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数字化骨科理念辅助椎弓根置钉在寰枢椎不稳中的临床应用*

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摘要 目的:探讨 3D 打印辅助置钉技术用于寰枢椎不稳椎弓根置钉的安全性及准确性。**方法:**收集 2013 年 1 月到 2015 年 1 月西安交通大学第一附属医院收治的寰枢椎不稳病例,术前采用 3D 打印技术构建个体化 3D 打印模型,在模型上模拟置钉,获取最佳置钉点、置钉角度等个体化置钉数据,并于术中辅助椎弓根螺钉置入。通过 CT 扫描评价置钉准确性,测量术前、术后患者寰齿间隙判断寰枢椎复位情况,测量颈延角评价脊髓压迫改善情况,并采用日本骨科学会(JOA)评分判断患者脊髓功能改善情况。术后定期随访观察固定效果、稳定性、神经损伤等手术并发症的发生情况。**结果:**13 例患者均采用 3D 打印辅助置钉技术进行内固定治疗,手术顺利,术中及术后无血管、神经损伤等并发症,复位及内固定效果满意。共置入椎弓根螺钉 31 枚,其中 29 枚完全在椎弓根内,置钉准确率为 93.5%。寰枢椎较术前明显复位,术后寰齿间隙、颈延角和 JOA 评分较术前明显改善,差异具有统计学意义($P<0.05$)。**结论:**3D 打印技术辅助上颈椎椎弓根置钉的准确性及安全性均较高。

关键词:数字化骨科;3D 打印;寰枢椎不稳;椎弓根螺钉;准确性

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Clinical Application of 3D Printing-assisted Posterior Screw Fixation for Pedicle Screw Fixation in the treatment of Atlantoaxial Instability*

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ABSTRACT Objective: To evaluate the safety and accuracy of 3D printing-assisted posterior screw fixation for pedicle screw fixation in the treatment of atlantoaxial instability. **Methods:** 13 patients diagnosed with atlantoaxial instability from Jan 2013 to Jan 2015 in the First Affiliated Hospital of Xi'an Jiaotong University were analyzed. Before the surgery, 3D printing models were established by 3D printing technology. Screw insertion was simulated on the 3D printing models and personalized data was acquired for assisting actual operations. The accuracy of pedicle screw insertion was assessed by CT scans. The anterior atlas-dens interval was measured to evaluate the reduction of atlantoaxial dislocation. The cervical extension angle was measured to evaluate the improvement of compression on the medulla. The JOA score was used to evaluate the improvement of spinal function. The clinical efficiency, stability of internal fixation, complications were observed after operation. **Results:** All of the 13 patients were treated with 3D printing-assisted posterior pedicle screw fixation. All the surgeries were successful without complications including neural and vascular injury. 31 transpedicular screws were implanted into cervical pedicle and 29 out of 31 were fully located within the vertebral pedicle. The placement accurate rate was 93.5%. Atlantoaxial reduction was recovered. After the operation, anterior atlas-dens interval, cervical extension angle and JOA score were all significantly improved ($P<0.05$). **Conclusions:** 3D printing-assisted screw fixation has high safety and accuracy for pedicle screw fixation in the upper cervical spine.

Key words: Digital orthopaedics; 3D printing; Atlantoaxial instability; Pedicle screw; Accuracy

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前言

寰枢椎位于枕颈移行区,解剖结构特殊,是颈椎活动范围最大最灵活区域,并且承载了颈椎 50% 的旋转功能^[1]。创伤、畸形、炎症、肿瘤等影响均可造成寰枢椎不稳定,并对延髓、椎-基底动脉等周围重要解剖结构造成直接压迫^[2],引发局部脊髓受压,造成肢体感觉、运动障碍,严重者可致呼吸功能障碍,由

此对患者生存质量造成严重威胁^[3]。重建寰枢椎稳定性目的是提供即刻稳定,解除对脊髓及神经压迫,促进融合,目前多采用前路和(或)后路手术治疗。因为后路手术具有感染率低、易于显露,且便于置入内固定物等优点,故临床上以后路手术为主。钢丝技术、椎板夹/椎板钩技术主要作为其他内固定的辅助技术。寰枢侧块螺钉技术与 Magerl 技术生物力学稳定,可以术中复位且不破坏寰枢侧块关节,但需暴露 C1 后弓深部结构,增大

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了寰枢椎间静脉丛及 C2 神经根损伤的风险^[4]。寰椎椎弓根螺钉技术符合三柱固定原理,可以直视下置钉、术中复位、血管神经损伤风险率低,且具有生物力学稳定性佳、脊柱活动影响小等优势,已成为上颈椎手术的首选固定方式^[5]。

颈椎椎弓根螺钉内固定系统是目前最有效的颈椎内固定方法之一,其松动率低、把持力高,具有优越的生物力学性能,显著优于包括侧块螺钉在内的其他内固定系统^[6]。颈椎椎弓根周围解剖结构复杂且变异性大,传统的徒手置钉法易出现偏差,准确性较低,且置钉过程中容易造成脊髓和椎动脉损伤。研究报道颈椎椎弓根螺钉内固定术中神经、血管的损伤或术后螺钉对神经的刺激发生率约达 2%-7%^[7]。椎动脉损伤是该区域手术中及其严重的并发症,轻则引起小脑梗死、重则危及生命,细致的术前影像学指导及评估、谨慎的术中操作可以降低椎动脉损伤的风险^[8]。如何安全、高效地按照椎弓根长轴轴线置入颈椎椎弓根螺钉是目前脊柱外科面临的一个重大难题。

骨科临床研究与数字化技术结合的一门新兴交叉学科称之为数字化骨科,目前已在骨盆骨折等复杂创伤、脊柱畸形、骨缺损等治疗方面广泛应用并取得良好效果^[9]。随着 3D 打印技术的不断发展及其在辅助上颈椎椎弓根置钉中的应用,使得患者个体化置钉成为可能,有效的提高了置钉的准确性、降低了手术并发症。本研究对我院采用 3D 打印模型进行术前评估及模拟上颈椎椎弓根置钉患者的临床资料进行分析,探讨了 3D 打印技术辅助上颈椎椎弓根置钉的疗效。

1 资料与方法

1.1 临床资料

选择 2013 年 1 月-2015 年 1 月我院采用 3D 打印模型辅助椎弓根置钉的 13 例寰枢椎不稳疾病患者,其中男性 9 例,女性 4 例;年龄 25-67 岁,平均 45.3 岁;寰枢椎骨折 4 例,颅底凹陷 7 例,游离齿状突 2 例;所有患者均有肢体麻木、无力等脊髓压迫症状;所有病例均为首次手术,共计置入椎弓根螺钉 31 枚。

纳入标准:①各种原因引起的寰枢关节不稳;②颈部疼痛,伴或者不伴随脊髓神经功能受损;③下颈椎发育良好。排除标准:①伴有心肝肾等重要脏器功能衰竭无法耐受手术;②肿瘤病变破坏骨性结构,椎动脉走行异常导致无法置钉;③研究过程中发生不良事件难以继续及依从性较差者。

1.2 术前主要检查方法

所有患者均接受颈椎 X 线平片、CT 三维重建、MRI 检查及 CT 血管造影检查。寰枢椎不稳常伴骨性结构异常,及入颅段椎动脉的走行异常^[10],手术中容易损伤椎动脉导致出血,甚至致命的后循环障碍。因此,术前了解椎动脉走行、是否存在变异及其同邻近组织结构的关系对术中保护椎动脉非常必要^[11]。虽然评价血管以血管造影为金标准,但是血管造影存在有创、操作复杂的缺点,并且 CT 血管造影在显示血管与周围组织的关系方面比 DSA 占优势,已经成为术前评估,手术入路选择的重要参考^[12]。本课题根据张爱莲等的研究成果^[13],造影剂用量 90-100 mL,注射速度 3.5-4.0 mL/s,扫描延迟时间 18-20 s,得到的图片质量较为理想。

1.3 治疗方法

1.3.1 术前数字化设计与实体模型快速成型

所有病例均行

枕颈部螺旋 CT 平扫,扫描参数:层厚 0.5 mm,电流 150 mA,电压 120 kv。扫描后将原始数据以标准 DICOM 格式导出保存,将 DICOM 格式文件导入 Mimics 15.0 软件进行头颈部病灶区域数字化三维重建。将上述数字化三维重建模型进行数控转换,生成 SLT 格式文件,接着用 MedCAD 切出 0.2 mm 的薄片层,数据传输到 AFS-320 成形机,采用 SLS 工艺(selective laser sintering)对 PSB 粉末烧结成型,制作枕颈部病变区域 1:1 的 3D 打印模型。

1.3.2 3D 打印模型体外模拟置钉 术者在 3D 打印模型上模拟手术操作,确定最佳螺钉直径、长度、进钉角度(钉道外倾角)、进钉点距中线距离。3D 打印模型进行环氧乙烷消毒,带往手术室,便于术中观察涉及的椎体、辅助置钉。同时,术前直观模型简化了与患者的沟通程序,节约时间且效果更好。

1.3.3 手术方法 麻醉后取俯卧位,前额置于头架上,行颅骨牵引(3-5 Kg)。术区常规消毒铺巾。做枕颈部正中切口,分层切开皮肤、皮下和项韧带直至暴露棘突,剥离需固定颈椎后方结构,显露置钉点。与 3D 打印模型仔细对比,确认置钉点及置钉角度、长度。磨钻磨除置钉点皮质,尖锥开口后用探针仔细探测钉道四壁,确定四壁为骨性结构。攻丝后再次用探针探查钉道四壁及底部均为骨性结构,置入椎弓根螺钉,透视见椎弓根钉位置满意。安装预弯的连接棒,待复位固定满意后锁紧钉帽。磨钻进行寰椎后弓及枢椎椎板表面去皮质化处理,取自体髂骨骨屑植骨。解剖证实枢椎椎弓根的下缘和外缘为椎动脉,椎动脉沟内上方骨质是置钉的安全区域^[14],枢椎置钉时可用神经剥离子探及上内缘,遵循“宁内勿外、宁上勿下”^[15]的原则来避免损伤椎动脉。

1.3.4 术后处理 术后质硬颈围制动,轴向翻身。予以低分子肝素预防血栓,根据手术出血量、手术时间及术后引流情况,24-48h 内使用抗生素。术前行存在脊髓损伤情况者给予激素及脱水药物 3-5 天。术后 1-3d(引流量小于 50 mL/d)拔除引流管。术后复查术后 X 线片了解内固定情况,术后 1 月、3 月、6 月及 1 年复查 X 线片,术后 3 月复查颈部 CT 确定植骨融合成功后指导颈部功能训练,术前行伴有脊髓受压者复查颈椎磁共振。

1.4 观察指标及疗效评定标准

术后定期随访观察临床疗效、固定效果及稳定性、神经损伤等手术并发症等情况。为评价置钉准确性,术后通过 CT 扫描观察螺钉的进钉点、螺钉走向及有无螺钉穿破骨皮质情况,并使用 Kawaguchi 等提出的颈椎螺钉分级评估系统进行螺钉位置分级^[16]。0 级:螺钉完全在椎弓根内;1 级:螺钉穿出椎弓根壁不超过 2 mm,且未出现并发症;2 级:螺钉穿出椎弓根壁超过 2 mm,且未出现并发症;3 级:出现神经根、椎动脉损伤等临床并发症。置钉准确率 = 置钉 0 级例数 / 总例数 × 100%。测量术前、术后患者寰齿间隙以判断寰枢椎复位情况,测量颈延角以评价脊髓压迫改善情况,采用日本骨科学会 (Japanese Orthopaedic Association, JOA)评分判断脊髓功能改善情况。颈椎 JOA 量表主要包括上、下肢运动功能、感觉以及膀胱功能 4 个方面,总分 0-17 分,得分越低表示颈椎功能障碍越严重^[17]。采用 Oswestry 功能障碍指数问卷表 (ODI 量表)评价治疗前后脊柱功能恢复情况。ODI 量表主要包括腰腿痛程度、生活自理情况、

提举重物、站立、行走、坐立、睡眠、性生活、社会生活及旅游共 10 个项目^[18]。

1.5 统计学分析

使用 SPSS19.0 软件进行数据分析, 计量资料以均数 $\pm$ 标准差表示, 组间比较采用 t 检验, 以 $P<0.05$ 为差异具有统计学意义。

2 结果

13 例患者均进行了颈部 CT 三维重建并通过 3D 打印技术制备了颈椎 3D 模型。术中所见实体结构与 3D 模型结构一致, 均按术前模拟规划完成, 共置入螺钉 31 枚, 手术顺利, 术中 C 臂透视 2 次定位, 置钉顺利。术中及术后无血管、神经损伤等并发症, 复位及内固定满意。术后随访 9-24 月, 平均 14.3 月, 无内固定松动及断裂等情况。术后 CT 平扫结果显示 31 枚螺钉中 29 枚完全在椎弓根内, 2 枚穿破椎弓根外壁, 穿出距离均小

于 1 mm, 置钉准确率为 93.5%, 无一例出现螺钉置入相关的血管、神经损伤等并发症。术后影像学检查结果提示寰枢椎较术前明显复位, 寰齿间隙由术前 (8.21 ± 0.75)mm 改善为术后的 (2.34 ± 0.54)mm ($P<0.05$), 颈延角由术前 (116.92 ± 7.76)° 改善为术后 (156.62 ± 6.9)° ($P<0.05$)。术后患者肢体麻木、肌肉无力等症状均较术前有明显改善, JOA 评分由术前的 (9.07 ± 0.63) 分恢复至术后 6 月 (11.89 ± 0.81) 分, 术后 12 月 (14.05 ± 0.85) ($P<0.05$)。ODI 指数由术前 (38.29 ± 3.35), 恢复到术后 6 月 (20.9 ± 2.23), 术后 12 月 (17.5 ± 2.06)。典型病例见图 1, 患者 66 岁女性, 颈部疼痛伴活动受限、行走不稳 2 年, 加重半月。术前 CT 提示: 寰枢关节脱位, 齿状突游离, 寰枢椎不稳, 枢椎后移, 颈髓受压变形。

3 讨论

数字化人体是 20 世纪新兴的信息技术, 将计算机图像与

表 1 术后寰齿间隙及颈延角的改善情况

Table 1 Improvement of anterior atlas-dens interval and cervical extension angle after operation

Time	N	Anterior atlas-dens interval(mm)	Cervical extension angle(°)
Postoperation	13	2.34 ± 0.54	156.62 ± 6.9
Preoperation	13	8.21 ± 0.75	116.92 ± 7.76

表 2 术前及术后的 ODI 评分及 JOA 评分比较

Table 2 Comparison of the ODI and JOA score before and after operation

Group	n	ODI score			JOA score		
		Pre-operation	At 6 months after surgery	At 12 months after surgery	Pre-operation	At 6 months after surgery	At 12 months after surgery
Experience group	13	38.29 ± 3.35	20.9 ± 2.23	17.5 ± 2.06	9.07 ± 0.63	11.89 ± 0.81	14.05 ± 0.85

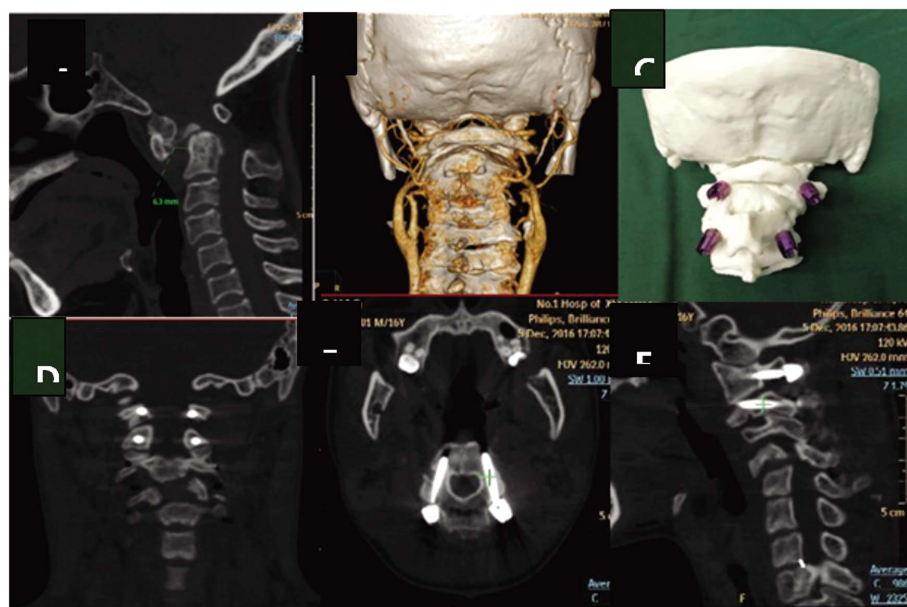


图 1 A. 术前颈椎的矢状位 CT 扫描; B. 术前椎动脉 64 层螺旋 CT 血管成像; C. 术前三维打印模型上确定进入点和角度, 并选择椎弓根螺钉直径和长度; D-F. 术后三维 CT 冠状位、横切位和矢状位显示椎弓根螺钉位置良好。

Fig.1 A. Preoperative sagittal CT scan of cervical spine; B. Preoperative CTA 3D reconstruction; C. The entry point and angle were determined on the 3D printing model before operation, and the diameter and length of pedicle screw were confirmed; D-F. Postoperative three-dimensional CT coronal, transverse and sagittal positions indicate good pedicle screw position.

临床解剖学相结合,建立数字化人体三维模型,实现人体的数字化描述,为医学研究与实际应用提供技术支持。上颈椎的发育和解剖具有其特殊性,枕寰枢毗邻多种重要血管、神经,为内固定手术高风险区域。寰枢椎脱位时,正常的解剖结构丧失、较多旋转重叠,常规影像学检查难以全面且清晰地观察病变具体情况。近年来,越来越多的学者提出应该遵循个体化椎弓根置钉原则^[6],利用数字化和快速成型技术治疗寰枢椎疾患取得良好效果,并进行了相关报道。李浩等采用个体化 3D 打印模型辅助后路内固定治疗儿童颈椎畸形,提高了置钉成功率,有效保护椎动脉及神经根,提高安全性^[9]。章凯等用 3D 打印技术辅助置钉治疗复杂性寰枢椎脱位,结果显示 3D 打印辅助个体化技术可提高寰枢椎脱位手术效率与精确度^[20]。尹一恒等用 3D 打印技术辅助置钉治疗颅底凹陷合并寰枢椎脱位,结果提示 3D 打印模型可全面评估骨性结构异常和椎动脉走向,有助于制定手术策略、设计置钉点和置钉角度,避免椎动脉和脊髓损伤,值得推广^[21]。吕柏康对 3D 打印技术在颈椎椎弓根螺钉内固定中的应用进行综述,认为其具有微创化、个体化及精确化的优势^[22]。吴超研究团队设计并探讨了逐级扩大 3D 打印导板在寰枢椎骨折脱位治疗中的应用,发现此项技术更精确的匹配了术前设计^[23]。

本课题进行了数字化骨科复杂寰枢椎脱位患者诊治中应用的初步探讨,发现其优势如下:① 模拟术中操作在模型上寻找最佳的置钉角度和方向,降低损伤重要血管神经的几率,也可以为变异的寰枢椎解剖结构设计一个导航模板,提高置钉的精确性,减少手术操作时间;② 辅助手术规划,与 CTA 技术结合打印椎椎动脉,为复杂解剖变异的颅颈交界区畸形提供强有力保障;③ 能够和患者家属进行更好地交流沟通,深入浅出进行直观讲解,减少医患之间的信息不对等产生的分歧和失误,容易获得患者的理解并且明显减少交流沟通的时间;④ 还可应用于医生间的经验交流和临床教学^[24],作为年轻医生临床规范化培训的平台,缩短学习曲线,提高临床教学成果^[25]。其不足之处在于计算机辅助设计对于小的血管、神经、韧带等软组织不能很好地重建,且由于 3D 打印机设备本身精度差异,不一定 100% 的还原解剖结构,可能会模糊或者变形。因此,为了提高模型精度,扫描的厚度尽量控制在 1 mm 左右,3D 桌面打印机的打印精度最好控制在 0.5 mm 以下,这样获得的数字模型也具有较高的平滑性和精确度^[15]。3D 打印模型以影像学资料为基础,还需要软件设计、打印等复杂过程,急诊创伤无法应用^[26]。此外,数字技术成本目前难以降低,多数无法将其纳入医疗保险目录范围,尚未完全普及应用,缺乏临床大数据进行评价^[27]。

人类寰枢椎弓根结构复杂、解剖变异较多,并且与脊髓、椎动脉相邻,故临床上治疗寰枢椎不稳难度较大^[28]。目前,临床上主要采用经椎弓根螺钉内固定治疗该类疾病,传统操作方式置钉准确率较低,具有较高的椎弓根螺钉穿透率,一定程度上增加了椎动脉与脊髓损伤的风险^[29,30]。本研究通过 3D 打印技术制作颈椎个体化 1:1 的模型,术先在模型上模拟置钉,确定最佳螺钉直径、长度并选择最佳进钉点及进钉角度,模拟置钉后将模型进行消毒,带往手术室,术中将 1:1 模型与实际情况相

互比对,直观定位及时调整^[31]。无一例出现周围血管、神经损伤等并发症,术后寰齿间隙、颈延角、ODI 评分及 JOA 评分较术前明显改善,提示 3D 打印技术辅助上颈椎椎弓根置钉准确性高、安全有效。

综上所述,对于寰枢椎脱位进行切开复位内固定手术治疗,术前 3D 打印辅助置钉有助于制定个体化策略,确定进钉点及角度,提高置钉精确性,减少手术时间及出血量,减少神经及血管损伤风险,有较好的临床应用前景。

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