·临床研究·

3D 打印导板在发育性髋关节发育不良全髋关节置换术中的应用

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【摘要】 **目的**:探讨 3D 打印导板在发育性髋关节发育不良全髋关节置换中的应用价值。**方法**:回顾分析 2016 年 2 月至 2018 年 5 月行全髋关节置换术的发育性髋关节发育不良患者 25 例,男 4 例,女 21 例;年龄 40~75 岁;CroweⅡ型 5 例,Crowe Ⅲ型 14 例,Crowe Ⅳ型 6 例。应用 3D 打印术中导板组 12 例,传统全髋关节置换术 13 例,两组均为同一手术组医师完成。比较两组手术时间、术中出血、术后引流及术后 6 个月 Harris 评分,患侧和健侧髋臼外展角、前倾角,旋转中心至坐骨结节连线垂直距离。**结果**:25 例获得随访,随访时间 12~26 个月,3D 打印导板组相对传统手术组手术时间短、术中术后出血量少、术后 6 个月 Harris 评分高($P<0.05$)。3D 打印导板组臼杯位置(旋转中心距坐骨结节连线距离、前倾角、外展角)与健侧髋臼相比差异无统计学意义($P>0.05$);传统手术组患侧旋转中心距坐骨结节连线距离、前倾角与健侧相比差异有统计学意义($P<0.05$),外展角差异无统计学意义($P=0.487$),两组均无术后感染和假体松动。**结论**:3D 打印术中导板技术对于发育性髋关节发育不良全髋关节置换术是一种个体化、精准化,有应用前景的技术。

【关键词】 髋脱位,发育性; 关节成形术,置换,髋; 外科手术,计算机辅助; 打印,三维
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Application of 3D printing guide plate in total hip arthroplasty for developmental dysplasia of the hip *YAN Liang, WANG Peng, and ZHOU Hai-bin*. *Department of Orthopaedics, the Second Affiliated Hospital of Suzhou University, Suzhou 215000, Jiangsu, China*

ABSTRACT **Objective**: To explore the value of 3D-printed navigation template using in total hip arthroplasty (THA) for developmental dysplasia of the hip (DDH). **Methods**: Twenty-five patients with DDH underwent total hip arthroplasty from February 2016 to May 2018 were analyzed retrospectively, including 4 males and 21 females, aged from 40 to 75 years old. Among them, 5 cases were Crowe type Ⅱ, 14 cases were Crowe type Ⅲ and 6 cases were Crowe type Ⅳ. Twelve cases of them underwent THA with the 3D printing navigation plate, another 13 cases underwent the same operation but without the aid of navigation templates. All patients were treated by the same operators. The operating time, intra- and post-operative hemorrhage and Harris Hip Score (HHS) at six months postoperatively were compared, anteversion angle, abduction angle and the distance from rotation center to the ischial tuberosity connection between ipsilateral and contralateral sides were also compared. **Results**: All of the patients were followed up for 12 to 26 months. The operation time, intra- and post-operative hemorrhage and Harris score in the 3D printing group were better than those in the conventional hip replacement group ($P<0.05$). There were no significant differences in anteversion angle, abduction angle and the distance from rotation center to the ischial tuberosity connection between ipsilateral and contralateral sides in 3D printing group ($P>0.05$). The abduction angle and the distance from rotation center to the ischial tuberosity connection were significantly different between the two sides in the traditional group ($P<0.05$), the abduction angles had no statistical difference ($P=0.487$) between two sides. **Conclusion**: The 3D-printed operation navigation template technique is an individualized, accurate and promising technique for THA with DDH.

KEYWORDS Hip dislocation, developmental; Arthroplasty, replacement, hip; Surgery, computer-assisted; Printing, three-dimensional

成人发育性髋关节发育不良(developmental dysplasia of the hip,DDH)是继发性髋关节炎最常见的病因[1],其基本病理改变是股骨头髋臼覆盖的减少,结果导致股骨头的不稳定及前外侧移位,使关节负重状态发生改变,大部分患者最终需行全髋关节置换术(total hip arthroplasty,THA)。THA 是当前医学中最成功外科干预手段之一,提供了髋关节可靠

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的疼痛缓解和功能改进[2]。DDH 患者的全髋关节置换术将面临髋臼重建，髋关节周围软组织平衡、股骨髓腔处理三大难点，就髋臼侧而言，表现为髋臼对股骨头覆盖不足，髋臼浅而小，大部分伴有前外侧壁缺损，特别是 Crowe Ⅲ、Ⅳ型患者，术中寻找真臼也是手术难点之一，如髋臼假体安放不当，假体因缺少支撑容易松动[3]。传统全髋关节置换术未充分考虑个体差异化，常导致置入假体产生偏差[4-5]，位置角度的精确安放和大小选择主要依赖于术者的经验，术前详细计划、术中技术缺一不可，任何失误都会影响手术效果，按照精准医疗的要求，需要一种精确而简单的手术方法。快速成型技术是一种新兴的工业技术，其与医学领域的逆向工程技术的联合应用使精确、个性化治疗成为可能。这对于解剖形态各异的 DDH 尤为适合，术前参数测量、手术计划，联合应用 3D 打印术中导航模板，可以有效减少因经验欠缺和手术技术欠佳而引起的失误。目前术中导航模板在精确螺钉植入、胫骨高位截骨、膝关节置换截骨中已应用[6-8]而应用术中导板辅助 DDH 全髋关节置换髋臼侧手术的技术未见相关报道，本研究的目的是利用数字三维重建和逆向建模技术联合 3D 打印生产髋臼侧导航模板，此导板用于术中寻找真臼、确定臼杯安放位置、角度和大小。

1 资料与方法

1.1 病例选择

纳入标准：行全髋关节置换术的单侧 DDH 患者。排除标准：因术后需与健侧髋臼比较臼杯位置，排除双侧 DDH 或健侧髋关节有骨性结构异常者；术前检查凝血功能不佳，长期口服阿司匹林，氯吡格雷等抗血小板的药物。

1.2 一般资料

回顾分析 2016 年 2 月至 2018 年 5 月收治的行全髋关节置换术的 DDH 患者 25 例，年龄 40~75 岁；Crowe Ⅱ型 5 例，Crowe Ⅲ型 14 例，Crowe Ⅳ6 例。应用 3D 打印术中导板 12 例，传统全髋关节置换术 13 例，两组均为同一手术组医师完成，两组患者术前一般资料差异无统计学意义（表 1）。

1.3 3D 打印过程

应用 CT 扫描患者骨盆获得 DICOM 数据，将数据导入 Mimics 15.0 软件（Materialize，Leuven，Belgium）进行三维重建（图 1）。以对侧髋臼中心为参考，在患侧寻找真臼位置，确定位置后以对侧髋臼外展角及前倾角为标准设置臼杯角度，以模拟臼杯不突破患侧真臼处前后壁为最终臼杯大小，制作一圆环与臼杯口在同一平面，且比臼杯口直径大 2 mm，以此圆环代表臼杯位置和大小，模拟臼杯安放后如上壁骨缺损超过 25%，术中植骨，以假臼不规则骨面为骨性参考点，应用逆向成型技术制作与骨面匹配基座，基座延伸与圆环相连形成导板，基座与圆环为卡槽式可拆卸设计，基座预留 3~4 枚直径 1.5 mm 圆孔，作为术中克氏针定位孔（图 1），模拟导板制作完成生成 STL 格式导入 3D 打印机，应用逐层打印方式生成导板和实体大小骨盆、髋臼模型，打印材料为聚乳酸。

1.4 手术方法

术前在骨盆模板模拟操作，熟悉术中操作（图 2），手术以髋关节前外侧入路，显露髋关节，清理假臼周围软组织，显露骨性结构，将导板中基座与假臼完全匹配后，钻入 3 枚克氏针固定，安装圆环导板于基座卡槽中，克氏针固定，圆环指向处即为真臼，将髋臼磨钻放入圆环中，磨钻平面与圆环平行且处于圆环中心，磨臼至髋臼直径小于圆环 2 mm，即可安装金属臼杯，臼杯方向与圆环一致（图 3），髋臼侧处理完毕，常规手术处理股骨侧，直至完成 THA（图 4）。

1.5 观察项目与方法

观察记录患者手术时间、术中出血、术后引流。术后 1 周行双侧髋关节 CT，应用 Mimics 15.0 软件重建后测量患侧和健侧髋臼外展角、前倾角、旋转中心至坐骨结节连线垂直距离。术后 6 个月采用 Harris[9]评分从疼痛、功能、畸形、运动范围 4 个方面评价髋关节功能。

1.6 统计学处理

采用 SPSS17.0 统计软件进行分析。定量资料以均数±标准差（$\bar{x}\pm s$）表示，组间比较采用独立样本 t

表 1 两组发育性髋关节发育不良患者术前一般资料比较

Tab.1 Comparison of general data of two groups of patients with developmental dysplasia of the hip

组别	例数	年龄（$\bar{x}\pm s$，岁）	性别（例）		患侧（例）		Crowe 分型（例）			
			男	女	左侧	右侧	Ⅰ型	Ⅱ型	Ⅲ型	Ⅳ型
3D 打印导板组	12	59.8±11.1	2	10	8	4	0	2	6	4
传统手术组	13	65.5±10.8	2	11	10	3	0	2	8	3
检验值		t=1.886	χ^2=0.008		χ^2=0.326		χ^2=0.389			
P 值		0.246	0.93		0.568		0.823			

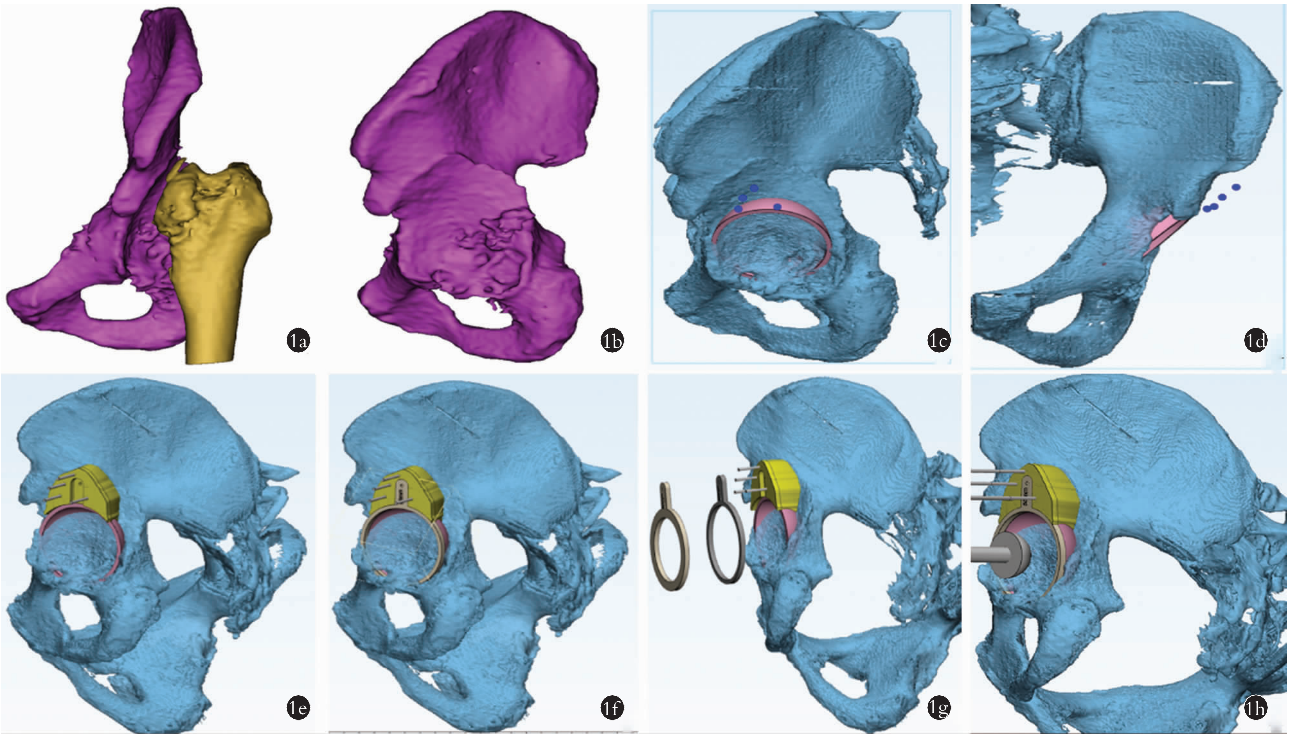

图 1 术前设计及模拟导板制作 **1a,1b.** DICOM 数据导入 Mimics 软件进行三维重建、去除股骨侧 **1c,1d.** 寻找真臼,设计臼杯大小及角度 **1e.** 以假臼骨面为基准点设计基座 **1f.** 以臼杯大小及方向设计圆环,圆环与基座可拆卸卡槽连接,利于安放导板 **1g.** 如骨赘过多影响圆环安放,可设计多个同心圆环,以利于逐步去除骨赘 **1h.** 模拟髋臼锉在圆环中心,髋臼锉平面与圆环平面平行

Fig.1 Preoperative design and template preparation **1a,1b.** DICOM data were imported into Mimics software for 3D reconstruction, the femur was removed **1c,1d.** The true acetabulum was identified according to the contralateral side, the cup`s size and angle was also designed **1e.** The base was designed with reverse modeling which matched with the false acetabulum **1f.** The ring was designed to fall on the same level of the cup, the base and the ring were detachable with a card slot **1g.** The concentric rings growing in size could be designed, if the osteophytes were too much to put the final ring **1h.** The grinding plane was parallel to and at the center of the ring

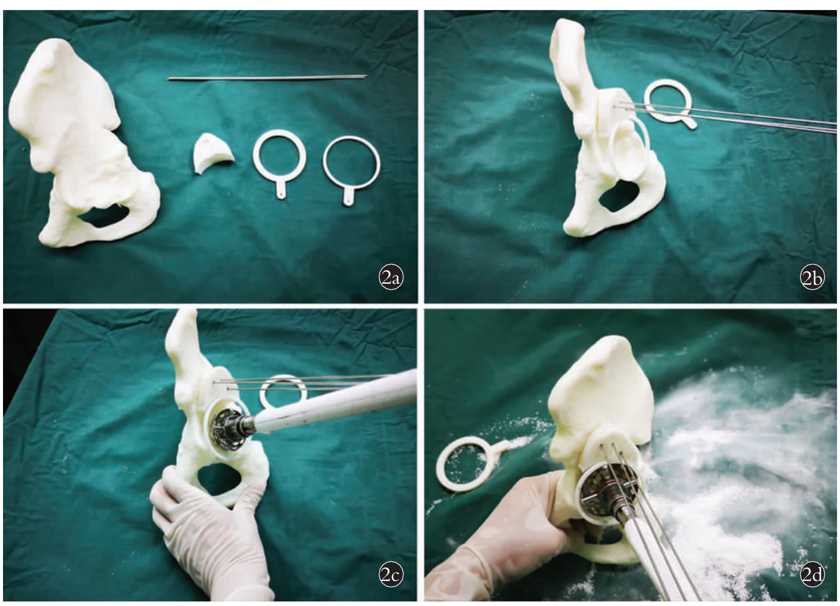

图 2 模拟手术 **2a.** 3D 打印导板组件 **2b.** 安装导板,克氏针通过预留钉道固定基座及圆环 **2c,2d.** 圆环内逐步磨臼,磨钻平面与圆环平行且处于圆环中心

Fig.2 Simulating operation **2a.** 3D printing guide plate components **2b.** The plate was installed, the Kirschner wire fixed the base and ring through the reserved nail path **2c,2d.** The acetabulum was grinded step by step, the grinding plane was parallel to and in the center of the ring

检验,组内手术前后比较采用配对 t 检验;分类变量资料组间构成比比较采用 χ^2 检验; 检验水准 α=0.05。

2 结果

25 例患者获随访, 时间 12~26 个月。3D 打印导板组手术时间、术中、术后出血少于传统手术组(P<0.05),见表 2,两组术后无感染和松动。两组内 DDH 患者术后双侧关节角度比较见表 3(此数据表达各组内术前术后假体安放精确度对比,通过对比说明 3D 打印组假体安放精度较高,故行组内术前术后对比有实际意义,两组间对比无实际意义),3D 打印组中,患侧和健侧髋臼角度(外展角、前倾角)、患侧和健侧位置(旋转中心距坐骨结节连线距离)比较,差异均无统计学意义(P>0.05)。传统手

术组中，患侧前倾角大于健侧（t=-2.844，P=0.015）；患侧旋转中心位置大于健侧（t=3.423 P=0.002）；患侧与健侧外展角差异无统计学意义（t=2.888，P=0.487）。两组术后 6 个月 Harris 评分见表 4，3D 打印组明显高于传统手术组（P=0.009）。

3 讨论

DDH 患者复杂的骨盆及髋臼形态，使术前评估及手术计划难度加大，利用 3D 打印技术，打印实体大小骨盆模型，可使术者充分认识解剖异常，制定更完备手术计划，Hurson 等[10]描述应用 3D 模型评估 20 例患者髋臼，其中 2 例在研究等比例模型后改变了原手术计划，随着数字医疗和 3D 打印技术的发展，骨科医疗正朝着个体化、精准化、微创化方向发展[11]。应用逆向建模和 RP 技术制作 3D 打印术中导板在国内外已广泛应用[12-14]，而应用环形导板术中辅助 DDH 全髋关节置换术未见相关报道。

本研究组此前基于 CT 扫描三维重建测量了 DDH 髋部解剖形态的异常[15]，发现 DDH 髋部解剖数据个体化差异较大，DDH 真臼形态各异，术中难以寻找，在此研究基础上，本研究组设计了基于假臼为基准点，定位真臼的导板，导板基座依靠 3 枚克氏针定位，基座与圆环以可拆卸卡槽连结，降低了导板置入难度，如真臼处骨赘较多，可设计由小到大同心圆环，随着磨锉去除骨赘，逐步更换大圆环，最终达到设定臼杯大小，操作方便，减少术中软组织剥离和手术时间，因此术中、术后出血较少。术后 CT 测量数据表明，导板组患侧臼杯位置、大小、角度和对侧髋臼角度基本一致，而传统手术组臼杯角度和对侧有显著差异，说明导板组置入臼杯准确性更高，一项关于膝关节置换应用 3D 打印术中导板的研究，

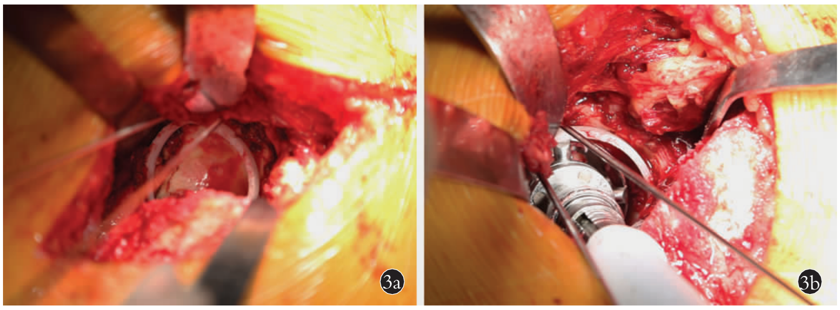

图 3 术中操作 **3a.** 圆环指向即为真臼 **3b.** 逐步磨臼

Fig.3 Operation **3a.** The ring was pointed to the true acetabulum **3b.** The acetabulum was grinded step by step

图 4 患者，女，60 岁，右侧 Crowe Ⅱ型发育性髋关节发育不良 **4a.** 术前正位 X 线片 **4b.** 术后正位 X 线片示臼杯置入真臼中 **4c.** 术后 1 年正位 X 线片示假体位置良好

Fig.4 A 66-year-old female patient with right Crowe Ⅱ developmental dysplasia of the hip **4a.** Pre-operative AP X-ray **4b.** Postoperative AP X-ray showed the acetabulum reconstructed in the true acetabular **4c.** AP X-ray at 1 year postoperative showed the prosthesis was in place

表 2 两组发育性髋关节发育不良患者术后观察指标比较（$\bar{x}\pm s$）

Tab.2 Comparison of postoperative observation indexes between two groups of patients with developmental dysplasia of the hip（$\bar{x}\pm s$）

组别	例数	手术时间（min）	术中出血量（ml）	术后引流量（ml）
3D 打印导板组	12	57.8±3.73	169.0±34.1	130.0±27.2
传统手术组	13	62.1±4.19	219.0±38.0	219.0±37.4
t 值		2.612	-3.477	-6.767
P 值		0.008	0.002	0.000

表 3 两组发育性髋关节发育不良患者术后双侧关节角度比较（$\bar{x}\pm s$）

Tab.3 Comparison of bilateral joint angles between two groups of patients with developmental dysplasia of the hip（$\bar{x}\pm s$）

组别	例数	髋臼外展角（°）				髋臼前倾角（°）				旋转中心距坐骨结节连线距离（mm）			
		患侧	健侧	t 值	P 值	患侧	健侧	t 值	P 值	患侧	健侧	t 值	P 值
3D 打印导板组	12	42.25±4.55	43.60±4.18	0.720	0.487	17.30±5.12	22.70±4.03	-1.315	0.215	80.84±6.21	78.77±4.69	0.919	0.368
传统手术组	13	38.60±3.25	43.30±6.24	2.888	0.487	15.01±5.68	13.01±5.62	-2.844	0.015	82.92±5.73	76.60±2.83	3.423	0.002

表 4　两组发育性髋关节发育不良患者术后 6 个月 Harris 评分结果($\bar{x}\pm s$,分)

Tab.4　Results of Harris score 6 months after operation in two groups of patients with developmental dysplasia of the hip ($\bar{x}\pm s$,score)

组别	例数	疼痛	功能	畸形	运动范围	总分
3D 打印导板组	12	39.00±2.13	40.80±0.83	3.83±0.93	3.75±0.96	93.90±2.87
传统手术组	13	40.00±1.11	40.30±1.25	3.53±1.12	3.53±0.66	91.80±3.69
t 值		−1.372	1.225	0.708	0.644	−2.875
P 值		0.183	0.233	0.486	0.526	0.009

通过尸体标本测量显示个体化截骨具有更高的精确性[16]。此外,术后 Harris 评分显示导板组优于传统手术组,可间接说明,导板组臼杯置入位置和角度更接近患者生理结构,符合人体生物力学。3D 打印导板技术辅助全髋关节置换可加速患者术后康复、提升生活质量。

髋关节置换术后假体松动常见于感染和无菌性松动,因此,比较术后两组数据,感染和松动率在两组均为 0,考虑由以下原因引起:样本数较小,随访时间较短,术后平均随访时间仅 24.6 个月,在接下来研究中,需要加大样本量、增加随访时间,相信导板组由于有更短的手术时间,更精确的假体置入,感染率和无菌性松动概率应该小于传统手术组。与同样具有个体化、精准化性质的导航手术相比,3D 打印导板具有较高性价比,准入门槛低,适合各阶层医院应用。

总之,本研究发现 3D 打印术中导板技术应用于全髋关节置换是一种个体化、精准化,性价比较高,有应用前景的技术。

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