·指　　南·

骨科3D打印技术临床应用指南

中华医学会骨科学分会；中国医师协会骨科医师分会；中国中西医结合医师协会骨伤科医师分会
通信作者：黄伟，Email: huangwei68@263.net；胡永成，Email: yongchenghu@126.com；王坤正，Email:Wkzh1955@163.com

【摘要】 3D打印技术是一种以数字模型文件为基础，以数字技术材料打印机为载体，采用金属、塑料、细胞、组织等特殊材料通过逐层打印的方式构造实体的技术。在医学领域中具有广阔的应用前景。随着3D打印技术、材料学和医工交互的不断融合，3D打印技术在骨科领域的应用逐渐向个性化、精准化和微创化发展，已涵盖骨科疾病诊断和治疗的各个方面。然而，3D打印技术在骨科临床中的应用尚缺乏指南。经中华医学会骨科学分会、中国医师协会骨科医师分会和中国中西医结合医师协会骨伤科医师分会组织专家共同讨论，基于Delphi法问卷调查的形式制订了《骨科3D打印技术临床应用指南》。指南详细阐述了骨科3D打印的医工交互、骨科3D打印技术实施以及3D打印技术在创伤、关节、脊柱和骨肿瘤领域的临床应用，最终形成17条推荐意见。指南旨在提高3D打印技术在骨科临床应用的规范化与标准化。

【关键词】 打印，三维；矫形外科学；指南
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Clinical guideline for the application of 3D printing technology in orthopaedics

The Chinese Orthopaedic Association, The Chinese Association of Orthopaedic Surgeons, The Chinese Integrative Medicine of Orthopaedic Surgeons
Corresponding author: Huang Wei, Email: huangwei68@263.net; Hu Yongcheng, Email: yongchenghu@126.com; Wang Kunzheng, Email: Wkz2009@163.com

【Abstract】 3D printing technology is a kind of technology based on digital model files, with digital technology material printer as the carrier, using metal, plastic, cells, tissues and other special materials to construct entities by printing layer by layer. It has a broad application prospect in the medical field. With the continuous integration of 3D printing technology, materials science and the interaction between medicine and engineering, the application of 3D printing technology in orthopedics has gradually developed to be personalized, precise and minimally invasive, covering all aspects of diagnosis and treatment of orthopaedic diseases. However, there is still a lack of guidelines for the application of 3D printing technology in orthopaedic clinical practice. Therefore, based on the Delphi questionnaire survey method, The Chinese Orthopaedic Association, the Chinese Association of Orthopaedic Surgeons and The Chinese Integrative Medicine of Orthopaedic Surgeons specialists developed "Clinical guideline for for the application of 3D printing technology in orthopaedics". The guideline elaborates on the medical and engineering interaction of 3D printing in orthopaedics, the implementation of 3D printing technology in orthopaedics, and the clinical application of 3D printing technology in the fields of trauma, joint, spine, and bone tumors. Finally, 17 recommendations are formed. The guideline aims to improve the normalization and standardization of 3D printing technology in orthopaedic clinical applications.

【Key words】 Printing, three-dimensional; Orthopedics; Guidebooks
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3D打印又称增材制造，是一种以数字模型文件为基础，以数字技术材料打印机为载体，采用金属、塑料、细胞、组织等特殊材料通过逐层打印的方式构造实体的技术。3D打印作为快速成型技术的一种，其核心特点为个性、精准与节能，与传统减材制造技术相比极大地提高了制造效率。

3D打印技术在生命科学领域的应用是学术热点，近十年相关研究达2万余项，中国占比为20.5%，仅次于美国（26.1%）。3D打印常用金属材料主要有钛及其合金、钽、钴铬合金及不锈钢；非金属材料主要有高分子材料（尼龙、聚乳酸、聚醚醚酮、光敏树脂）、无机非金属（生物陶瓷）及复合生物材料。3D打印常用的技术主要有光固化技术、熔融沉积制造技术、三维印刷技术和选区激光烧结技术

等。3D打印的精准度、打印成品的物理特征、生物学特征和性价比是由上述基础技术决定的。这些基础技术的进步将不断拓展3D打印在骨科的临床应用。近年来,3D打印技术逐渐向个性化、精准化和微创化发展,已涵盖骨科疾病的诊断、治疗和康复等各个方面。然而,3D打印技术在骨科临床中的应用尚缺乏标准性文件,且医疗人员对3D打印的认知不够深入与全面。

为促进医工交互,提高3D打印技术在骨科的普及和推广,中华医学会骨科学分会、中国医师协会骨科医师分会和中国中西医结合医师协会骨伤科医师分会组织有关专家制订了《骨科3D打印技术临床应用指南》。指南工作组通过第一轮开放性问卷调查收集了185个临床问题,然后对问题进行汇总与去重,得到30个临床问题;第二轮通过对临床问题的重要性进行赋值和汇总,将30个临床问题进行了重要性排序;第三轮对重要临床问题再次解构、删减和综合,并最终确定了17个临床问题,并形成推荐意见。指南的推荐意见形成和推荐强度基于Delphi法,推荐专家的比例>80%定义为强推荐、60%~80%为中推荐、30%~60%为弱推荐、<30%为不推荐。本指南在国际实践指南注册平台完成注册(PREPARE-2024CN359)。

一、骨科3D打印的基本要求和实施原则

推荐意见1　3D打印过程中骨组织重建使用CT数据,软组织重建使用MRI数据(推荐强度:强推荐,97.7%)。

证据概述:3D打印技术和现代医学影像技术结合,主要是基于CT的DICOM数据经三维重建后进行3D打印[1],CT是医学3D打印最常用成像方式[2]。Izatt等[3]基于CT数据制作26例复杂脊柱病变的患者模型,发现约65%的生物模型的解剖细节比影像学更清晰。MRI是一种无电离辐射的检查方法,具有较高的组织分辨力,尤其是对血管、神经、软骨、半月板、韧带等的成像更具优势,与CT结合可弥补单纯CT图像的不足。Guenette等[4]报告在基于MRI和CT数据的3D打印模型辅助下冷冻消融治疗C_7椎弓根骨样骨瘤和L_1椎板成骨细胞瘤,实现了肿瘤的精准治疗。

推荐意见2　影像学数据的扫描精度直接影响3D打印骨科模型的精确性。扫描精度取决于设备选择、扫描范围、分辨率和扫描体位等(推荐强度:强推荐,94.4%)。

证据概述:基于3D打印设计需要,推荐CT参数如下:(1)设备选择:多排螺旋CT;(2)扫描范围:以满足临床需要为准,包含全部目标区域;(3)扫描间距:≤1 mm[5];扫描层厚:≤1 mm;(4)分辨率:像素矩阵512×512,像素尺寸≥0.5 mm×0.5 mm[5];(5)扫描体位:按照解剖学姿势摆放,肢体长轴与扫描方向一致,肢体存在外固定或骨关节畸形时减少两者的成角;(6)造影剂:必要时可选择造影剂,但要求不影响3D打印的精度;(7)数据格式:符合DICOM 3.0格式[6]。

MRI对软组织有较好的解析力,但层厚较大,很少用于精确数据采集,可用于标注软组织及其病变范围。不推荐直接采用MRI图像用于3D打印模型的三维重建,MRI与CT数据可以融合、配准[7]。

推荐意见3　骨科3D打印常用的重建软件有Mimics、Simpleware和3D-Doctor,应根据医学图像类型和重建用途选择适合的软件(推荐强度:强推荐,88.9%)。

证据概述:Mimics(Materialisc,比利时)是一款交互式医学影像控制系统,可在横断面、冠状面和矢状面浏览薄层CT和MRI数据,实现任意断层重组、图像增强和体渲染,并对感兴趣区进行三维重建;重建模型可进行任意组合,从任意角度观察和调整透明度,从而清楚显示局部解剖的空间立体位置关系,是骨科最常用的重建软件[8]。

Simpleware(Simpleware,英国)是一套集成逆向工程、材料工程、生物力学工程、有限元分析等多学科领域统一解决方案的专业软件,不仅可处理CT和MRI数据,还能处理micro-CT、聚焦离子束显微镜等数据,兼容性优于Mimics。

3D-Doctor(Able Software,美国)支持常用的二维和三维的灰度和彩色图像[9],主要用于CT、MRI、正电子发射计算机断层显像、聚焦离子束显微镜的图像处理,是美国食品药品监督管理局批准的用于医学成像和3D可视化应用的软件,缺点是不能单独输出有限元网格。

3DSlicer(3DSlicer,美国)是一套用于医学图像分析、三维重建可视化以及图像引导治疗研究等方面的软件,其核心功能为图像分割、配准及三维渲染[10-11],对骨骼、血管、软组织或受病理影响的内脏器官的图像采集精度低于Mimics[12]。

Amira(Amira,澳大利亚)可利用自动与交互式的分割及建模工具创建人体的三维和有限元模型[13]。Amira基于曲面重建方法能输出高质量有限元网格进行划分与优化[14];与Simpleware相似,Amira并不是完全应用于医学图像领域的三维重建软件,在骨科领域的应用存在局限。

推荐意见4 骨科3D打印定制假体应从临床需求出发,根据解剖形态实现结构匹配,根据力学需求实现仿真重建,通过空隙结构实现新骨长入,通过组织黏附实现生物稳定(推荐强度:强推荐,81.6%)。

证据概述:骨科3D打印定制假体设计的优劣决定了是否能实现解剖重建、力学匹配、新骨长入和组织黏附,同时应充分考虑患者的骨质条件,打印设备是否满足设计需求等因素[15-18]。在此基础上应满足在形态上符合解剖或功能重建的要求;在结构上实现假体与宿主骨匹配,有利于促进新骨长入,达到组织黏附和固定的要求;在强度上实现力学支持。为提高假体生存期应尽量避免应力遮挡和假体松动,保证生物力学稳定;同时,假体应易于安装,减少对周围软组织和宿主骨的破坏,降低术后并发症发生率[19-21]。

推荐意见5 骨科3D打印假体应设计为多孔结构,以实现仿生重建和促进骨长入(推荐强度:强推荐,88.9%)。

证据概述:骨组织具有多层板状结构和蜂巢状多孔结构,能够实现血管长入、营养物质交换等功能。因此,模拟骨小梁结构的多孔结构更有利于新骨形成和骨长入,促进营养物质交换和血管长入;同时,多孔结构可降低假体弹性模量,避免应力遮挡,实现仿生重建。3D打印技术能够将不同的材料加工为不同的孔径和孔隙率,实现强度与结构的匹配[22-26]。研究证实不同孔径和孔隙率的多孔钽结构的骨长入存在差异,其中400~600 μm最利于骨长入[27]。模拟骨小梁结构非均一孔径的多孔结构能够很好地实现骨整合与长入[28]。有关多孔钛的研究也发现多孔结构更利于骨长入,且孔径大小和孔隙率会影响骨长入[29-33]。此外,从流体力学、渗透性能、物质交换等方面,多孔结构也显示出其优越性。因此,应根据3D打印假体的用途调整适当的孔径和孔隙率[25,27,29,34-35]。

推荐意见6 3D打印定制假体的精确安装是实现精准解剖和功能重建的关键环节。医生通过术前模拟手术操作的方式确保手术的准确性,通过术中透视、导航或机器人辅助等手段确保假体的精准安装和解剖学匹配(推荐强度:强推荐,86.1%)。

证据概述:3D打印定制假体的精确安装是临床应用的关键环节之一,也是精确解剖和功能重建的基础[36-38]。术前精准设计和精准加工是3D打印定制假体的基础[39]。术中精准切除病灶或按照术前规划截骨可为3D打印定制假体的精确安装提供条件。术中根据透视定位、计算机导航或机器人辅助等手段有助于实现假体或螺钉放置的可视化和精准安装,同时减少周围结构的损伤[40]。术中尽量提供良好的初始稳定性并保证假体与截骨面的解剖学匹配,为骨长入与骨整合提供条件。

推荐意见7 3D打印定制假体的术后评估是验证其有效性的关键环节。术后应进行临床、影像和病理学综合评估有效性(推荐强度:强推荐,83.3%)。

证据概述:3D打印定制假体的术后评估主要包括对患者进行术后随访和功能评价[41-43],制定适合的随访周期。临床评价建议采用评分量表的方式,如疼痛评分、功能评分、活动评分、生活能力评分、行走能力评分、步态评分、心理评分等。通过影像学检查评估假体是否松动、脱位、断裂、骨折,是否存在骨吸收和溶解;同时,评估是否存在血管和神经损伤、下肢深静脉血栓形成等。借助去金属伪影可评估假体骨长入,了解假体与宿主骨的整合情况;结合病理学检查对肿瘤是否复发或转移、假体排异、假体周围感染等进行评价。

推荐意见8 骨科3D打印定制假体失败的主要原因包括3D打印导板或内植物与宿主不匹配、术前计划忽略了软组织的影响、消毒灭菌或术中操作不当所致导板或内植物变形或断裂、骨折复位和内固定技术欠佳、术后存在应力集中等(推荐强度:强推荐,91.7%)。

证据概述:由于骨科3D打印导板或内植物是基于骨性结构设计并制作的,临床医生术前应提供精确的解剖数据,并且将局部软组织可能带来的影响纳入手术计划,避免因导板或内植物与宿主不匹配以及忽视局部软组织而导致手术失败[44-45]。同时,3D打印材料种类众多、性能各异,临床医生在选用时需注意采用适合的消毒灭菌方式,避免因消毒灭菌不当引起导板或内植物变形或断裂,导致手术延期或失败[46-47]。此外,与常规器械相比,3D打印导板或内植物可能外形更大、结构更复杂,术者应谨慎选择手术入路、术中仔细操作,避免因术中操作不当导致导板或内植物变形或断裂,同时避免3D打印导板或内植物应力集中[46-49]。

二、骨科3D打印技术在创伤骨科的应用

推荐意见9 与常规手术相比,采用3D打印技

术辅助胫骨平台骨折固定可减少术中出血量,明显缩短手术时间和骨折愈合时间(推荐强度:中推荐,77.8%)。

证据概述:胫骨平台解剖结构复杂,骨折类型多样,治疗难度大。使用3D打印技术打印等比例骨折模型,可指导手术入路选择,模拟复位、安放接骨板及螺钉固定,有助于提高治疗效果。Xie等[50]纳入17项前瞻性研究的736例患者行系统评价和meta分析证实,3D打印辅助切开复位内固定治疗胫骨平台骨折的手术时间(P=0.032)和骨折愈合时间(P<0.000)较常规手术更短,术中出血更少(P<0.032),而二者术后并发症发生率(P=0.084)和术后膝关节功能(P=0.083)的差异无统计学意义。

推荐意见10 采用3D打印技术可于术前对骨盆骨折进行准确的诊断及分型,有助于外科手术计划的制定,可明显缩短手术时间、减少术中出血量及降低并发症发生率,提高围手术期安全性(推荐强度:中推荐,77.8%)。

证据概述:精确和细致的模型有助于外科手术计划的制定,并能辅助术者选择合适的手术方式[51]。Wang等[52]纳入7项前瞻性研究的348例骨盆骨折患者,其中174例接受3D打印模型辅助切开复位内固定术、174例常规切开复位内固定术。结果显示3D打印组的手术时间、术中出血量和术后并发症发生率均低于常规组,复位优良率高于常规组。Banierink等[53]纳入18项研究的988例骨盆骨折患者行系统评价同样证实,3D打印模型辅助手术有利于减少透视次数、降低术中出血、增加骶髂螺钉置入精准性及改善复位质量。在3D打印模型上可进行骨盆内固定物的预塑形和模拟手术[54-56]。由于3D打印内固定物是基于骨性结构设计制造,未充分考虑软组织影响,可能导致内固定与宿主骨不匹配,因此术中仍需备用标准内固定钢板[44]。

三、骨科3D打印技术在关节外科的应用

推荐意见11 使用3D打印个性化导板辅助下的全膝关节置换治疗骨关节炎能减少术中出血量、改善术后膝关节功能,术后下肢力线较传统全膝关节置换更精确(推荐强度:强推荐,94.4%)。

证据概述:基于患者术前影像学资料采用3D打印技术制作的个性化截骨导板可实现个性化、精确化截骨和避免髓内定位[57]。Qiu等[58]回顾性分析了10例接受3D打印个性化导板辅助的全膝关节置换和16例接受传统全膝关节置换患者的临床疗效,结果显示前者术后冠状面的髋-膝-踝角、股骨组件角、冠状面胫骨组件角、矢状面胫骨组件角与目标参数的差异无统计学意义。为分析3D打印个性化导板在全膝关节置换中的有效性,Gemalmaz等[59]回顾性纳入80例患者,干预组采用3D打印个性化导板辅助截骨,对照组采用传统定位器截骨,术后偏离目标力线3°以上定义为矫形失败,结果显示对照组矫正失败率更高。

推荐意见12 胫骨高位截骨术中应用3D打印个性化导板实施截骨可实现内翻畸形和下肢力线的精准矫正(推荐强度:强推荐,91.7%)。

证据概述:胫骨高位截骨通过调整下肢力线,将压力从患侧间室转移至正常间室或正常力线位置,从而缓解膝关节疼痛,力线的精准性是手术成功的关键[60]。马信龙等[61]回顾性分析了241例行3D打印个体化截骨矫形导向器下完成的内侧开放胫骨高位截骨和100例传统内侧开放胫骨高位截骨的患者,前者术中透视次数和手术时间明显低于后。此外,应用3D打印个体化截骨矫形导向器术后截骨相关骨折、植入物相关感染的风险更低。也有文献报道接受3D打印个性化导板截骨患者的股胫角和胫骨近端内侧角的矫正误差更小、膝关节功能评分更佳、短期临床疗效更好[62-63]。

推荐意见13 3D打印辅助全髋关节置换在协助术前规划、指导术中定位及假体选择等方面有重要作用,相比传统全髋关节置换可提高术中假体安放的精准度和减少手术时间(推荐强度:中推荐,69.4%)。

证据概述:全髋关节置换是治疗伴有严重骨关节炎的晚期成人发育性髋关节发育不良的首选治疗方式[64]。利用3D打印技术可在术前分析髋关节的变异情况,识别髋臼解剖变化及损伤程度,制定合理的手术方案并进行手术预操作,从而对假体选择、臼杯大小、假体安放高度及角度进行预判;术中利用髋臼导航模板的引导功能可提高髋臼假体放置的准确性[65-67],缩短手术时间[67-69],减少术中出血量[68]。Yan等[70]的回顾性研究发现,成人发育性髋关节发育不良术中使用3D打印导航模板与透视辅助组相比手术时间更短、术中出血量更少、术后6个月Harris髋关节评分更高,且前倾角、外展角、旋转中心距坐骨结节连线的距离更接近正常值。Liu等[67]研究发现3D打印组的手术成功率、住院天数、康复时间、术后再脱位发生率均优于传统组,臼顶倾斜角和中心边缘角更接近正常值。Geng等[68]对92例发育性髋关节发育不良患者采用3D打印多孔

钛髋臼小梁杯进行全髋关节置换，经平均48.2个月随访证实髋臼杯与宿主匹配精确且稳定。Tu等[69]的研究结果证实发育性髋关节发育不良术中使用3D打印个性化导板可实现精准手术，为髋臼重建和股骨截骨提供个性化手术方案。

四、骨科3D打印技术在脊柱外科的应用

推荐意见14　与透视辅助置钉相比，3D打印辅助手术可提高置钉精准性，降低医患的辐射暴露量（推荐强度：中推荐，69.4%）。

脊柱侧凸是青少年常见的躯干畸形，可引发多种并发症，对进行性加重的严重侧凸常需手术矫正[71]。3D打印联合椎弓根导向器辅助置钉技术可根据患者的解剖特点确定最佳置入钉点和轨迹，并选择大小合适的螺钉，有助于提高椎弓根螺钉置入的精准性。Cao等[72]回顾性分析67例先天性脊柱侧凸患者，3D打印组（34例）的置钉优良率高于透视辅助组（33例），术后并发症发生率低于透视辅助组，两组术后脊柱后凸和侧凸Cobb角的差异无统计学意义。Lu等[73]纳入16例特发性脊柱侧凸和先天性脊柱侧凸的患者，基于术前CT设计并打印椎弓根导向器辅助术中置钉，结果显示该技术可显著减少手术时间，降低辐射暴露量。

推荐意见15　3D打印导板辅助置钉技术可提高上颈椎脱位手术中椎弓根钉放置的精准性，降低手术并发症的发生率（推荐强度：中推荐，75.0%）。

证据概述：后路椎弓根螺钉置钉技术因其较高的骨性融合率及优良的生物力学性能广泛应用于上颈椎不稳的手术治疗。采用3D打印导板辅助置钉可预先明确患者个体解剖差异，并根据数字模型对钉道做适当地调整以实现精准置钉[74-75]。Wang等[76]回顾性分析43例寰枢椎脱位接受后路椎弓根钉内固定的患者，其中3D打印导板辅助置钉19例、透视辅助置钉24例，结果显示3D打印组的置钉准确率高于传统组，平均透视次数、术中出血量和手术时间均低于传统组。Pu等[77]对49例寰枢椎脱位患者进行回顾性分析，根据置钉方法不同分为3D打印导航模板组（25例）和透视辅助组（14例），结果显示3D打印导航模板组的置钉优良率为98%，高于传统组的75%；手术时间、置钉时间、透视次数均低于透视辅助组。此外，3D打印椎体模型可实现术前规划和手术模拟，提高手术精准性和安全性[78-79]。

五、骨科3D打印技术在骨肿瘤的应用

推荐意见16　3D打印定制骨盆假体治疗髋关节周围原发恶性肿瘤可获得良好的骨整合和髋关节功能，短期疗效显著（推荐强度：中推荐，77.8%）。

证据概述：3D打印技术可制造任意形状的假体以实现假体与截骨面的精确配对，同时可在假体上预留任意方向的钉道用于固定以恢复正常力学传导，还能制造出固定孔径及孔隙率的表面结构诱导骨长入，最终在假体重建的基础上实现生物重建[80]。Zoccali等[81]回顾性分析14例骨盆恶性肿瘤术后接受3D打印组配式半骨盆假体重建的患者，术后5年无瘤生存率为85.7%，国际骨与软组织肿瘤协会评分为46.3%。末次随访时无一例患者出现假体松动、股骨假体脱位，功能状态均良好。Liang等[82]回顾性分析35例接受骨盆肿瘤切除、3D打印组配式骨盆假体重建手术的患者，术后无瘤生存率71.4%，国际骨与软组织肿瘤协会-93评分为（19.8±3.2）分，优于既往文献的结果[83]。

推荐意见17　3D打印人工椎体可有效辅助术前规划、准确重建骨缺损、诱导骨长入、增加骨融合，并能降低内固定失败、假体塌陷及沉降的发生率，是目前复杂椎体肿瘤患者椎体重建的理想方案（推荐强度：强推荐，80.6%）。

证据概述：3D打印人工椎体适合复杂椎体肿瘤的整块切除和重建[45,84]。纪经涛等[85]对33例胸腰椎椎体恶性肿瘤患者采用后路全锥体切除重建，并根据重建方式分为3D打印人工椎体重建组（21例）和钛网重建组（12例），平均随访时间10.9个月。结果显示两组术中出血量、手术时间、术后并发症发生率差异无统计学意义；末次随访时钛网重建组5例出现不同程度的假体下沉，而3D打印人工椎体重建组无一例出现假体下沉。Girolami等[86]的前瞻性研究纳入13例椎体肿瘤（8例原发性，5例转移性）接受肿瘤整块切除联合3D打印钛合金人工椎体重建的患者，术后所有患者出现人工椎体下沉，11例无症状，1例接受翻修，1例因局部复发行假体取出。Tang等[87]回顾性纳入27例多节段胸腰椎肿瘤整块切除后接受3D打印人工椎体重建的患者，平均随访时间22个月，结果显示平均出血量为4100 ml，局部复发率为19.2%，无一例出现内固定失效或人工椎体脱位。然而，3D打印人工椎体制作周期长、成本高，且远期疗效还有待进一步观察。

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