，並應用於組織工程材料上。
- 微震盪刺激細胞生長的研究→以各種不同震盪系統刺激細胞生長

生物有機材料實驗室

【指導教授：張健忠】



研究方向主要集中在螢光材料 (Fluorophores) 與光感物質 (Photosensitizers) 的設計與合成並應用於生醫檢測與治療。研究內容包括：

- 生物顯影劑 (Biomarkers)
- 近紅外光感測劑 (Near-IR Sensors)
- 金屬離子生物感測劑 (Metal-Chelating Biosensors)
- 光動力治療 (Photodynamic Therapy)

生醫光電實驗室

【指導教授：廖國智】



本研究室主要研究方向以『光纖感應器平台開發』和『奈米醫學影像技術』為主軸。『光纖感應器平台』利用光化學微感測技術，可於臨床即時且連續監控特定微量生理物質濃度(如血糖)或生理現象變化程度(如細胞凋亡)等情形。『生醫奈米技術』利用奈米元件的物理化學特性(如奈米金屬粒子的表面電漿共振能量轉移)或生理特性(如奈米級微脂體的滲透與留滯增強效應)，增強醫學影像對病灶的顯影對比，或進行特定藥物傳輸模式。

生物電子介面實驗室

【指導教授：林淑萍】



主要研究方向為『生物電子介面』，乃利用半導體精密製程、材料科學、生物醫學科技等技術，製作設計奈微米電子元件與奈微米生醫材料。研究方向包括：

- 奈微米生醫電子於生物分子或細胞生物體的檢測與應用：利用材料功能性改質技術，增加電子元件的偵測靈敏度、專一性、生物相容性。
- 奈微米生醫材料製作：陶瓷材料與高分子材料於生醫及組織工程上的應用，如：軟組織再生與修復。

生醫檢測系統實驗室

【指導教授：陳建甫】



研究主要以可攜式一次使用性生化檢測元件為主，內容包含以下幾個研究課題

- 可攜式整合性免疫系統偵測及蛋白質體學研究實驗室晶片系統
- 奈米材料整合型元件應用在生醫檢測與環境監測
- 精密塑膠元件製程

畢業出路

醫工所屬於跨多重研究領域的研究所，繼續進修之畢業生可選擇醫工、材料、生醫機械、醫用電子、生醫光電等領域之研究所；選擇就職之畢業生可進入生技公司、醫院之研究單位、工研院或國衛院等研發單位，或者醫療器材產業及電子、光電等產業，均有可發展之處。本所目前已有 25 位畢業校友，仍保持密切聯繫中，其中 60% (15/25) 的校友進入職場就業，所從事之行業為本科系相關，12% (3/25) 的校友繼續於國內知名學府博士班深造。畢業校友對於本所提供之專業訓練深表肯定，有 75% 以上的畢業校友認為不管是升學或就業上都符合他們的需求。整體而言，本所於就業及研究上之表現都相當出色。

現有學制及入學評量方式

本所碩士班入學方式分為甄試入學及考試入學二種管道。

1. 甄試入學：評分方式為資料審查 100%；甄試入學的招生流程，由本所所有專任及合聘教師成立甄試委員會，對於申請甄試學生進行資料審查，資料審查成績依各委員之成績排名統計排序而成，經甄試委員會確認無誤後送交本校招生組，再由校方放榜會議通過後，錄取優秀甄試生。
2. 考試入學：評分方式為資料審查 70%、筆試(共同科目：英文)30%；一般考試入學的招生流程，由本所成立甄試委員會負責資料審查的部分，而筆試為全校共同考科(英文)，由校方統一負責該考科之試務及成績計算。總成績經甄試委員會確認無誤後送交本校招生組，再由校方放榜會議通過後始公佈榜單。

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台灣醫療器材管理現況與發展

前言

醫療器材係為特定需求而設計製造之特性產品，隨著科技日新月異的發展以及醫療保健需求科技化的期待，再加上台灣已邁入老年化的社會，以及中國、美國醫療政策改革的推波助瀾下，醫療保健科技產品需求的成長牽動全球醫療器材市場發展。

醫療器材產業同時也是我國所有生技產業領域中，成長最為快速的新興產業。從 2007 年產值僅為新台幣 515 億，至 2011 年已成長到新台幣 682 億元，平均每年以約 6.3% 的複合成長率成長。其中我國醫材的出口金額由 2007 年新台幣 290 億，成長至 2011 年 412 億新台幣，年複合成長率高達 9.2 %。目前國內約有 38,000 家醫療器材廠商，約 32,000 張產品許可證，每年約 780 億元市場產值的生產製造、查驗登記、進口和上市，這些都與民眾的生活福祉和健康安全息息相關。

環境的變遷，我國最高主管機關也啟動組織變革，行政院衛生署參考先進國家管理精神及組織體例，將原衛生署食品衛生處、藥政處、藥物食品檢驗局、管制藥品管理局四個單位加以整併，於 99 年 1 月 1 日成立食品藥物管理局(Taiwan Food and Drug Administration, TFDA)，並將醫療器材管理與發展任務，交由醫療器材及化粧品組來專責規劃推動。TFDA 成立後，積極推動各項醫療器材管理改革措施，構築合理化與透明化的審查與管理法規環境，在政府單位與業界共同合作與努力之下，已達成現階段任務的目標，一步一腳印持續朝向促進及提升我國生技製藥產業方向發展。

醫療器材及化粧品組—專責把關民眾健康，提升新興產業發展

著眼於醫療器材產品與民眾健康生活與品質息息相關，及其產業未來發展的重要性，食品藥物管理局醫療器材及化粧品組，承擔起為民眾健康把關與醫療器材產業發展的重要任務，並在該組下設置了六個科，包含醫療器材安全品質管理科、醫療器材法規及專案管理科、醫療器材諮詢輔導暨產品審查科、醫療器材臨床試驗暨產品審查科、醫療器材產品審查科、化粧品管理科等。負責全國所有醫療器材產品的管理法規、政策之擬定與執行，產品上市前之查驗登記作業，生產流程之稽查與輔導，檢驗研究與科技發展，風險評估與風險管理，安全監視、危害事件調查及處理，以及消費者保護措施之推動等業務。以努力不懈的精神來創造更美好的醫藥衛生環境，達成國人健康品質的期待。

有鑑於醫療器材的特性及風險程度，TFDA 對於醫療器材之安全與品質管理，是以消費者保護為核心，分別從生產源頭控管、上市前把關、上市後監督及藥商及產品通路管理等四階段，來精確控管醫療器材之安全性、有效性與品質(圖 1)。以下分別從該四階段之管理措施與策略詳述：

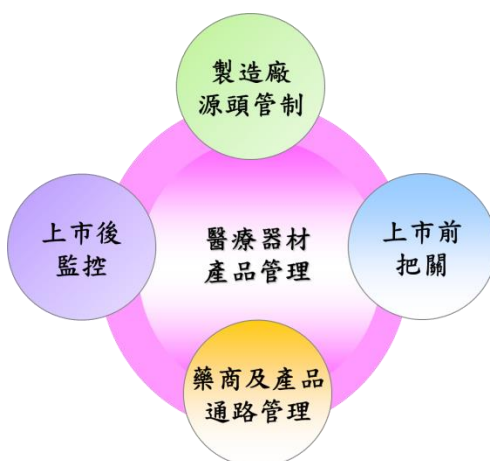


圖 1.我國醫療器材管理架構

源頭控管-確保醫療器材製造品質

我國自 86 年起推動實施醫療器材優良製造規範(Good Manufacturing Practice, GMP)，持續以 GMP 實地查廠及 QSD(Quality System Documentation)書面審查方式，確認國內、外醫療器材製造業者均建立與維持符合優良製造規範之品質系統。目前受委託代施查核機構包括工研院量測技術發展中心、財團法人台灣電子檢驗中心、金屬工業研究發展中心及財團法人塑膠工業技術發展中心等四家。截至民國 101 年底止，醫療器材 GMP 及 QSD 認可登錄函有效認可件數已達 3,596 件。

為與國際管理趨勢一致，衛生署於今 (102) 年 3 月公告「藥物優良製造準則」及修正「藥物製造工廠設廠標準」，採行 ISO 13485 之 2003 年版標準，並將「臨床試驗用醫療器材」及「未滅菌或不具量測功能之第一等級醫療器材」，也就是低風險性醫療器材製造廠全面納入自主性符合醫療器材優良製造規範，落實全面實施 GMP 規範，提升國內醫療器材製造廠品質。

上市前把關-以高效率審查醫療器材安全性及有效性

衛生署自 94 年 6 月 30 日起將醫療器材全面列管，凡符合藥事法及醫療器材管理辦法規定之醫療器材，均應取得許可證後，始得製造、輸入販售。截至 101 年底止，共有 32,774 張醫療器材許可證，其中約 20% 為國產產品；80% 為輸入產品。

第二、三等級醫療器材查驗登記，在提升審查時效及品質上，TFDA 自 99 年成立後陸續公告多項精進措施，包含「醫療器材類似品判定流程及函詢申請說明」、「第二等級且無類似品醫療器材查驗登記申請之簡化流程」、「醫療器材臨床試驗計畫及變更案之簡化審查程序」及「簡化第三等級體外診斷醫療器材部分品項之查驗登記流程」等，此外，並依據醫療器材之風險等級分別建立精簡及優先審查機制，研訂 37 項醫材產品臨床前技術基準，採認 1,002 項國際標準、導入實質對等性之審查模式及調整諮議會作業方式等，已達到逐年提升審查時效，縮短醫療器材產品上市時程及兼顧產品之安全品質效益。

上市後監督-為使用者築起安全網

醫療器材取得上市許可後，為及早發現產品缺失及潛在危險並即時改正，TFDA 建置系統化監控制度，首先於 92 年起，陸續建置全國藥物不良反應通報系統及全國藥物不良品通報系統，透過此機制，可即時發現產品上市後安全性疑慮問題，同時評估並採行風險管控措施。醫療器材不良反應及不良品通報案件數已由 99 年之 49 件、366 件提升至 101 年之 285 件及 1422 件。TFDA 並針對風險較高之醫療器材，依據藥事法第 45 條及藥物安全監視管理辦法，要求廠商執行上市後風險管理並定期回報。

此外，TFDA 每日主動監控先進國家發布之嚴重醫療器材警訊，截至 101 年 12 月底止，共有 1385 則產品警訊、1119 則回收通知，並已摘譯公布其中 160 則於全國藥物不良反應通報系統網站。另我國於 99 年 12 月 17 日加入國際醫療器材法規官方論壇（IMDRF）轄下主管機關警訊報告交換系統（NCAR），藉由該系統接收各參與會員國之醫療器材回收通知、安全警訊、風險警訊、產品通知及其他產品警告資訊，以及早採取因應措施，至 101 年底已接獲 649 件通報。

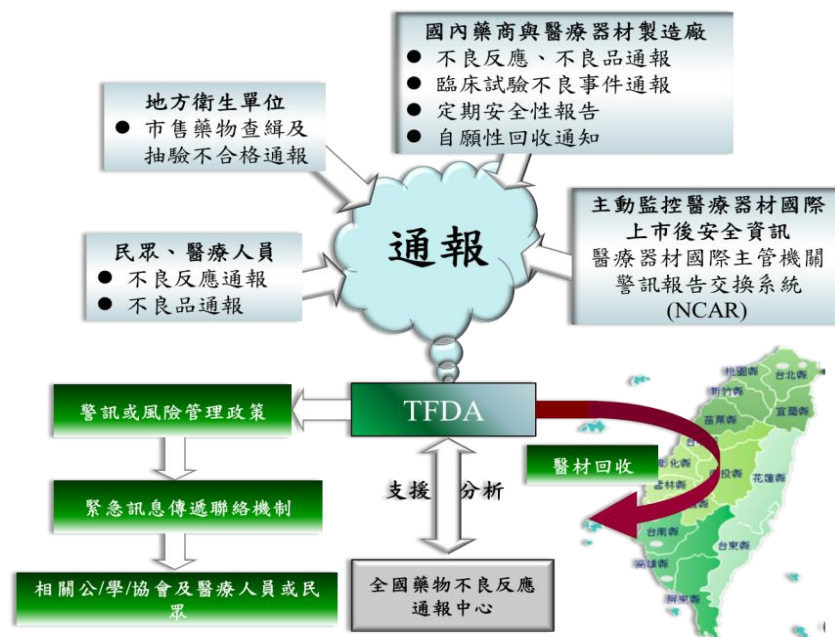


圖 2. 醫療器材上市後通報機制

藥商及產品通路管理- 流通安全 便民服務

網路資訊無遠弗屆，跨國購買商品已非難事，為保障民眾使用醫療器材之安全，TFDA 於 101 年 11 月 1 日公告「藥商得於郵購買賣通路販賣之醫療器材及應行登記事項」，明確規範販賣藥商資格、可販賣醫療器材種類及民眾購買應注意事項，提供消費者取得醫療器材之通路更加便利外亦兼顧安全。另外，規劃研擬之優良流通規範（Good Distribution Practice, GDP），確保醫療器材能夠不受流通傳遞過程而影響產品品質，並能有效加強醫療器材販賣業藥商管理。

精進措施 有效達成管理目標

醫療器材管理策略，從落實四階段之管理措施做起，此外，對於提升與精進醫療器材品質與產業發展，有二項重要措施：包含全方位的法規諮詢輔導與法規國際協和化，加速產業布局國際市場，以多元化策略，精進台灣品質，布局海外市場，完整有效達成管理目標。

TFDA 於 100 年成立「醫療器材法規諮詢輔導中心」，成立服務單一窗口，每年提供超過 2000 件醫療器材一般法規諮詢。此外，針對未於國內上市、尚在研發中之國產第二、三等級醫療器材或多國多中心醫療器材臨床試驗計畫申請案，提供專案諮詢輔導，已有效加快由學研界之研發成果，轉譯予產業界商品化上市之腳步。成功輔導產品，締造出三項第一佳績，包括全球第一的高階治療軟骨缺損臨床試驗，與全球第一核准上市基因型核酸分子檢測套組，創新第一的負壓設計睡眠呼吸中止治療裝置臨床試驗，以及國產第一的一階式人工牙根，進而取代進口產品，另外還有治療壓迫性骨折的網袋椎體復位固定系統以及用於減重之胃夾具等產品，也是國產第一。

另外，在提升產業走向國際策略，TFDA 已分別與澳洲、中國大陸、列支敦斯登、歐盟、英國等完成簽署合作備忘錄(Memorandum of Understanding, MOU)或技術合作方案，透過雙方互信交流，藥物管理資訊之訊息交換，有效減少重複審查及查廠，加速產品上市時程。TFDA 成立至今舉辦多場醫療器材法規研討會，帶動業界熱烈迴響。99 年我國 TFDA 劉麗玲組長當選亞洲醫療器材法規調和會 (AHWP) 國際組織官方副主席，此為我國首度殊榮，藉此也爭取到我國於 101 年 11 月 2 日至 8 日主辦第 17 屆亞洲醫療器材調和會年會 (17th Asian Harmonization Working Party, (AHWP) Annual Conference) 等系列會議，共有 27 國、300 餘人報名參加，創下台灣醫療器材產業有史以來參加國家最多、各國政府法規人員參與人數最多及國外學員報名人數最多之三多紀錄(圖 3)，大大增加我國能見度，展現我國醫療器材法規及技術量能。今(102)年 3 月我國更代表 AHWP，參加國際醫療器材法規管理論壇管理階層(IMDRF Management Committee)會議，再次為我國具突破性創舉。



圖 3 第 17 屆亞洲醫療器材調和會年會

期許與展望

醫療器材是全民健康照護的憑藉，對於全民所託為醫療器材品質把關的責任，TFDA 醫療器材及化粧品組責無旁貸，對於品質的要求更是不容妥協。隨著科技進步，品質精進還須再精進，也希望能達到好還要更好的管理目標。期望在醫療器材及化粧品組的堅持及努力之下，醫療器材品質與安全管理制度能日益精進，全體國人能夠率先全球使用最優質的醫療器材，帶給民眾最大的健康福祉。

102 年醫工證書考試相關訊息

本會將於 2013 年 8 月 3 日(六)舉行本年度之臨床工程師、醫療設備技師、醫學工程師之醫工證書考試。今年考試重要變革為，開放非會員者，亦可參加考試；非會員報考者，考試通過後，必須完成入會申請並審核通過，才可進行領證程序。入會相關規定請至學會網站進入「各式辦法與表格下載區」，參考「中華民國生物醫學工程學會會員入會申請須知」(http://www.bmes.org.tw/download_list.php)。

醫工證書考試報名已於 102 年 7 月 1 日截止，報名統計預計今年將有 318 名考生參加證書考試。考試結果將於 8 月底以專函個別通知並公佈於學會網站上。最新證書考試訊息，請至醫工學會網站查詢。

筆試日期：2013 年 8 月 3 日(六) 上午 09:30-11:30

口試日期：2013 年 8 月 3 日(六) 下午 13:30-17:00

考試地點：私立中原大學工學館(32023 桃園縣中壢市中北路 200 號)

2013 Vol. 33, No. 2

Review: Vitreous Cryopreservation of Tissue-engineered Compositions for Tissue Repair

Zhi Wang, Ting-Wu Qin

The most important strategy in tissue engineering is combining scaffolds with living cells to form tissue-engineered compositions (TECs) to promote the repair and regeneration of tissues. Such scaffolds are expected to support cell colonization, migration, growth, and differentiation, and to guide the development of the required tissues. TECs stored at ambient temperature require expensive human involvement to satisfy metabolic demands and can potentially be infected and biologically altered. For the commercialization and large-scale clinical applications of tissue engineering, long-term and stable methods that preserve TECs that contain living cells and maintain their adhesion to scaffolds are required. Cryopreservation can be achieved by vitrification, which can improve the post-rewarming viability of cells and reduce intra- and intercellular ice formation. The present paper reviews the literature and clarifies the basic technological advances of vitreous cryopreservation of TECs. The specific requirements for the vitreous cryopreservation of TECs are defined. The physicochemical basis for vitreous cryopreservation, cryoprotectant properties, and model studies are emphasized. Examples of TEC vitrification are given. It is concluded that vitrification is a promising method for the preservation of TECs and is likely to lead to the off-the-shelf availability of TECs for tissue repair.

Influence of Looped Colonoscope on Deformation of Intestinal Wall in Colonoscopy

Wu-Bin Cheng, Yun-Yun Di, Sivaruban Kanagaratnam, Michael Moser, Edwin M. Zhang, Wen-Jun Zhang

Colonoscopy that is a very commonly carried out procedure has several problems, including a risk of perforation of the colon and significant discomfort for patients. Loop formation can be the reason of these problems. Loop formation is further associated with the configuration of the colon, in particular the rectum-sigmoid and sigmoid-descending segments that have a small curvature and “S”-shaped profiles where the looped colonoscope exerts a quasi-static force on intestinal wall, and then results in deformation of the intestinal wall. Variable-stiffness colonoscope and over-tube colonoscope may be used to prevent loop formation; however, conflicting results relating to their use have been reported. In this paper, influence of a looped colonoscope on deformation of the intestinal wall is analyzed. It was found that the flexural rigidity of the looped colonoscope contributes deformation of the intestinal wall.

Enhanced Migration of Wharton's Jelly Mesenchymal Stem Cells Grown on Polyurethane Nanocomposite

Chih-Yang Huang, Chien-Hsun Lin, Tung-Tso Ho, Hui-Chen Chen, Mei-Yun Chu, Wei-Shen Sun, Wei-Chien Kao, Huey-Shan Hung, Shan-hui Hsu

Mesenchymal stem cells can sense and respond to substrate stiffness and topography, which modulates their differentiation into special cell lineages. Vascular cells reside in an elastic extracellular environment and are subjected to normal as well as shear forces. Polyurethane (PU), a synthetic elastomer, is investigated in this study for its potential to promote the attachment and migration of Wharton's jelly mesenchymal stem cells (WJMSCs). A nanocomposite of PU containing gold nanoparticles (PU-Au) with distinct phase separation on the nanometer scale is also tested because it provides better mechanical/topographical cues compared to those of pristine PU. PU-Au up-regulates the protein expression of focal adhesion kinase (FAK)/Rho-GTPase/matrix metalloproteinase-9 in WJMSCs upon the stimulation of vascular endothelial growth factor (VEGF) and stromal-derived factor-1 (SDF-1). Furthermore, PU-Au improves the attachment and migration of WJMSCs and increases the expression levels of cell surface markers such as CXCR4 and $\alpha_5\beta_3$ integrin after VEGF and SDF-1 stimulation. Collectively, these results suggest that elastic nanocomposites such as PU-Au may enhance WJMSC migration in response to tissue and blood vessel injury, which may in turn contribute to neovascularization in a vascular lesion.

Effect of Chang Run Tong on The Biomechanical and Morphometric Remodeling of Colon and Rectum in Streptozotocin-Induced Diabetic Rats

Hong Sha, Dong Zhao, Jingbo Zhao, Guifang Liu, Zhong Zhen, Pengmin Chen, Xiaolin Tong, Hans Gregersen

The present study investigates the effect of Chang Run Tong (CRT) on the biomechanical and morphometrical remodeling of colon and rectum in streptozotocin-induced diabetic rats. The colonic and rectal segments were obtained from diabetic (DM), CRT-treated diabetic (T1, high dosage: 50 g/kg/day; T2, low dosage: 25 g/kg/day) and normal (Con) rats. The experimental period was 60 d. The blood glucose level and body weight were measured. The circumferential length, wall thickness, and opening angle were measured from the segments in the no-load and zero-stress states. The residual strain was computed from the morphometry data. The step-wise distension was done on the colonic segment (from 0 to 20 cmH₂O). The circumferential and longitudinal stresses and strains were computed. The blood glucose level was significantly higher and the body weight was significantly lower in the DM, T1, and T2 groups compared to those in the Con group ($p < 0.01$, $p < 0.001$). The glucose level did not differ among the DM, T1, and T2 groups. The wet weight per unit length to body weight ratio, wall thickness, cross-sectional wall area, opening angle, and absolute value of residual strain of colonic and rectal segments in the DM group were significantly higher than those in the Con group ($p < 0.05$ and $p < 0.01$), and those in the T1 group, but not those in the T2 group, were significantly lower than those in the DM group ($p < 0.05$, $p < 0.01$). Furthermore, the circumferential and longitudinal stiffness of the colonic wall in the DM group was higher than those in the Con group. T1, but not T2, treatment could significantly decrease the colonic wall stiffness in both directions ($p < 0.01$). CRT (high dose) treatment could partly restore the morphometric and biomechanical remodeling of the lower gastrointestinal tract in diabetic rats.

Effects of LED Light Irradiation on Human Foreskin Fibroblasts and Its Implication to Wound Healing

Yueh-Feng Hsieh, Jui-Hsiang Hsieh, Eng-Kean Yeong, Wen-Tyng Li, Yu-Chi Chou, Ruoh-Chyu Ruaan

The photostimulation of skin can possibly improve wound healing. However, the effects of light stimulation on the process of wound healing are not fully understood. This study shows that red light emitted from a light-emitting diode (LED) device can effectively stimulate the proliferation of human foreskin fibroblasts (HFFs) and the synthesis of important cytokines related to wound healing. The proliferation of HFFs was found to be significantly accelerated after exposure to a red LED light (630 nm) at 16.3 mWcm⁻² for 400 seconds. The syntheses of Transforming growth factor beta 1, Keratinocyte growth factor, and Adenosine triphosphate were increased by light irradiation. Importantly, our findings indicate that the LED light irradiation could stimulate the proliferation of fibroblasts and may facilitate the wound healing.

Effects of Matrix Viscoelasticity on HepG2 Cell Metastasis in A Microfluidic Device

Qun-Fang Ye, Shao-Xi Cai, Xiao-Zhen Dai, Xiao-Qing Yan, Mi-Sha Zou, Zhiling Xu

Cancer metastasis is a complex dynamic cascade with multiple steps, and is influenced by various kinds of biochemical and biophysical factors in the microenvironment. The stiffness of the substrate is considered one of the most important factors for appropriate physiological function in numerous contexts. The extracellular matrix (ECM) around the cell is a material with viscoelasticity, the role of which in the cascade of events of cancer metastasis is poorly understood. This study establishes a 3D metastasis research model to investigate the influence of ECM viscoelasticity on the cascade of events of cancer metastasis in a suitable in vitro microenvironment. In the model, tumor cells and ECM can be precisely patterned in microfluidic channels, affording cancer cell an in vivo-like pathophysiologic three-dimensional (3D) microenvironments. The viscoelasticity of collagen gel was controlled via collagen gel concentration, measured by rheometer. The effects of viscoelasticity on the viability, cytoskeleton, invasion, and migration of hepatocellular carcinoma (HepG2) cells were investigated. our results reveal that the viscoelasticity of collagen gel increased with increasing concentration of collagen. The viability decreased with increasing viscoelasticity. The cytoskeleton seems denser in collagen gel with high viscoelasticity. The migration rate decreased with increasing viscoelasticity. These results suggest that the microfluidic device fabricated as a metastasis model could provide an in vivo-like pathophysiologic microenvironment for cancer cells to monitor the response of cancer cells to changes in their environments in real-time. We conclude that the viscoelasticity of collagen gel, mainly the elasticity, plays a role in the viability, cytoskeleton, capacity, and rates of invasion and migration of HepG2 cells.

Plasma Treatment of Random and Aligned Electrospun PCL Nanofibers

Da Yan, John Jones, Xiaoyan Yuan, Xinhua Xu, Jing Sheng, James C-M Lee, Guiqiu Ma, Qingsong Yu

Plasma treatment of electrospun poly(ϵ -caprolactone) (PCL) nanofiber random mats and aligned meshes is studied. The changes in the surface chemistry, and mechanical and biological properties of the PCL nanofibers induced by $\text{NH}_3 + \text{O}_2$ plasma treatment are evaluated using surface contact angle measurements, X-ray photoelectron spectroscopy (XPS), scanning electron microscopy (SEM), tensile tests, and cell culture. It was found that plasma treatment resulted in a significant increase in surface hydrophilicity of the PCL nanofibers, with the water contact angle reduced from $\sim 135^\circ$ to 0° . XPS surface characterization indicates that the plasma treatment introduced new functional and polar groups on the fiber surface. Tensile test results show that, after the plasma treatment, the ultimate tensile strength and the ultimate strain of both the PCL nanofiber random mats and aligned meshes were reduced. The phenomenon indicates that the plasma etching effect occurred on the PCL nanofiber surfaces. When cultured with mouse osteoblast cells (MC3T3-E1), the plasma-treated PCL nanofiber random mats and aligned meshes yielded much higher cell proliferation rates compared to those obtained for the untreated controls. Environmental SEM examination shows that the plasma treatment significantly enhanced cell growth along the aligned PCL nanofibers. These results indicate that plasma surface modification of electrospun nanofibers has great potential in the development of novel polymeric scaffolds for tissue engineering applications, such as bone healing and cartilage repair.

In Vitro Cell Study of Possible Anti-inflammatory and Pain Relief Mechanism of Far-infrared Ray-emitting Ceramic Material

Ting-Kai Leung, Yu-Chuan Liu, Chien-Ho Chen, Hsieh Nien-Fang, Kun-Cho Chen, Chi-Ming Lee

Inflammation and pain are the major chronic symptoms in geriatric medicine. This study examines the possible mechanism of a far-infrared ray-emitting ceramic material (bioceramic) on these symptoms using cell models. Effective doses of lipopolysaccharides (LPS) were added to induce acute episodes of inflammation in murine macrophage (RAW 264.7) and human chondrosarcoma (SW1353) cells. The inducible nitric oxide synthetase (iNOS), cyclo-oxygenase-2 (COX-2), and prostaglandin E2 (PGE2) levels were determined for the cell lines. Bioceramic treatment was found to have significant inhibitory effects on COX-2 and PGE2 and a probable effect on iNOS in the cell models of LPS-mediated inflammation. Bioceramic treatment may be an alternative method for palliative pain control to reduce chemical drug dependence for the protection of renal functions in the chronic pain disease population.

Design and Validation of Perfusion Bioreactor with Low Shear Stress for Tissue Engineering

Anneh Mohammad Gharravi, Mahmoud Orazizadeh, Mahmoud Hashemitabar, Karim Ansari-Asl, Salem Banoni, Ali Alifard, Sina Izadi

The generation of three-dimensional tissue substitutes in vitro requires the development of new culture strategies, including bioreactor concepts. The present study designs and validates a perfusion bioreactor to facilitate skeletal tissue engineering. The perfusion bioreactor has four main components: a culture chamber, a circulation unit, which consists of a peristaltic pump and silicon tubes, a mechanical device, and sensors. Analysis of flow behavior within the bioreactor was performed using computational fluid dynamics (CFD). Flow distribution was determined using dye tracer experiments to visualize the mixture effects with and without alginate hydrogel. Bovine chondrocytes were isolated from nasal septum, seeded into alginate hydrogel, and cultured dynamically in the perfusion bioreactor. 7- μm sections of bouin-fixed and paraffin-embedded alginate/chondrocyte constructs were prepared. The sections were stained histochemically for cell and tissue morphology assessments. Results of CFD indicate a very low wall shear stress on the surface of the culture chamber at a flow rate of 0.5 mL/min. The peak velocity and maximum wall shear stress were 8.816×10^{-4} m/s and 0.001237 dyne/cm², respectively. Under a steady flow of 0.5 mL/min, nearly all of the dye was distributed through the alginate gel. An average mixing time of 5-7 min was obtained with the perfusion bioreactor setup. After 12 days of chondrocyte culture in alginate, all chondrocytes were clearly surrounded with a stained matrix. The matrix volume surrounding each cell increased with time. In the matrix, fairly large round cells rich in cytoplasm were scattered individually or as an isogenous group at two weeks. Chondrocytes were housed in lacuna-like structures. The dissolved oxygen and pH of the culture medium were approximately constant at biological levels. The developed perfusion bioreactor is demonstrated to mimic various environmental conditions found in vivo for cartilage tissue engineering.

Optimization of Intradural Spinal Cord Stimulator Designs via Analysis of Thoracic Spine Imaging Data

Stephanus Viljoen, Brian D. Dalm, Chandan G. Reddy, Saul Wilson, Charles Smittkamp, George T. Gillies, Matthew A. Howard III

Axial magnetic resonance images of the thoracic spinal cord of 50 patients are analyzed in order to measure the length of the dorsal arc span between the dorsal root entry zones for the purpose of optimizing the mechanical design dimensions of the Human Spinal Cord Modulation System (HSCMS), which delivers electrical stimuli directly to the spinal cord. Two mathematical approaches are used to assess the data, with validation of the results conducted via a direct physical measurement using a magnified image. Results show that the nominal value of the arc length is 6.7 ± 1.0 mm (1), with high and low values of 8.8 and 5.1 mm, respectively. The mean radius of the spinal cord was found to be 3.6 ± 0.5 mm. Taking into account previously reported measurements, it is suggested that values at the high end of this range be used for further morphometric studies of the cord in the thoracic region. The implications of these findings on the design of the HSCMS are discussed.

Effects of Substrate Rigidity on Human Hepatic And Hepatocellular Carcinoma Cell Migration Behavior

Yan-zi Yangben, Hong-bing Wang, Qiao-yan Tan, Song Li, Li Yang

During cancer cell metastasis, the microenvironment stiffness around tumor cells dramatically changes. This study investigates the effects of substrate stiffness on cell migration behavior, especially on the mesenchymal and amoeboid migration adoption of human hepatic (L02) and hepatocellular carcinoma (HCCLM3, abbreviated as M3) cells. Polyacrylamide gels with different various stiffnesses were prepared by varying the concentration of acrylamide and bis-acrylamide. The cell morphology and migration were observed using recorded by a microscope observation, and cytoskeleton organization was visualized by F-actin staining. In addition, the expressions of cofilin and integrin $\beta 1$ were analyzed by western blotting, and matrix metalloproteinase-2 (MMP-2) levels were measured by zymography. The rigid gel promoted the mesenchymal mode of cell migration via the maintenance of directional migration, organization of polarized stress fibers, and enhancement of MMP-2 and integrin $\beta 1$ expression. Conversely, the soft substrate induced the tendency for amoeboid migration, with loss of directional migration, deprivation of actin stress fibers, and a decrease of MMP-2 and integrin $\beta 1$ expression. Furthermore, L02 cells exhibited typical mesenchymal migration on rigid gel but M3 cells did not. The soft gel induced M3 cells, but not L02 cells, to adopt amoeboid migration. These differences in L02 and M3 cell responses resulted from the differences in the cell intrinsic properties (i.e., the pattern of cytoskeleton organization and the expression of migration-related proteins). Our findings suggest that substrate rigidity amplifies the mesenchymal or amoeboid migration potential of cells. The tendency to adopt one specific mode or a mixture of modes is likely attributable to cell intrinsic properties. Understanding the influences of substrate rigidity on such distinct modes of tumor migration may lead to the development of more effective anti- invasive therapies.

Bioactivity and Biocompatibility Studies on Silk-Based Scaffold for Bone Tissue Engineering

Sahba Mobini, Mehran Solati-Hashjin, Habibollah Peirovi, Noor Azuan Abu Osman, Mazaher Gholipourmalekabadi, Mahmoud Barati, Ali Samadikuchaksaraei

Novel materials with promising properties can be used to achieve scaffold-based tissue engineering goals. Natural silk (NS) polymer has remarkable biomedical and mechanical properties as a material for bone tissue engineering scaffolds. This study describes the fabrication of a silk-based composite, in which natural silk and regenerated silk (RS) are combined to achieve better mechanical properties in the three-dimensional (3D) porous form. The biocompatibility and bioactivity of these scaffolds are evaluated. RS was made using mulberry-silk cocoons. RS/NS composite scaffolds were fabricated using the freeze-drying technique. Silk protein extract was evaluated by Fourier transform infrared spectroscopy (FTIR), with sharp amide peaks appearing at 1655 cm⁻¹ and 1530 cm⁻¹ in the FTIR spectrum, confirming the existence of fibroin. The fabricated 3D scaffolds were morphologically analyzed by scanning electron microscopy (SEM). An inter-connective spongy structure was found. Mechanical characterizations were carried out using a universal testing machine. Results show that the mechanical properties of the RS/NS composites are better than those of scaffolds fabricated with RS alone. In addition, in vitro tests, including those for cell viability and adhesion, were carried out with osteoblast cells by the MTT assay with a new calculation approach, which confirmed biocompatibility. The bioactivity potential of the RS and composites fibers was tested by introducing scaffolds to normal simulated body fluid for 21 days. Energy-dispersive X-ray spectroscopy and SEM analyses proved the existence of CaP crystals for both configurations. Thus, reinforced silk composite is a bioactive and biocompatible alternative for bone tissue engineering applications.

Finite Element Model of The Chick Eye to Study Myopia*Reno Genest, Naveen Chandrashekar, Elizabeth L. Irving*

Myopia is a refractive error of the eye and is characterized by an increase in the axial length of the eye. The exact mechanisms for the axial elongation are still unknown. Higher intraocular pressure (IOP) has been associated with myopia and could be involved in eye enlargement along with other factors. However, studying the creep behaviour of the scleral tissue of the eye due to increased IOP and extraocular muscle forces is difficult. The present study develops a finite element (FE) model of the chick eye to study the development of refractive error in the eye due to external mechanical forces and IOP. Chick eyes were harvested from young chickens. The IOP inside the eye was increased using a specialized apparatus. The deformation of the eyes was measured in the axial and radial directions using digital photographs. A chick eye was frozen, sliced, and photographed. The images were aligned and segmented. A three-dimensional geometric model of the corneo-scleral shell was built from the segmented images. A FE model of the chick eye was then developed. Hyperelastic material properties were used to model the cornea and scleral tissues. The pressure inside the FE model was increased and the resulting deformation of the model was measured. The results were compared with the experimental measurements. The deformation modes of the FE model were similar to those observed in experiments. The FE model of the eye was elongated in the axial direction and contracted in the radial direction, similar to the eyes in the experiment. The developed FE model can be used to study the development of myopia due to mechanical forces.

Characterization of a Hybridization Scaffold Based on PLGA/Acellular Pigskin for Nerve Regeneration

Xiaozhen Dai, Lan Wang, Kaiwang Ma, Bin Liu, Hong Li, Kejian Pan

Peripheral nerve regeneration across a long defect is a challenge in nerve reconstructive surgery. Nerve tissue engineering is a promising strategy for such regeneration. Artificial nerve scaffold design is an important part of nerve tissue engineering. In this study, a hybridization nerve scaffold was designed and fabricated with poly (lactide-co-glycolide acid) (PLGA) and acellular pigskin. Its potential as an artificial nerve scaffold is investigated in vitro. Acellular pigskin was prepared by enzymolysis and detected by hematoxylin and eosin (HE) staining, scanning electron microscopy (SEM), and examination of the DNA that remains in it. The hybridization scaffold was fabricated from PLGA and acellular pigskin using a high-pressure permeation technique. The microstructure, water absorption behavior, biodegradation, mechanical properties, and biocompatibility of the scaffold were investigated. SEM images show that the scaffold is a homogeneous three-dimensional porous structure. The maximum swelling index of the scaffold was about 124%, the thickness of the wall increased by about 56%, and the ultimate mass loss was about 9.05% in phosphate buffered saline (pH 7.4) after 8 weeks. PLGA improved the mechanical properties of acellular pigskin. The biocompatibility was evaluated by assessing the morphology and proliferation of Schwann cells (SCs) on the hybridization scaffold. Many SCs attached and adhered to the surface of the scaffold. The scaffold exhibited no cytotoxicity effects, increasing the proliferation of SCs. Therefore, the hybridization scaffold made of PLGA and acellular pigskin has suitable biodegradability, proper mechanical properties, and good biocompatibility for SCs, and thus has potential as an artificial nerve scaffold.

Role of FAK-ERK1/2 Signaling Pathway in Proliferation of Rat Bone-marrow Mesenchymal Stem Cells Stimulated by Cyclic Stretching*Lin Yuan, Qing Luo, Li Yang, Guan-Bin Song*

Mechanical stretching is known to play an important role in regulating the proliferation of mesenchymal stem cells (MSCs). However, information regarding the molecular mechanisms that link mechanical stretching and MSC proliferation is still limited. In this study, the signaling molecules likely involved in the mechanical-stretching-induced bone-marrow-derived rat MSC (rMSC) proliferation are examined. The results show that rMSCs subjected to a cyclic stretching of 10% amplitude at a 1-Hz frequency for 15 min exhibited a significant increase in their proliferation and c-fos expressions compared to those of statically cultured rMSCs. Furthermore, cyclic stretching (10%, 1 Hz) markedly promoted focal adhesion kinase (FAK) activation in rMSCs, followed by rapid extracellular signal-regulated kinase 1/2 (ERK1/2) phosphorylation for up to 1 h, while no significant difference was found in total FAK (t-FAK) or total ERK1/2 (t-ERK1/2) expressions between all detection time points. FAK inhibitor completely abolished the effect of cyclic stretching on rMSC proliferation, c-fos expression, and ERK1/2 activation. The same phenomenon was observed when ERK1/2 activation was inhibited, where cyclic stretching did not compensate for the effect of inhibition. These results demonstrate that the FAK-ERK1/2 signaling pathway is necessary for mechanical-stretching-induced rMSC proliferation.

國內研討會：

- 第十七屆奈米工程暨微系統技術研討會
地點：逢甲大學
會議時間：2013-08-22 ~ 2013-08-23
網址：<http://140.134.32.184/nmtc/>
- 2013 化工-環工-醫工技術國際研討會
6th International Symposium on Chemical-Environmental-Biomedical Technology
地點：國立清華大學
會議時間：2013-09-04 ~ 2013-09-07
網址：<http://www.bmes.nthu.edu.tw/actnews/actnews.php?Sn=3&action=view>
- 2013 生物醫學工程科技研討會暨國科會醫學工程學門成果發表會
地點：清華大學（醫工學會會員可取得主要學分 20 學分）
會議時間：2013-11-15 ~ 2013-11-16
網址：<http://bmes2010.xwing.com.tw/2013>
- 2013 國際奈米科技研討會 (2013ISNST)
地點：南台科技大學
會議時間：2013-11-15 ~ 2013-11-16
網址：<http://chem.stust.edu.tw/en/node/call>
- 2013 臨床工程基礎訓練課程-X 光基本概論
地點：童綜合醫院梧棲院區 20 樓視聽教室
會議時間：2013-08-17
網址：<http://www.bmes.org.tw/>

國際研討會：

- The 35th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC'13)
Osaka, Japan. July 03-07, 2013.
<http://embc2013.embs.org/>
- 6th World Association of Chinese Biomedical Engineers (WACBE)
World Congress on Bioengineering
Beihang University, Beijing, China. Aug. 05-08, 2013.
<http://www.asiaminstitute.org/symposia/6thWACBE.html>
- Can'2013: AES-ATEMA 14th International Conference
Toronto, Canada. Aug. 05-09, 2013.
<http://aesatema2013.wordpress.com/>
- 7th Asian Pacific Conference on Biomechanics
Seoul, Korea. Aug. 29-31, 2013.
<http://www.apbiomech2013.org/>
- The 7th International Conference on Bioinformatics and Biomedical Engineering (iCBBE 2013)
Beijing, China. Sep. 26-28, 2013.
<http://www.icbbe.org/2013/>
- 8th International Conference on Surfaces, Coatings and Nanostructured Materials (NANOSMAT-2013)
Granada, Spain. Sep. 22-25, 2013.
<http://www.nanosmat-conference.com/>

- The 15th IEEE International Conference on e-Health Networking, Application Services (IEEE Healthcom 2013)
Lisbon, Portugal. Oct. 09-12, 2013.
<http://www.ieee-healthcom.org/2013/index.html>
- ISOT 2013 International Symposium on Optomechatronic Technologies
Seoul, Korea. Oct. 28-30, 2013.
<http://www.isot2013.org/main/>
- MEDICA-World Forum for Medicine - International Trade Fair with Congress
Dusseldorf, Germany. Nov. 20-23, 2013.
<http://www.medica-tradefair.com/>
- The 15th International Conference on Biomedical Engineering (ICBME 2013)
National University of Singapore, Singapore. Dec. 04-07, 2013.
<http://www.icbme.org/>

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