

3D 打印个体化器械操作在全膝关节置换术中的应用现状

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【摘要】 当今关节置换术已经逐渐成为骨科常见手术,关节置换手术的相关研究亦成为热点,其研究程度也逐渐加深。3D 打印技术应用于髌膝关节置换的相关报道逐渐增多,如基于 3D 打印技术的患者个体化器械操作,其手术辅助作用可观,尤其对于复杂病例的关节置换更为重要,但总体来说个体化器械操作在关节置换术中的运用还处于发展阶段。本文通过回顾相关文献,分析、整理 3D 打印个体化器械操作在全膝关节置换术中的应用的研究现状,主要从个体化术前规划、术中操作、术后功能恢复等方面总结其在膝关节置换术中的应用的有效性以及在肥胖、膝关节畸形等特殊复杂的膝关节手术病例中应用的必要性,并简述其在当前的临床应用中存在的问题和争议,以期为今后的研究方向及临床应用提供参考。

【关键词】 3D 打印技术; 关节成形术,置换,膝; 综述文献

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ABSTRACT Recently, the joint replacement has gradually become a common operation of orthopedics. It's also the hot spot in current investigations. The increasing number of reports about the 3D printing technology such as patient-specific instrumentation (PSI) is applied to hip and knee replacement. It plays an important role in supporting operation especially for complex cases. However, it is still at the primary stage. This article reviews the relevant literature, analyzes and collates the research status of the application of 3D printing PSI in total knee arthroplasty, and summarizes its effectiveness in the application of knee arthroplasty from the aspects of individual preoperative planning, intraoperative operation and postoperative functional recovery, especially complex knee surgery such as obesity and knee deformity. The necessity of clinical application is discussed, and the existing problems and controversies in the current clinical application are summarized in order to provide references for the future research direction and clinical application.

KEYWORDS 3D printing technology; Arthroplasty, replacement, knee; Review literature

在医学临床中,从医学成像到 3D 打印的一站式制造的实现,正迎合了近期医学趋向“个性化”和精准医疗的需求^[1]。3D 打印技术在临床中的益处已在多个学科尤其是骨科、矫形外科等得到证实,在临床中的应用,其益处已得到公认^[2-3]。在骨科临床领域,关于 3D 打印技术辅助关节置换的相关报道日益增多,尤其在复杂性关节置换中更为推荐^[4-5]。传统手术方法对于特殊患者的膝关节置换未能取得满意的疗效,而 3D 打印技术的发展,能够缓和甚至打破这种窘境,即使对于骨折后轴向肢体畸形的膝关

节置换,3D 打印技术也能辅助手术得到良好疗效^[6]。对于较难处理而经常出现在膝关节翻修术中遇到的骨缺损问题,构建新型多孔金属钽垫块来应对也是 3D 打印技术的运用实例^[7]。本文着重针对个体化器械操作(patient-specific instrumentation, PSI)在全膝关节置换术(total knee arthroplasty, TKA)中现阶段的应用优劣总结相关问题进行阐述。

1 PSI 在全膝关节置换术中的应用优劣

1.1 利于术前个性化手术方案的制定

由于种族、性别等造成的不同患者之间解剖结构的差异,对 TKA 术者提出了严峻的挑战。接受膝关节置换的每个患者,因不同种族、性别,致使解剖结构必定存在差异,尤其是亚洲人,其变异率比欧美

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人更高^[8-10],若下肢力线不能得到良好恢复,从长期疗效来看,假体松动、不稳定的风险就会增加,从而造成关节磨损和骨质溶解,以致需要接受膝关节翻修手术^[11]。因此解剖结构的异常会对手术医生的评估能力提出进一步考验,故如何提高术前评估准确度及设计个性化手术方案就显得尤为重要。对于特殊膝关节置换患者,进行术前建模能够有效提高截骨准确性及假体安放稳定性从而提高手术效果^[12]。3D 打印 PSI 能构造拟施术关节的三维模型,实现复杂解剖结构的可视化,并能对股骨外翻角(FMAA)、外侧角(LFA)、髌膝踝角(HKA)、股胫角(FTA)等量化数据进行精确测量采集并处理,又可在模型上进行手术模拟,确定假体设计及定位,截骨的方向、程度及长度,若与预期情况有所偏差,可以及时进行手术策略调整,从而制定最佳个性化手术方案^[13-14]。充分及有针对性的术前准备是手术成功的前提保障,PSI 可使术前准备更充分,可实现假体最佳安放位置和假体大小的准确预测,还能最大程度减少试模次数。而假体位置不当及假体尺寸过大被认为是 TKA 术后膝关节僵硬的重要因素^[15]。Ettinger 等^[16]的研究结果表明 PSI 在术前假体大小尺寸预测方面有非常高的准确性。Ollivier 等^[17]依据 CT 扫描结果使用 PSI 辅助初次膝关节表面置换,PSI 组患者术中使用假体均为术前计划时所选的尺寸,可以认为,PSI 对于假体的大小和位置的预测是可靠的。

通过在模型上进行手术预演,不但能预测术中可能出现的问题,可以及早制定应对方案,还有利于临床教学的开展^[18],使手术过程更加直观,原理更加明朗。此外,还能一定程度上使与家属的沟通解释工作进行得更为顺利。

1.2 利于提高术中操作准确性及手术效率

传统 TKA 对于股骨假体的放置定位,使用股骨远端髓内定位方法,根据股骨解剖轴来判断与机械轴相垂直的方向来推断截骨面,由此截骨面的确定必然不够客观,会更依赖于术者经验,手术时间的延长在所难免而且精确度难以保证^[5]。如果患者存在骨骼发育异常或是骨折后畸形愈合,解剖变异较大时,对线的准确性将更加难以保证。PSI 技术的应用,胫骨平台截骨厚度、角度,股骨面的旋转角度在术前已经精确计算后确定,对于膝关节术后力线的重建会更理想。Kievit 等^[19]在尸体标本上的研究也得出了同样结论。假体的稳定性将决定膝关节置换术后的远期疗效,假体的稳定性虽然受病例的选择、假体的材料、骨水泥的固定等诸多因素的影响,但截骨的准确度将直接影响假体的服贴程度。

PSI 进行的髓外定位截骨方式是根据机械轴垂

直方向来进行截骨,与传统方法相比,既可以一定程度上克服传统手术方式因解剖轴与机械轴的差异所致的准确性有限的问题,也可以避免进行扩髓,减少出血^[20]。

下肢机械轴力线和假体旋转轴线是膝关节置换术成功极为关键的 2 个因素,良好的下肢力线对远期疗效及降低翻修率具有重要意义^[21]。传统的膝关节置换术,其下肢机械轴偏离中立位 $\leq 3^\circ$ 的精确度并不理想^[22],而使用 PSI 辅助 TKA,能够提高精确度,减小下肢力线误差。没有良好的股骨假体旋转轴线是出现髌股关节炎等术后并发症的首要因素,严重影响人工关节的使用寿命^[23]。经 PSI 精确设计的股骨假体内植,不但能够获得理想的股骨假体旋转轴线,还能缩短手术时间^[5,24],提高手术效率^[25-26]。

1.3 利于减少术后并发症及功能重建

TKA 术后并发症中膝关节术后感染是最常见也是最严重的并发症之一,不仅会对关节功能恢复造成影响,如果感染得不到有效控制,还要进行二次手术取出假体,给患者带来生理上及心理上的痛苦,而且对患者的经济承受能力也是一种挑战,感染严重者甚至还面临着截肢的风险。TKA 术后并发症之一的脂肪栓塞综合征越来越受到重视,其发生机制可能是因为术中操作使脂肪组织、血管遭到破坏,或者髓内假体的置放和生物粘合剂的使用,进一步增加了髓内压,脂滴混合血肿进入血液循环^[27]。与传统 TKA 采用胫骨近端截骨髓内定位相比,应用 PSI 导板截骨方式没有开髓过程,则能够大大减少术后脂肪栓塞及潜在感染发生的风险^[28-29]。

关节术后引流对于外科手术的意义在预防关节血肿,减少切口延迟愈合,如果术后出血过多,引流时间增加,会增加术后感染的机会。PSI 的应用能减少术中创伤的同时,亦能减少术后的出血。Vertullo 等^[30]的研究结果显示,与常规 TKA 相比 PSI 用于 TKA 术后引流量明显降低。

TKA 术后膝关节功能重建与患者自身状态、手术技术、术后康复锻炼等多种因素有关。美国特种外科医院(Hospital for Special Surgery, HSS)膝评分可反映患者膝关节局部及机体整体功能状态,术前 HSS 评分较低者表明其骨关节炎病变更为严重,术后 HSS 评分低者表明其关节功能没有得到良好恢复。PSI 的 TKA 术后 HSS 评分总分得分较高,而术后患者疼痛评分(visual analog scale, VAS)显著降低^[31]。最终来说,PSI 能够降低 TKA 手术失败率,有统计称其 5 年随访翻修率为 1.2%^[32]。

1.4 PSI 应用存在的争议

在积极进行 3D 打印技术推广的大背景下,也

有诸多研究者提出异议。Victor 等^[33]认为 PSI 并不能提高 TKA 手术的准确性;即使由经验丰富的医生主刀,使用的技术定位系统再精细,其对线误差超过 3° 的发生率也至少为 10%。Abane 等^[34]的研究对比了 59 例 PSI 辅助 TKA 和 61 例传统膝关节手术,结果表明两者在手术时间、术中出血量和术后力线恢复方面并无明显差异。Huijbregts 等^[35]的研究表明,两者术后并发症的差异无统计学意义。Schotanus 等^[32]认为其与传统方式 TKA 术后中期效果无明显区别。要进一步验证 PSI 在 TKA 中应用的优劣,则需要更大样本量、范围更广、随访时间更长的研究。

2 PSI 在特殊患者 TKA 中的应用

2.1 肥胖患者

体重指数 (body mass index, BMI) 对于膝关节炎病人人群来说,是关节炎发生发展的重要因素,高 BMI 或者肥胖人群罹患膝关节炎的风险明显升高,并且关节炎后期接受 TKA 术后感染和血栓并发症发生风险也越高^[36]。Ward 等^[37]认为 BMI > 40 kg/m² 的患者 TKA 术后有更高的翻修率和感染风险。Culliford 等^[38]分析英国综合医疗研究数据库中 1988-2011 年记录的 54 276 例 TKA 患者发现,严重肥胖患者 (BMI ≥ 40 kg/m²) TKA 术后 5 年行翻修术风险比体重正常患者增加 43.9%。肥胖和术后体重增加对关节置换术后的负面影响已被证实^[39]。所以高 BMI 和肥胖患者进行术前减重,不但能够降低术后早期感染、深静脉血栓等并发症,还能降低后期进行膝关节置换术后翻修的概率。寻求一种方法使 BMI 和肥胖患者 TKA 术后并发症最小化的研究也极具意义。Anwar 等^[40]研究认为 BIM > 30 kg/m² 的患者推荐使用 PSI 行 TKA,以降低术后多种并发症发生的风险。

2.2 膝关节畸形患者

膝骨性关节炎、创伤性关节炎、类风湿性关节炎等晚期症状通常伴随一定程度的膝关节内翻畸形。治疗方法一般是接受膝关节置换以缓解疼痛,改善关节活动度及下肢力线^[41]。有统计称 TKA 患者膝外翻畸形约占 10%,且同时存在骨性结构及周围软组织异常,此时手术难度会较大^[42]。同样,骨折后的畸形愈合、下肢发育畸形等原因导致的关节外畸形也会增加 TKA 手术的难度^[43]。少数重度畸形并非能依靠截骨和软组织复合松解达到满意效果,需要采用限制性假体或铰链型膝关节假体进行关节置换^[44]。而对于有特殊病理解剖的膝关节置换患者,使用依靠解剖标志定位截骨的传统膝关节置换术,其下肢力线获取无疑乏力,术后下肢力线误差也会相对较大^[45],术后易发生髌骨轨迹不良、早期假体松动、聚

乙烯垫片磨损等并发症。因此,对于伴有严重关节外畸形患者,TKA 手术中使用传统截骨器械会受到巨大的限制。而 PSI 的个体化为同期治疗关节炎和关节畸形提供了保障,其优越性尤为明显。Rahm 等^[46]研究表明严重内外翻畸形患者 PSI 是更优选择。

2.3 膝关节肿瘤患者

对于膝关节肿瘤患者,骨肿瘤生长在胫骨近端或股骨远端,常常合并大范围的骨质侵蚀,骨质缺损严重,可利用支撑的骨质明显不足,而且可能存在软组织问题,在常规肿瘤膝关节置换术后,术后易发生假体松动和假体周围骨折等术后并发症,通常具有很高的翻修率,且手术难度较高,患者 5 年生存率为 57%~93%^[47]。因此,对术后效果具有较高要求,也就意味着要有精准的术前规划,而 PSI 的术前高预测性能为手术的成功加码。肿瘤型膝关节置换术后股骨侧假体周围骨折,常常是由于肿瘤复发、感染、无菌性松动、假体周围骨折、假体柄折断和铰链结构失败等导致^[48-49],尽管不及髌关节置换术后假体周围骨折常见,但其治疗难度更具挑战性。对于该种病例,国外有报道应用 PSI 进行全股骨假体定制后置换,以保证患者患侧股骨能够有足够强度的支撑的病例^[50]。可见 PSI 于肿瘤型膝关节置换中具有很高的应用价值。

2.4 膝关节置换术后翻修术

膝关节骨性关节炎的高发,TKA 手术量的增加,也就意味着更多的膝关节置换术后翻修术 (revision total knee arthroplasty, RTKA),无疑会耗费更大的社会及医疗资源,所以对 RTKA 的研究也是临床研究的热点。PSI 最初是用于初次全膝或者单髌置换,近年来已有人将其应用至 RTKA^[51]。RTKA 主要难点在于更好地恢复股骨假体的旋转力线。因为术后股骨后髌解剖定位不明确,关节屈伸轴线难以确定,此技术难题会影响对假体判断的准确性^[52]。RTKA 术中还会涉及如何处理可能存在的骨缺损,是否需要更改为加长柄假体等诸多不确定问题,想要顺利完成翻修术,精密的术前计划是必不可少的。基于 3D 打印技术的 PSI 能为特定的膝关节解剖量身定制手术计划,在手术前可以精确地了解解剖异常和预测假体大小,并且可以根据特定的要求制定特定型号的假体。Schotanus 等^[53]的研究表明 PSI 应用于膝关节翻修术,其假体预测准确度及旋转力线恢复较为理想。因此 PSI 或许可以作为关节翻修术的一种有效可靠的新方法,相关研究也值得进一步深入。

3 小结与展望

科学技术的日新月异,使得 PSI 在 TKA 中的应用取得了很大进步。基于社会老龄化一步步加重的

现实,人工膝关节置换将会愈来愈常见,提高膝骨性关节炎患者的生活质量对整个社会意义非凡。基于 3D 打印技术的发展,许多膝骨性关节炎晚期患者已受益于 PSI 技术,从术前假体的制定、术中截骨的确 定,到术后膝关节功能恢复,与传统膝关节置换术相比 PSI 都体现出了一定的优势。即使在当前应用存在一些不确定因素,广泛使用的必要性仍有待商榷,但在面对肥胖患者、关节畸形患者或存在膝关节骨缺损等复杂膝关节手术时传统的手术方式往往不能取得的满意疗效,PSI 的优越有效性已得到初步验证和认可。PSI 技术的相关研究逐渐加深日趋成熟,其应用范围亦能得到进一步完善扩大。交叉学科概念的兴起,也为 PSI 的更进一步研究提供了参考,比如在 PSI 中运用生物型材料、损伤修复因子等。充分运用其他领域的新兴技术,将其与 PSI 灵活地结合在一起,对提高 TKA 的近期、远期疗效有相当可观的前景。

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