

可吸收固定材料应用于髁突骨折的研究进展

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[摘要] 目前临床髁突骨折开放复位内固定材料为钛合金及可吸收材料。钛合金固位及稳定性佳,但可能影响磁共振检查,通常需要二次取出。具有人体相容性的可吸收聚合物材料是基于能够被人体利用的可吸收单体合成的共聚物及其改性的衍生物,固位及稳定性可靠,如无特殊情况,一般不需要二次取出。随着科学技术的发展,出现了超声激活可吸收聚合物螺钉、可吸收镁基金属螺钉及可吸收生物陶瓷材料。这些可吸收材料都展现了足够的力学性能及临床疗效。本文就可吸收材料的类型、适应证、技术发展、临床应用及未来展望作一综述。

[关键词] 髁突骨折; 内固定; 可吸收; 聚乳酸; 镁基金属

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Research and application progress of absorbable material for condylar fracture fixation

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[Abstract] The materials currently used for the open reduction and internal fixation of condylar fractures in clinical practice are titanium alloys and absorbable materials. Titanium alloys have excellent retention and stability but may interfere with magnetic resonance imaging and usually require secondary removal. Biocompatible, absorbable polymers are copolymers synthesized from absorbable monomers and their modified derivatives and can be utilized by the human body. They provide reliable retention and stability and generally do not require secondary removal unless special circumstances arise. Advances in science and technology have led to the development of ultrasound-activated absorbable polymer screws, absorbable magnesium-based metal screws, and absorbable bioceramics. These absorbable materials have demonstrated sufficient mechanical properties and clinical efficacy. This work aims to review the types, indications, technological advancements, clinical applications, and future prospects of absorbable materials.

[Key words] condylar fracture; internal fixation; absorbable; poly lactic acid; magnesium-based metal

可吸收聚合物材料是基于能够被人体利用的

乳酸以及其他可吸收单体合成的共聚物及其改性的衍生物。在髁突骨折内固定中应用可吸收聚合物材料,不仅可以达到正常骨愈合强度,也可以避免二次手术取出带来的风险。随着科学技术的发展,出现了超声激活可吸收聚合物螺钉及可吸

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收镁基金属螺钉。这些可吸收材料都展现足够的力学性能及临床疗效。

本文就可吸收材料的类型、适应证、技术发展、临床应用及未来展望作一综述。

纳入和排除标准：根据系统评价和Meta分析的首选报告指南（preferred reporting items for systematic reviews and meta-analyses, PRISMA），在Pubmed、Web of Science和Cochrane Library及中国知网中进行文献检索。1) 纳入评估可吸收材料在髌突骨折中应用的生物力学研究及主要临床研究；2) 中文文献搜索策略包括：[SU%=(‘髌突骨折’+‘下颌骨骨折’+‘颌面部骨折’)*（‘可吸收’+‘可降解’+‘生物降解’+‘生物吸收’+‘聚乳酸’+‘镁’）*（‘板’+‘螺钉’+‘针’+‘固定’+‘开放’）]；英文文献搜索策略包括：[（“condylar fracture” OR “mandible fracture” OR “maxillofacial fracture”）AND（“resorbable” OR “absorbable” OR “biodegradable” OR “bioabsorbable” OR “Polylactic acid/PLA” OR “Magnesium”）AND（“plate” OR “screw” OR “pin” OR “fixation” OR “open reduction”）]；3) 排除钛板固定、保守治疗、临床研究中不含髌突骨折内固定的相关中英文文献。

根据以上标准，共查询到242篇文章，纳入42篇，其中中文3篇、英文39篇，关于聚合材料31篇、金属基材料11篇。

1 可吸收材料类型

可吸收材料主要分为两大类：聚合物材料[聚乙醇酸（polyglycolic acid, PGA）；聚乳酸（polylactic acid, PLA）、聚对二氧环己酮（polydioxanone, PDO）及其共聚物等]、金属材料（镁基、锌基、铁基及其改性产物等）；主要形式包括：螺钉、接骨板、针等^[1]。此外，可吸收生物陶瓷材料[如羟磷灰石（hydroxyapatite, HA）、β-磷酸三钙（β-tricalcium phosphate, β-TCP）]作为新类别，由于其脆性大，多与可吸收聚合物材料及可吸收金属材料结合应用^[2-3]。

可吸收聚合物材料在体内的降解过程与水解反应有关，最终代谢为二氧化碳和水，降解速率与材料组成、材料结晶形态、合成方式及材料的几何形状相关，可根据治疗需求选择不同的降解时间的可吸收材料^[4]。PLA属于手性分子，有3种

形态：左旋聚乳酸（poly L lactic acid, PLLA）、右旋聚乳酸（poly D lactic acid, PDLA）、外消旋聚乳酸（poly D,L lactide, PDLLA），其中PLLA、PDLA力学性能较好，通常用于医用缝线、固定材料等，PLLA在体内最终可被降解为L-乳酸，可被人体完全代谢。而PDLA的代谢产物D-乳酸不能够被人体完全降解，但可经过尿液排出体外^[5]。镁基、锌基、铁基作为新兴的可吸收金属材料，三者分解产生的主要元素都是人体必需元素，在体内适当浓度有利于人体新陈代谢，降解速度过快可能造成高镁、高锌、高铁血症，影响人体正常功能^[1]。可吸收金属材料通过化学改性、表面修饰、与3D打印技术结合等，可延长降解时间、改善生物力学性能、提升成骨活性及抗菌能力^[6-8]。

可吸收聚合物降解时间一般为1~4年，患者需保持良好依从性、定期复查以防延迟愈合、瘘管、感染等并发症，必要时进行影像学复查，直至可吸收聚合物材料完全降解，被骨组织替代^[9]。聚合物力学性能较金属差^[10]，在有限元分析模型^[11]中发现：PLLA板较钛板易出现应力集中区域，在压力过大的局部区域也会导致压迫性骨吸收，可通过改变螺钉或接骨板设计和固定方法来增强固定的稳定性^[12]，单PLLA板的稳定性和强度都较差，而双板固定效果好^[13]。未烧结HA结合PLLA板应力分布介于金属板与PLLA板之间，可用于髌颈下骨折切开复位内固定^[14-15]。可吸收镁基螺钉拉伸强度强于钛螺钉、聚乳酸-羟基乙酸共聚物[poly(lactic-co-glycolic acid), PLGA]螺钉，抗扭转强度稍弱于钛螺钉，有足够的固定及稳定效能^[16]，其设计与几何形状影响应力分布和愈合稳定性^[17]，可吸收镁基螺钉与PLGA螺钉对骨碎片固定效能随时间推移而减弱程度相同，但镁基金属的弹性模量优于聚合物，适合应用于下颌骨髌突骨折的多螺钉固定术^[18-19]。镁基金属在3种可吸收金属中降解速率最快，可能导致材料机械强度变弱、骨愈合前变形，但可通过合金改进其力学性能^[20]，目前较常用产品主要成分为MgYREZr^[21]。此外，镁基金属降解产生的氢气 $[Mg+2H_2O \rightarrow Mg(OH)_2+H_2]$ 可能在邻近组织形成气腔，影响骨-植入物的接触面积^[1,22]。

2 可吸收材料的适应证

对于儿童（<12岁），80% PLLA和20% PGA组成的PLGA吸收更快，降解速率与骨生长同步，

对儿童骨骼生长影响更小,有利于髌突正常发育^[23]。对于成人髌突骨折,髌突头(关节面)骨折可选择镁基螺钉或超声激活可吸收针,避免钛及钛合金的应力遮挡,超声激活可吸收针还可避免对髌突头造成压迫性吸收;髌颈或髌后骨折适合可吸收聚合物宽板或者双板固定,更加贴合解剖形态;髌突矢状骨折适合长螺钉固定;髌突粉碎性骨折时,远离关节面的部位可以使用钛螺钉,涉及关节面的贯穿固定时使用可吸收镁基螺钉^[16]。

可吸收聚合物降解的单体或镁基金属中的稀土元素(钇、锆、镧等)可能会引发过敏,需术前筛查;严重骨质疏松或感染性骨折禁用可吸收材料^[9,16]。

3 可吸收材料技术发展

可吸收材料应用于临床已有30余年,学者^[12]通过改变螺钉或板的设计和固定方法来增强可吸收材料的固定稳定性,如梯形PLLA板较普通的PLLA板更加稳固。

在材料学方面,生物陶瓷材料如HA是人体骨无机物的主要成分,有良好的骨诱导能力且机械强度,可增强可吸收聚合物的生物相容性及机械强度^[24],通过添加纳米HA或纳米蛋壳颗粒有利于成骨细胞的黏附及增强材料力学强度(抗弯强度可提升30%~50%)^[25];在镁基材料表面涂覆PLGA或HA可延缓降解速率,改善材料结构与骨组织的相互作用,促进骨愈合^[26-29]。临床应用超声技术将针头熔融使可吸收针完全进入髌突,避免传统钛螺钉或可吸收螺钉时钻入的侧向压力,降低对组织的机械性创伤及压迫性损伤^[30-33]。3D技术可定制个性化可吸收植入物,减少手术时间,精准适配患者髌突解剖结构,降低并发症风险^[34-35],能更好的进行解剖复位。

可吸收镁基金属是颌面部固定的新兴材料,有良好的生物性能及机械强度,目前制作符合颌面部骨折固定使用规格的镁基螺钉公司较少,获得国际认证的仅4个品牌,德国MgYREZr可降解镁基螺钉主要用于成人的足踝等低承重区,韩国Mg-Ca镁基螺钉用于指骨等非承重区,东莞可降解纯镁螺钉的生物相容性高过敏风险较低,芬兰的MgZnCa镁基骨钉主要用于儿童长骨的固定^[21],根据临床报道,可吸收镁基螺钉在脚拇指外翻术、血管化髂骨骨瓣移植的保髌治疗、手掌骨折、踝

关节骨折、桡骨远端骨折等方面已有应用^[36-42],一定程度证明可吸收镁基金属在临床固定的安全性及稳固性,但应用于颌面部的病例较少^[43]。

4 可吸收材料临床效果

4.1 儿童髌突骨折可吸收材料的临床应用

一些学者^[44-46]使用可吸收聚合物板进行儿童髌突骨折内固定,术后2~3年未出现明显的不良反应、错骀畸形及髌突发育受限。Li等^[47]使用可吸收聚合物板对7例单侧髌突骨折以及2例双侧髌突骨折的患儿进行内固定,术后3个月髌突高度恢复良好,术后6个月后患儿开口度恢复正常,未见明显的错骀畸形与咬合异常,CT复查示髌突形态及位置恢复良好。Zhang等^[48]使用可吸收聚合物板对5例严重脱位的儿童髌突骨折进行内固定,术后患儿咬合关系、功能恢复良好。随访3~10年,患儿髌突完全重塑,未出现不良并发症。但Xu等^[49]使用可吸收聚合物长螺钉8例固定儿童髌突囊内骨折时,结果发现:5例患儿术后3个月髌突头降低至原髌突高度的1/2至2/3,而在成人髌突头骨折中,髌突头降低最多至原髌突高度的2/3^[50-52],他们推测造成儿童髌突头降低程度大于成人是由于手术钻孔时儿童髌突头血供被破坏,螺钉上方血供阻断导致髌突头吸收至与螺钉表面平齐。

4.2 成人髌突骨折可吸收材料的临床应用

可吸收聚合物板与钛板在髌颈下骨折的固定效果、术后咬合恢复等没有明显差异^[53],刘子健等^[54]发现:在双侧髌突骨折固定中可吸收聚合物板相比于钛板,能缩短骨折愈合时间且提高治疗有效率。髌突后部适合安放较宽的双可吸收聚合物板,可作为常规可吸收聚合物板固定位置空间不足时的替代位置^[55]。Yerit等^[56]对14例髌突骨折使用自增强PLLA螺钉进行内固定,术后并发症发生率低且轻微,随访2年未观察到与固定螺钉相关的严重不良组织反应。Song等^[57]在12例髌颈下骨折应用HA-PLLA板进行内固定,结果发现:其在男性固定时不稳定性较女性明显。髌突矢状骨折一般采用1~2颗长螺钉固定,但当其伴外侧嵴缺损时,采用可吸收板结合可吸收长螺钉效果可达到良好固位,且由于钻孔角度几乎垂直于骨表面,可避免软组织过度拉扯,降低腮腺和面神经损伤的风险^[58]。

一些学者^[59-60]使用可吸收镁基螺钉对5例髌突骨折患者进行固定,在1年随访中,所有患者的髌

下颌关节功能(结构)恢复良好,未出现并发症。术后6个月骨折间隙消失、髁突内存在气体腔隙(镁基金属气体反应)。术后1年时气体腔隙消失,髁突表面光滑。还有一些学者^[61-62]通过32例可吸收镁基螺钉与29例钛螺钉髁突骨折内固定疗效对比,结果发现:可吸收镁基螺钉促进骨愈合能力与钛螺钉相似,固定效能良好,术后12个月仍可保持稳定,可作为髁突骨折内固定的另一种选择。

目前,报道儿童髁突骨折采用可吸收材料进行固定临床试验总病例不超过300例,成人髁突骨折采用可吸收材料超过400余例,总体术后效果优良。

5 展望

可吸收材料在骨科及颌面部骨折均有应用,但可吸收聚合物材料在儿童髁突骨折内固定的应用仍缺乏大规模的临床数据,可吸收聚合物与纳米颗粒结合可增强其韧性及抗弯强度;可吸收金属材料机械强度较好,目前通过表面微孔结构设计促进氢气扩散或涂层技术(PLGA/HA涂层)减少气腔体积,但控制降解速率及气腔问题仍需深入研究^[20,63-64],可继续探究与3D打印及纳米生物材料结合调控材料孔隙率及生物活性,匹配不同患者骨愈合速度^[34-35,65-67]。可吸收镁基螺钉价格高于传统钛钉^[6]及可吸收聚合物材料,但从手术整体成本及疗效来看,采用可吸收镁基螺钉似乎更加划算,目前报道仅有国外学者将镁基金属应用于髁突骨折固定,临床病例较少,且术后缺乏对患者血镁的监测,其在人体长期安全性及远期疗效需要更多的国内外大量样本临床研究。

未来研究应聚焦于优化可吸收材料性能、可吸收生物复合材料的开发或表面涂层技术改进,平衡降解速率与机械强度,扩大临床应用规模与延长随访时间,深入探究其在不同类型髁突骨折中的应用效果,为患者提供更优治疗选择。

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