3D 打印技术辅助全膝关节置换术治疗骨关节炎膝外翻畸形的临床研究

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摘　要　目的:观察 3D 打印技术辅助全膝关节置换术(total knee arthroplasty,TKA)治疗骨关节炎膝外翻畸形的临床疗效。**方法**:将 32 例骨关节炎膝外翻畸形患者随机分为 3D 打印技术辅助 TKA 组和单纯 TKA 组,每组 16 例。记录并比较 2 组患者手术时间、失血量,及术前和术后 2 周的膝关节活动范围、股胫角、美国特种外科医院(hospital for special surgery,HSS)膝关节评分及简明健康状况调查表(short form 36 health survey questionnaire,SF-36)评分。**结果**:3D 打印技术辅助 TKA 组患者的手术时间短于单纯 TKA 组[(64.69±8.46)min,(72.31±5.44)min,t=3.033,P=0.005],失血量小于单纯 TKA 组[(448.13±48.20)mL,(495.00±49.13)mL,t=2.724,P=0.011]。术前 2 组患者膝关节活动范围比较,差异无统计学意义(71.06°±5.54°,72.63°±5.46°,t=0.803,P=0.428);术后 2 周,2 组患者膝关节活动范围均大于术前(116.63°±7.81°,71.06°±5.54°,t=19.024,P=0.000;112.94°±8.38°,72.63°±5.46°,t=16.121,P=0.000);2 组患者膝关节活动范围比较,差异无统计学意义(t=1.288,P=0.208)。术前 2 组患者股胫角比较,差异无统计学意义(17.75°±6.02°,18.94°±6.71°,t=0.527,P=0.602);术后 2 周,2 组患者股胫角均小于术前(4.19°±1.11°,17.75°±6.02°,t=8.867,P=0.000;5.38°±0.89°,18.94°±6.71°,t=8.018,P=0.000);3D 打印技术辅助 TKA 组股胫角小于单纯 TKA 组(t=3.348,P=0.002)。术前 2 组患者 HSS 膝关节评分比较,差异无统计学意义[(50.75±6.26)分,(51.25±5.73)分,t=0.236,P=0.815];术后 2 周,2 组患者 HSS 膝关节评分均高于术前[(81.19±4.72)分,(50.75±6.26)分,t=15.534,P=0.000;(81.69±4.91)分,(51.25±5.73)分,t=16.131,P=0.000];2 组患者 HSS 膝关节评分比较,差异无统计学意义(t=0.294,P=0.771)。术前 2 组患者 SF-36 评分比较,差异无统计学意义[(53.75±5.32)分,(52.88±5.25)分,t=0.468,P=0.643];术后 2 周,2 组患者 SF-36 评分均高于术前[(80.00±3.74)分,(53.75±5.32)分,t=16.138,P=0.000;(78.50±4.40)分,(52.88±5.25)分,t=14.964,P=0.000];2 组患者 SF-36 评分比较,差异无统计学意义(t=1.039,P=0.307)。**结论**:采用 3D 打印技术辅助 TKA 治疗骨关节炎膝外翻畸形,能改善膝关节活动范围,恢复下肢力线,促进膝关节功能恢复,提高患者生活质量;且 3D 打印技术辅助 TKA 比单纯 TKA 手术时间短、失血量少、下肢力线恢复好,值得临床推广应用。

关键词　骨关节炎;膝外翻;关节成形术,置换,膝;3D 打印

A clinical study of total knee arthroplasty assisted by 3D printing technology for treatment of valgus knee secondary to osteoarthritis

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ABSTRACT　Objective:To observe the clinical curative effects of total knee arthroplasty(TKA)assisted by 3D printing technology in treatment of valgus knee secondary to knee osteoarthritis(KOA). **Methods**:Thirty-two patients with valgus knee secondary to KOA were randomly divided into 3D printing assisted TKA group and traditional TKA group,16 cases in each group. The operative time and intraoperative blood loss were recorded and compared between the 2 groups respectively. Moreover,the range of motion(ROM)of knee,femorotibial angle,hospital for special surgery(HSS)knee score and short form 36 health survey questionnaire(SF-36)score were measured and compared between the 2 groups before the surgery and at 2 weeks after the surgery respectively. **Results**:The operative time was shorter and the blood loss was less in 3D printing assisted TKA group compared to traditional TKA group(64.69 +/- 8.46 vs 72.31 +/- 5.44 min,t=3.033,P=0.005;448.13 +/- 48.20 vs 495.00 +/- 49.13 mL,t=2.724,P=0.011). There was no statistical difference in ROM of knee between the 2 groups before the surgery(71.06 +/- 5.54 vs 72.63 +/- 5.46 degrees,t=0.803,P=0.428). The ROM of knee increased in both of the 2 groups at 2 weeks after the surgery compared to pre-surgery(116.63 +/- 7.81 vs 71.06 +/- 5.54 degrees,t=

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19.024, P = 0.000; 112.94 +/− 8.38 vs 72.63 +/− 5.46 degrees, t = 16.121, P = 0.000), and there was no statistical difference in ROM of knee between the 2 groups (t = 1.288, P = 0.208). There was no statistical difference in femorotibial angles between the 2 groups before the surgery (17.75 +/− 6.02 vs 18.94 +/− 6.71 degrees, t = 0.527, P = 0.602). The femorotibial angles decreased in both of the 2 groups at 2 weeks after the surgery compared to pre − surgery (4.19 +/− 1.11 vs 17.75 +/− 6.02 degrees, t = 8.867, P = 0.000; 5.38 +/− 0.89 vs 18.94 +/− 6.71 degrees, t = 8.018, P = 0.000), and the femorotibial angles were smaller in 3D printing assisted TKA group compared to traditional TKA group (t = 3.348, P = 0.002). There was no statistical difference in HSS knee scores between the 2 groups before the surgery (50.75 +/− 6.26 vs 51.25 +/− 5.73 points, t = 0.236, P = 0.815). The HSS knee scores increased in both of the 2 groups at 2 weeks after the surgery compared to pre − surgery (81.19 +/− 4.72 vs 50.75 +/− 6.26 points, t = 15.534, P = 0.000; 81.69 +/− 4.91 vs 51.25 +/− 5.73 points, t = 16.131, P = 0.000), and there was no statistical difference in HSS knee scores between the 2 groups (t = 0.294, P = 0.771). There was no statistical difference in SF − 36 scores between the 2 groups before the surgery (53.75 +/− 5.32 vs 52.88 +/− 5.25 points, t = 0.468, P = 0.643). The SF − 36 scores increased in both of the 2 groups at 2 weeks after the surgery compared to pre − surgery (80.00 +/− 3.74 vs 53.75 +/− 5.32 points, t = 16.138, P = 0.000; 78.50 +/− 4.40 vs 52.88 +/− 5.25 points, t = 14.964, P = 0.000), and there was no statistical difference in SF − 36 scores between the 2 groups (t = 1.039, P = 0.307). **Conclusion**: The 3D printing technology assisted TKA can improve knee ROM, restore lower limb force − lines, promote knee functional recovery and improve patient's life quality in treatment of valgus knee secondary to KOA. Moreover, the 3D printing technology assisted TKA has the advantages of shorter operative time, less blood loss and better lower limb force − lines compared to traditional TKA, so it is worthy of popularizing in clinic.

Keywords osteoarthritis; genu valgum; arthroplasty, replacement, knee; three − dimensional printing

人工全膝关节置换术(total knee arthroplasty, TKA)是治疗各种终末期膝关节疾病如骨关节炎、类风湿关节炎等的有效方法,在缓解膝关节疼痛、恢复下肢力线、纠正膝关节畸形及改善患者生活质量方面疗效显著。随着人工关节置换技术的进步和假体材料的持续改进,接受人工 TKA 的患者逐年增加,而在接受 TKA 的患者中存在外翻畸形者达 10% ~ 15%[1]。近些年随着微创治疗技术及快速康复技术的持续发展,传统 TKA 的诸多弊端逐渐显现,如手术时间长、髓内定位失血量多、术中需反复试模匹配假体等[2]。骨关节炎膝外翻畸形多伴有内外侧软组织不平衡,术中需行软组织松解,且精确截骨有助于下肢力线及内外侧软组织平衡的恢复[3]。有研究指出 TKA 术的临床疗效很大程度上取决于术前准备及手术操作[4]。在骨科手术中应用 3D 打印技术可以更精确地预测内植物的大小和位置[5]。为了比较 3D 打印技术辅助 TKA 与单纯 TKA 治疗骨关节炎膝外翻畸形的临床疗效,2015 年 1 月至 2017 年 5 月我们分别采用这 2 种方法治疗骨关节炎膝外翻畸形患者 32 例,现报告如下。

1 临床资料

1.1 一般资料 纳入研究的患者共 32 例,男 12 例、女 20 例。年龄 48 ~ 76 岁,中位数 63 岁。均为浙江省湖州市第一人民医院的住院患者。均为骨关节炎膝外翻畸形患者,其中左膝 15 例、右膝 17 例。2 组骨关节炎膝外翻畸形患者基线资料比较,差异无统计学意义,有可比性(表 1)。试验方案经医学伦理委员会审查通过。

1.2 诊断标准 采用骨关节炎诊治指南(2007 年版)中的 KOA 诊断标准[6];并参考 Ranawat 等[7]和 Elkus 等[8]制定的膝外翻畸形的诊断标准:股胫角(股骨解剖轴线与胫骨解剖轴线所形成的夹角)5° ~ 10°为正常,10° < 股胫角 < 20°为膝外翻,股胫角 ≥ 20°为重度膝外翻。

1.3 纳入标准 ①符合上述诊断标准;②年龄 45 ~ 85 岁;③需初次行单侧TKA;④自愿参与本研究,并

表 1 2 组骨关节炎膝外翻畸形患者基线资料比较

组别	样本量(例)	性别(例)		年龄($\bar{x} \pm s$,岁)	病变部位(例)	
		男	女		左膝	右膝
3D 打印技术辅助 TKA 组	16	5	11	61.81 ± 9.22	6	10
单纯 TKA 组	16	7	9	64.94 ± 9.71	9	7
检验统计量				t = 1.125		
P 值		0.716		0.258	0.479	

TKA:全膝关节置换术

签署知情同意书。

1.4　排除标准　①合并恶性肿瘤等影响骨代谢的疾病者;②需行髌骨置换者;③凝血功能异常者。

2　方　法

2.1　分组方法　采用随机数字表将符合要求的 32 例骨关节炎膝外翻畸形患者随机分为 3D 打印技术辅助 TKA 组和单纯 TKA 组,每组 16 例。

2.2　治疗方法

2.2.1　术前准备　行术前常规检查,全面评估患者重要器官功能及明确有无手术禁忌证,必要时请相关科室会诊;行双下肢全长正位 X 线及三维 CT 检查,将影像检查所得数据导入 3D 打印机,利用快速成型技术打印出膝关节假体 3D 模型及截骨导板(图 1),依照模型确定术中操作所需假体型号、截骨量及截骨角度等。

2.2.2　3D 打印技术辅助 TKA　采用全身麻醉,患者仰卧位,患侧大腿根部上止血带,常规消毒铺巾。取髌骨旁内侧入路,显露膝关节,清除增生滑膜、半月板、交叉韧带及增生骨赘等,并根据膝关节平衡情况,适度松解髂胫束、外侧副韧带及后外侧关节囊等软组织。咬除骨赘及关节软骨后,将术前准备的 3D 打印膝关节模型与患侧膝关节进行比对,并确保截骨导板定位于解剖位置。将 3D 打印股骨远端截骨导板紧贴股骨远端骨皮质,确保截骨导板定位模块与膝关节解剖结构匹配后,沿定位孔打入 4 枚骨针,安装、固定截骨器,依次对股骨前髁、后髁、前斜角、后斜角进行截骨,完成股骨远端截骨;将 3D 打印胫骨近端导板紧贴胫骨近端骨皮质,保证截骨导板定位模块与胫骨近端解剖结构匹配后,沿定位孔打入 2 枚骨针,安装、固定截骨器,于胫骨平台最低点远端 1 ~ 2 mm 处进行截骨,完成胫骨近端截骨。检测膝关节屈伸活动度及内外侧软组织平衡情况,满意后用脉冲冲洗枪彻底冲洗膝关节,根据所需型号置入相应的膝关节假体,用骨水泥固定,待骨水泥固化后清除多余骨水泥。冲洗切口,留置负压引流管,逐层缝合。

2.2.3　单纯 TKA　术区显露过程同 3D 打印技术辅助 TKA 组,术中使用常规截骨导板进行截骨。采用髓外定位器辅助确定假体安放方向,做胫骨平台截骨;采用髓内股骨定位器进行股骨远端截骨。截骨完成后,用脉冲冲洗枪彻底冲洗膝关节,反复比对后选择合适的假体型号,并分别于膝关节伸直位及屈曲位置入间隙试模,判断膝关节内外侧软组织平衡情况。根据所需假体型号置入相应膝关节假体,用骨水泥固定,待骨水泥固化后清除多余骨水泥。冲洗切口,留置负压引流管,逐层缝合切口。

2.2.4　术后处理　切口缝合完成后,于关节腔内注入氨甲环酸 100 mL,并夹闭引流管 2 h;常规使用抗凝药物和抗生素,监测引流量;术后 24 ~ 48 h 拔除引流管;术后第 3 天开始行患肢功能锻炼。

2.3　疗效评价方法　记录并比较 2 组患者手术时间、失血量(术中失血量和术后引流量),及术前和术后 2 周的膝关节活动范围、股胫角、美国特种外科医院(hospital for special surgery,HSS)膝关节评分[9]及简明健康状况调查表[10](short form 36 health survey questionnaire,SF - 36)评分。

2.4　数据统计方法　采用 SPSS17.0 统计软件对所得数据进行统计学分析,2 组患者性别、病变部位的组间比较采用确切概率法,年龄、手术时间、失血量、膝关节活动范围、股胫角、HSS 膝关节评分、SF - 36 评分的组间比较采用 t 检验,检验水准 $\alpha = 0.05$。

(1)膝关节假体模型　(2)胫骨近端截骨导板　(3)股骨远端截骨导板

图 1　3D 打印模型实物图

3 结 果

3D 打印技术辅助 TKA 组患者的手术时间短于单纯 TKA 组,失血量小于单纯 TKA 组(表2)。术前2组患者膝关节活动范围比较,差异无统计学意义;术后 2 周,2 组患者膝关节活动范围均大于术前;2 组患者膝关节活动范围比较,差异无统计学意义(表 3)。术前 2 组患者股胫角比较,差异无统计学意义;术后 2 周,2 组患者股胫角均小于术前,3D 打印技术辅助 TKA 组股胫角小于单纯 TKA 组(表 4)。术前 2 组患者 HSS 膝关节评分比较,差异无统计学意义;术后 2 周,2 组患者 HSS 膝关节评分均高于术前;2 组患者 HSS 膝关节评分比较,差异无统计学意义(表 5)。术前 2 组患者 SF - 36 评分比较,差异无统计学意义;术后 2 周,2 组患者 SF - 36 评分均高于术前;2 组患者 SF - 36 评分比较,差异无统计学意义(表 6)。典型病例图片见图 2。

表 2 2 组骨关节炎膝外翻畸形患者手术时间和失血量比较

组别	样本量(例)	手术时间($\bar{x} \pm s$,min)	失血量($\bar{x} \pm s$,mL)
3D 打印技术辅助 TKA 组	16	64.69 ± 8.46	448.13 ± 48.20
单纯 TKA 组	16	72.31 ± 5.44	495.00 ± 49.13
t 值		3.033	2.724
P 值		0.005	0.011

TKA:全膝关节置换术

表 3 2 组骨关节炎膝外翻畸形患者手术前后膝关节活动范围比较 $\bar{x} \pm s$,°

组别	样本量(例)	术前	术后 2 周	t 值	P 值
3D 打印技术辅助 TKA 组	16	71.06 ± 5.54	116.63 ± 7.81	19.024	0.000
单纯 TKA 组	16	72.63 ± 5.46	112.94 ± 8.38	16.121	0.000
t 值		0.803	1.288		
P 值		0.428	0.208		

TKA:全膝关节置换术

表 4 2 组骨关节炎膝外翻畸形患者手术前后股胫角比较 $\bar{x} \pm s$,°

组别	样本量(例)	术前	术后 2 周	t 值	P 值
3D 打印技术辅助 TKA 组	16	17.75 ± 6.02	4.19 ± 1.11	8.867	0.000
单纯 TKA 组	16	18.94 ± 6.71	5.38 ± 0.89	8.018	0.000
t 值		0.527	3.348		
P 值		0.602	0.002		

TKA:全膝关节置换术

表 5 2 组骨关节炎膝外翻畸形患者手术前后 HSS 膝关节评分比较 $\bar{x} \pm s$,分

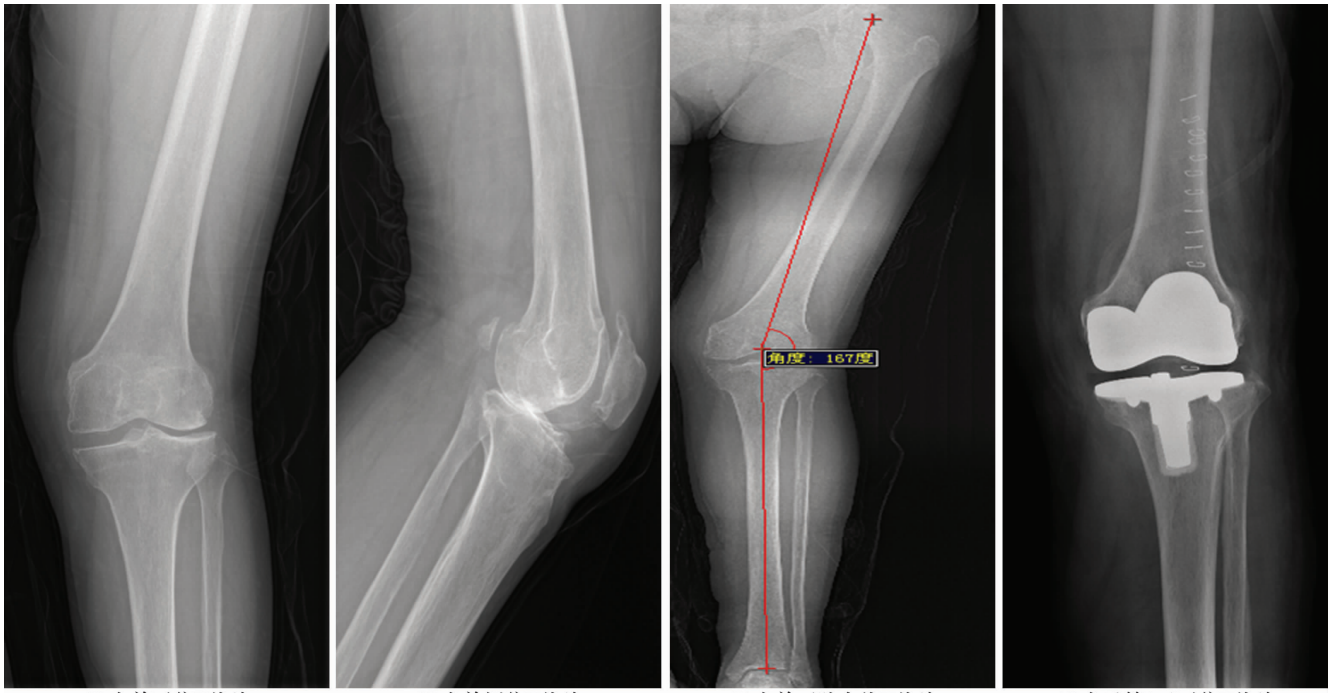
组别	样本量(例)	术前	术后 2 周	t 值	P 值
3D 打印技术辅助 TKA 组	16	50.75 ± 6.26	81.19 ± 4.72	15.534	0.000
单纯 TKA 组	16	51.25 ± 5.73	81.69 ± 4.91	16.131	0.000
t 值		0.236	0.294		
P 值		0.815	0.771		

TKA:全膝关节置换术;HSS:美国特种外科医院

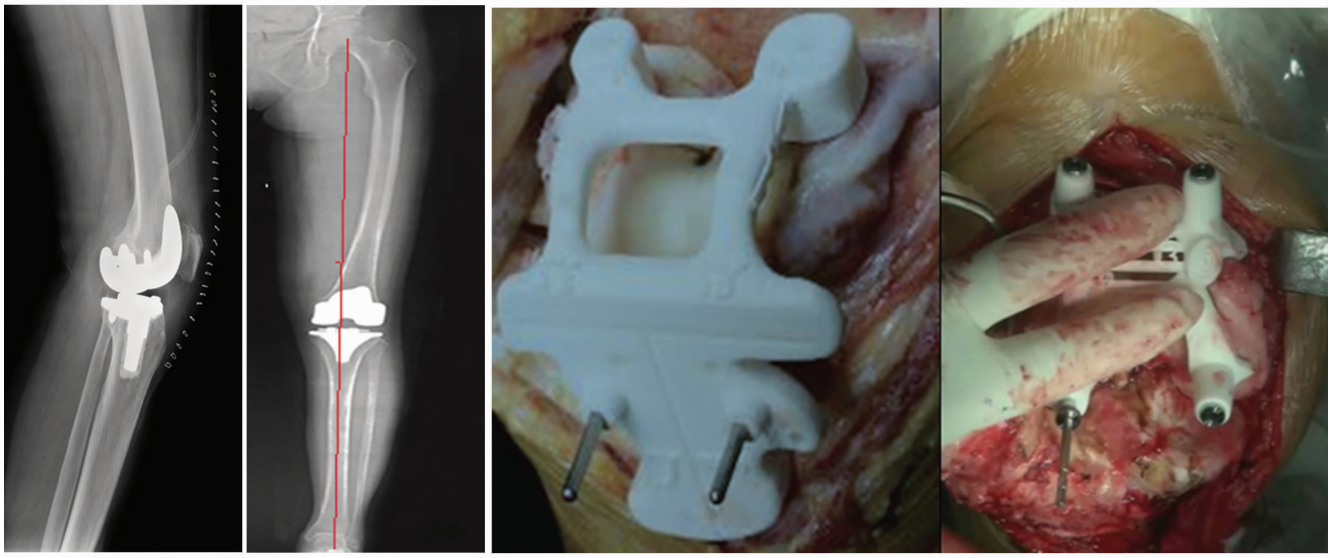
表 6 2 组骨关节炎膝外翻畸形患者手术前后 SF - 36 评分比较 $\bar{x} \pm s$,分

组别	样本量(例)	术前	术后 2 周	t 值	P 值
3D 打印技术辅助 TKA 组	16	53.75 ± 5.32	80.00 ± 3.74	16.138	0.000
单纯 TKA 组	16	52.88 ± 5.25	78.50 ± 4.40	14.964	0.000
t 值		0.468	1.039		
P 值		0.643	0.307		

TKA:全膝关节置换术;SF - 36:简明健康状况调查表



(1)术前正位X线片　(2)术前侧位X线片　(3)术前下肢力线X线片　(4)术后第1天正位X线片



(5)术后第1天侧位X线片　(6)术后2周下肢力线X线片　(7)术中截骨图片

图 2　骨关节炎膝外翻畸形手术前后图片

患者,女,67 岁,左膝骨关节炎膝外翻畸形,采用 3D 打印技术辅助全膝关节置换术治疗后膝关节外翻畸形得到矫正,下肢力线恢复

4　讨　论

骨关节炎膝外翻畸形患者的下肢正常生理力线会发生改变,长期发展会导致膝关节外侧关节囊、韧带挛缩和内侧副韧带松弛,甚至会出现股骨外侧髁骨缺损、胫骨平台塌陷及髌骨半脱位等。精确的截骨及软组织松解是重建外翻膝关节下肢力线的关键。膝关节力线对位决定膝关节载荷分布情况和股胫关节稳定性,是决定 TKA 远期疗效的重要因素[11-13]。临床上治疗此类疾病常采用 TKA 治疗,但该术存在一定的弊端,如手术创伤大、手术时间长、髓内定位失血量多等。近年来随着 3D 打印研发技术的不断突破,该技术也越来越多地被应用到 TKA 术中。

但目前国内外学者对于膝外翻畸形 TKA 术中截骨角度及软组织平衡顺序尚存分歧[14-19]。在本研究中,我们所用的截骨方法是根据膝外翻畸形的程度而定,对于外翻畸形角度大于 20°者采取 7°截骨,对于外翻畸形小于 20°者采取 6°截骨;而在膝关节内外侧软组织平衡方面,则采取多点状松解,并非直接切断,最大限度减少膝关节失稳的发生。

与传统 TKA 相比较,采用 3D 打印技术辅助 TKA 治疗骨关节炎膝外翻畸形具有以下优点:①截骨精确,能更有效恢复下肢正常生理力线和膝关节内外侧软组织平衡,提高假体生存率和恢复膝关节正常功能[20-23];②个体化治疗方案可以有效缩短手术时间、降低失血量,手术安全性更高[24];③三维实体模型可直观展示手术部位的解剖结构,在截骨导板的辅助下可以精确截骨,提高手术精确度,减少工具使用次数,实现真正的精确截骨[25-29];④髓外定位较髓内定位,手术损伤更小,更符合微创及快速康复的理念,有助于提高患者满意度[30]。

采用 3D 打印技术辅助 TKA 治疗骨关节炎膝外翻畸形需注意以下事项:①应充分了解膝关节周围解剖组织结构及其作用;②熟练掌握传统 TKA 的操作步骤和技术要点,因 3D 打印技术辅助 TKA 是对传统 TKA 的升级;③充分理解微创及快速康复理念,对于不同的患者能制定个体化治疗方案。

本研究结果显示,采用 3D 打印技术辅助 TKA 治疗骨关节炎膝外翻畸形,能改善膝关节活动范围,恢复下肢力线,促进膝关节功能恢复,提高患者生活质量;且 3D 打印技术辅助 TKA 比单纯 TKA 手术时间短、失血量少、下肢力线恢复好,值得临床推广应用。本研究纳入的病例数较少、随访时间较短,尚需进一步开展大样本、多中心的随机对照研究。

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