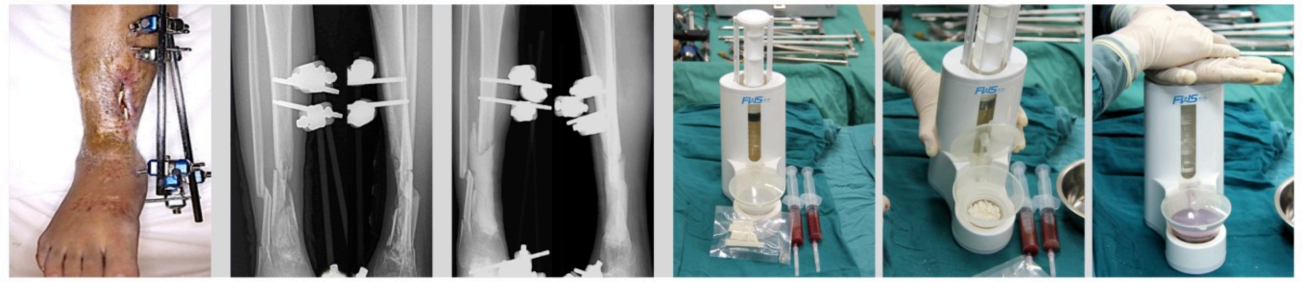
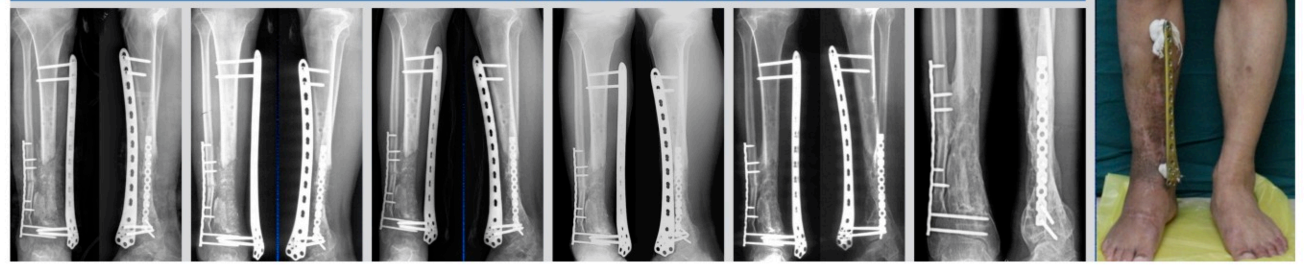
典型病例
Typical cases

病例 03 男，22岁，车祸致右侧胫腓骨开放性骨折，骨缺损7.6CM。右胫腓骨开放性骨折术后感染1年



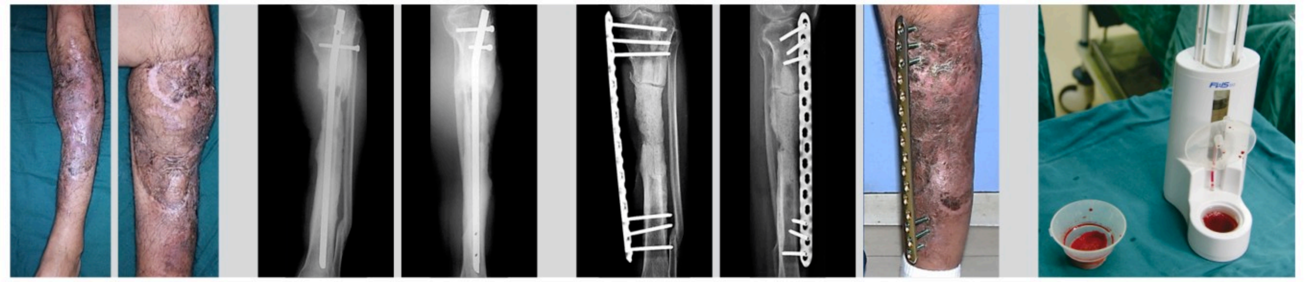
术前 术前X片 I 期术后 术中使用骨生长负压富集器

使用骨生长负压富集器骨移植后



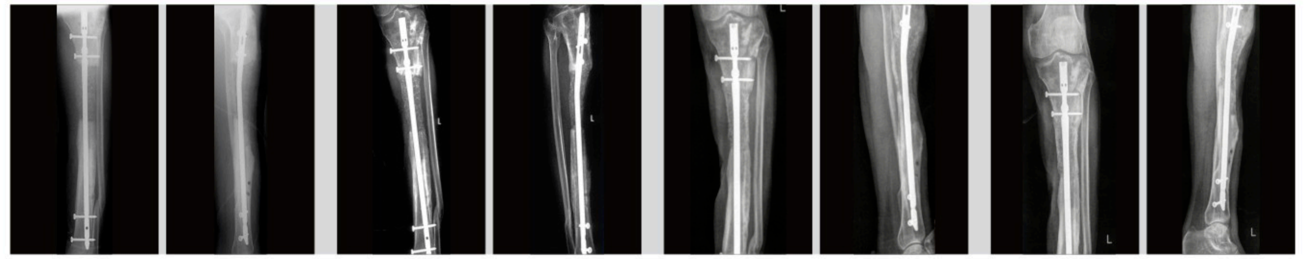
II 期术后 术后1月 术后2月 术后4月 术后8月 术后12月 术后大体照

病例 04 男，41岁，左胫骨骨折术后3年，骨缺损10.8CM，左胫骨慢性骨髓炎



术前 术前X片 I 期术后 术中使用骨生长负压富集器

使用骨生长负压富集器骨移植后



II 期术后 术后2月 术后6月 术后16月

适应症 Indications

所有需要增加成骨活性的非结构性骨移植手术，尤其是大段骨组织修复、长节段脊柱融合等骨修复材料需求较大的手术。

禁忌症 Contraindications

主要包括全身及局部活动性感染、造血系统疾病、免疫抑制或过敏体质等。

操作步骤
Operating step

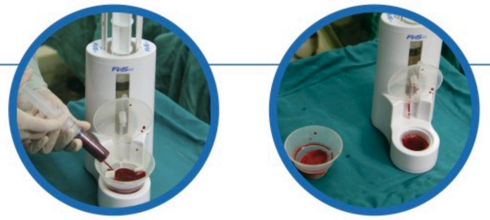
A 器材准备

● 配置1000U/ml的肝素生理盐水10~20ml，按拟抽取骨髓体积的1/5提前吸入注射器中备用。准备16号骨髓穿刺针1~2枚。将骨修复材料放入锥杯中，加盖上层滤网。

B 骨髓抽取

● 选择髂前上棘或髂后上棘为骨髓穿刺点，用含肝素盐水的注射器抽取适量的骨髓，建议每个位点抽吸骨髓2.5~5ml，即刻摇匀，总量以每克植骨材料准备5~6ml骨髓为宜。也可在植入椎弓根螺钉的步骤中同上方法获取骨髓。

C 循环富集



● 将骨髓注入锥杯中，盖紧外盖，均匀用力按压骨生长富集器手柄至平齐顶部后松开，待骨髓完全回流、手柄恢复到初始位置后，再次按压手柄开始第二次循环。累计4~5次上述富集操作。

D 材料移植

● 打开外盖，逆时针旋转将锥杯从底座取出，根据手术需要，可将骨修复材料取出后直接植入所需植骨区，或者装填椎间融合器、钛笼后植入所需部位。

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重庆富沃思医疗器械有限公司
CHONGQING FWS MEDICAL DEVICES CO,.LTD.
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骨生长负压富集器
Bone Marrow Concentrator

全国独家

重庆富沃思医疗器械有限公司
CHONGQING FWS MEDICAL DEVICES CO,.LTD.

可选择的骨修复材料
Choice of materials


同种异体骨颗粒


同种异体骨粉

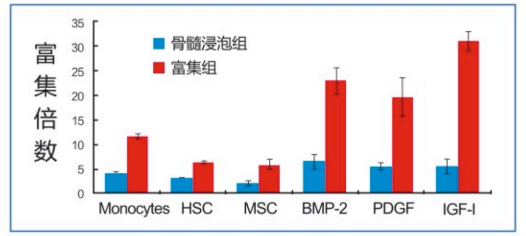

磷酸三钙


羟基磷灰石

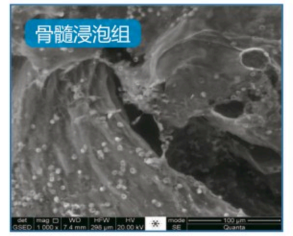
研制背景
Research background

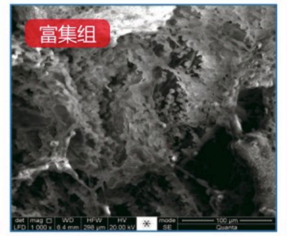
◎ 由于感染、肿瘤、创伤等因素，导致的骨缺损在临床上十分常见，其治疗对骨移植材料的需求量巨大。
◎ 骨修复材料需要良好的传导性和骨诱导性，自体骨移植是金标准，而自体取骨导致的额外创伤、取骨量受限、取骨区疼痛、血肿、骨折、感染等并发症常见；同种异体骨、羟基磷灰石（HA）、磷酸三钙（TCP）等骨修复材料虽已应用于临床，由于该类材料缺成骨生物活性成分，而成骨活性欠佳。
◎ 临床上已证实自体红骨髓中含有的大量干细胞及成骨相关生长因子等成分具有促进骨修复的能力。据此原理，骨生长负压富集器可在手术过程中快速将患者自体骨髓中的干细胞、生长因子等有效成骨成分富集到骨修复材料中，使其具有类自体骨的生物活性。
◎ 大量研究报道，动物实验及临床病例证明该技术能显著提高骨移植材料的生物活性，提高骨骼合率。

富集组与骨髓浸泡组的对比研究



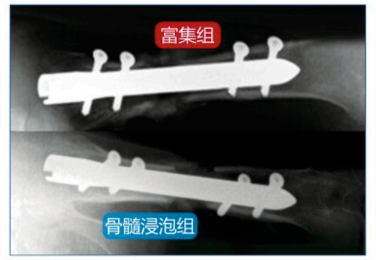
干细胞和生长因子的富集效果对比



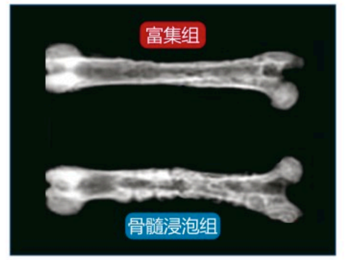


细胞在支架材料中的粘附效果（扫描电镜1000×）

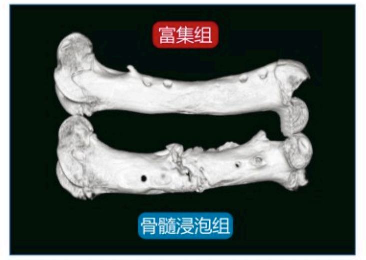
青山羊股骨2cm缺损修复实验



术后8周



术后16周



术后16周CT 3D重建

骨生长负压富集器
Bone Marrow Concentrator

论文摘要
Abstracts

A A composite demineralized bone matrix e Self assembling peptide scaffold for enhancing cell and growth factor activity in bone marrow

The need for suitable bone grafts is high; however, there are limitations to all current graft sources, such as limited availability, the invasive harvest procedure, insufficient osteoinductive properties, poor biocompatibility, ethical problems, and degradation properties. The lack of osteoinductive properties is a common problem. As an allogenic bone graft, demineralized bone matrix (DBM) can overcome issues such as limited sources and comorbidities caused by invasive harvest; however, DBM is not sufficiently osteoinductive. Bone marrow has been known to magnify osteoinductive components for bone reconstruction because it contains osteogenic cells and factors. Mesenchymal stem cells (MSCs) derived from bone ma rrow are the gold standard for cell seeding in tissue-engineered biomaterials for bone repair, and these cells have demonstrated beneficial effects. However, the associated high cost and the complicated procedures limit the use of tissue-engineered bone constructs. To easily enrich more osteogenic cells and factors to DBM by selective cell retention technology, DBM is modified by a nanoscale self-assembling peptide (SAP) to form a composite DBM/SAP scaffold. By decreasing the pore size and increasing the charge interaction, DBM/SAP scaffolds possess a much higher enriching yield for osteogenic cells and factors compared with DBM alone scaffolds. At the same time, SAP can build a cellular microenvironment for cell adhesion, proliferation, and differentiation that promotes bone reconstruction. As a result, a suitable bone graft fabricated by DBM/SAP scaffolds and bone marrow represents a new strategy and product for bone transplantation in the clinic.

脱钙骨基质/自组装肽是一种可以富集骨髓中细胞及生长因子活性成份的复合支架

骨移植材料的需求量巨大，但是目前所知的骨移植材料都有其局限性，例如有效性不高，取材导致额外的创伤，骨诱导性不足，生物相容性差，涉及伦理问题及降解性等。骨诱导性差是一个普遍存在的问题。脱钙骨基质作为一种同种异体骨材料，来源相对不受限，也可以避免取自体骨造成的额外创伤。但是，脱钙骨基质缺乏足够的骨诱导性。众所周知，骨髓中包含了大量利于骨重建的骨诱导复合成份，例如骨原性细胞及因子等。来源于骨髓的间充质干细胞是骨组织工程构建中种子细胞的金标准，这些细胞已经彰显了其有效性能。但是，组织工程骨构建的昂贵费用及复杂的程序限制了其临床应用。我们用自组装肽修饰脱钙骨基质形成复合物，通过简单的选择性细胞滞留技术可以使脱钙骨基质富集更多的骨原性细胞及因子。通过减小脱钙骨基质孔径及增加电荷吸附等方法，可以使脱钙骨基质/自组装肽复合支架较单纯的脱钙骨基质材料对骨原细胞及因子有更高的富集效果。同时，自组装肽自身可以构建为一种促进骨原细胞粘附，增殖和分化的微环境，利于骨重建。因此，富含骨髓的脱钙骨基质/自组装肽复合骨移植材料可作为一种临床骨移植产品，同时代表一种新的骨移植策略。[1]

References:
1. Tianyong Hou, Zhiqiang Li, Fei Luo, Zhao Xie, Xuehui Wu, Junchao Xing, Shiwu Dong, Jianzhong Xu. A composite demineralized bone matrix – Self assembling peptide scaffold for enhancing cell and growth factor activity in bone marrow. Biomaterials 2014, 35(22): 5689–5699.

B The Osteogenetic Efficacy of Goat Bone Marrow–Enriched Self–Assembly Peptide/Demineralized Bone Matrix In Vitro and In Vivo

In clinical practice, the prolonged duration, high cost, critical technique requirements, and ethical issues make the classical construction method of tissue–engineered bones difficult to apply widely. The major essentials in tissue engineering strategies include seed cells, growth factors, and scaffolds. This study aimed to incorporate these factors in a rapid and cost–effective manner. A self–assembly peptide/demineralized bone matrix (SAP/DBM) composite was artificially established and used for bone marrow enrichment via a selective cell retention approach. Then, goat mesenchymal stem cells (gMSCs) were seeded onto the SAP/DBM or DBM. The proliferation status of gMSCs in different scaffolds was analyzed, and the osteogenetic efficacy was evaluated after osteogenic induction. Bilateral critical–sized femoral defects (20–mm in length) were created in goats, and then the defects were implanted with the postenriched composite or DBM. Then, bone scan imaging, micro–computed tomography (CT) analysis and histological examination were performed to assess the reparative effects of the different implants. Compared with the DBM scaffolds, the growth of gMSCs in the postenriched SAP/DBM composite was faster and the expression levels of the osteo–specific genes (i.e., alkaline phosphatase, osteocalcin, osteopontin, and runt–related transcription factor 2) were significantly higher after 14 days of osteogenic induction. More importantly, the postenriched SAP/DBM composite significantly enhanced bone metabolic activity in the defect area compared with DBM at 2 and 4 weeks postoperation. Moreover, bone reconstruction was complete in marrow–enriched SAP/DBM composite, but not in the DBM. In addition, all of the osteo–related parameters, including the ratio of bone volume to total bone volume, bone mineral density, new trabecular number, and new trabecular thickness, were significantly higher in the marrow–enriched SAP/DBM than those in the DBM. These results indicated that the SAP/DBM composite held great potential for clinical applications; immediate implantation after marrow enrichment could be a new and effective strategy for treating bone defect.

基于使用骨髓富集技术后的自组装多肽/脱钙骨基质复合物在对山羊骨缺损修复效果的体外和体内骨生长效果的研究

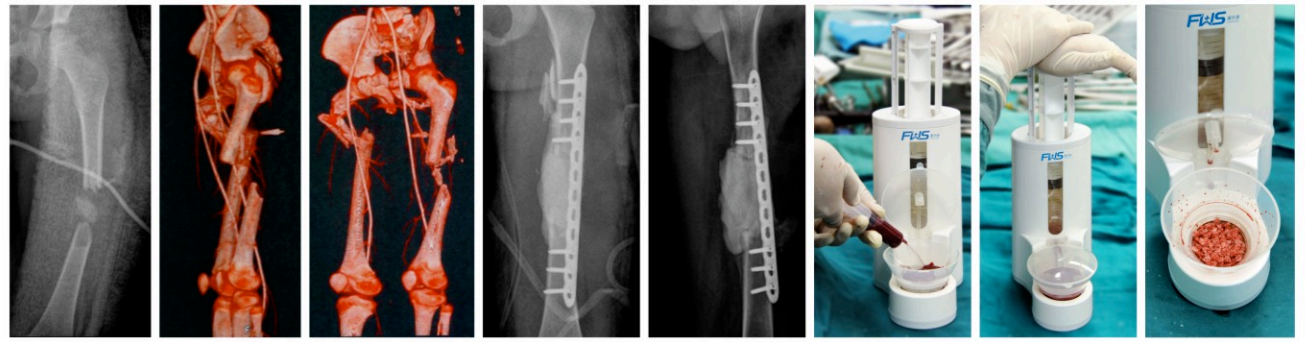
由于冗长的操作时间、高成本、很高的技术难度以及伦理问题，使得传统的组织工程骨构建方案很难广泛运用于临床实践。在组织工程骨构建策略中的主要基本要素包括了种子细胞、生长因子和支架材料。此研究致力于寻找快速且低成本的富集这些生长因子的方法。自组装多肽/脱钙骨基质(SAP/DBM)复合物是人工建立的复合材料，且能通过选择性滞留的方法富集骨髓中的种子细胞。然后，山羊的间充质干细胞接种于SAP/DBM或者DBM上。我们分析了使用不同支架的骨再生状态和评价了骨诱导后的成骨效果。在山羊两侧股骨制造临界骨缺损（长度约为20mm），并将富集后的复合物以及DBM分别植入缺损处。然后做影像扫描、微型计算机断层扫描（CT）分析和组织检查去评估不同植入物骨修复的效果。在经过14天成骨诱导后，对比DBM支架和富集骨髓后的SAP/DBM复合物上gMSCs（间充质干细胞）生长速度，后者生长速度较快，且成骨相关特异性基因表达水平（例如：碱性磷酸酶、骨钙素、骨桥蛋白和RUNX2）显著较高。更重要的是，术后2周和4周在骨缺损区域，骨富集后的SAP/DBM复合物比DBM在骨代谢活力方面有显著的提高。此外，在骨髓富集后的SAP/DBM复合物组的骨缺损被完全修复，而在DBM组缺损未能完全修复。另外，骨富集后的SAP/DBM复合物在包括骨体积分数、骨密度、新生骨小梁数量，新生骨小梁的厚度等相关的参数要显著高于比DBM。这些结果表明通过骨髓富集后的SAP/DBM复合物有很大的临床使用潜力；骨髓富集后立刻植入的方法可以是用于治疗骨缺损的一个新的且有效的策略。[1]

References:
1. Zhiqiang Li, Tianyong Hou, Moyuan Deng, Fei Luo, Xuehui Wu, Junchao Xing, Zhengqi Chang, Jianzhong Xu.The Osteogenetic Efficacy of Goat Bone Marrow–Enriched Self–Assembly Peptide/Demineralized Bone Matrix In Vitro and In Vivo.TISSUE ENGINEERING: Part A Volume 21, Numbers 7 and 8, 2015

骨生长负压富集器
Bone Marrow Concentrator

典型病例
Typical cases

病例 01 男，10岁，车祸多发伤，车祸致左股骨中段9cm大段骨缺损，全同种异体骨植骨


术前　I 期术后　术中使用骨生长负压富集器

使用骨生长负压富集器骨移植后


II 期术后　术后1月　术后2月　术后3月　术后4月　术后6月　术后12月


术后大体照

病例 02 女，30岁，右胫骨开放性骨折，骨缺损11CM。清创+外固定+VSD引流术后18天，右胫腓骨开放性骨折术后感染


术前　术前X片　I 期术后　术中使用骨生长负压富集器

使用骨生长负压富集器骨移植后


II 期术后1月　术后4月　术后6月　术后10月


术后大体照