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3D 打印技术在颈椎后路寰枢椎椎弓根置钉中的对比分析研究 *

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摘要 目的:探讨和比较通过 3D 打印技术制作的标杆型导板在颈椎后路手术寰枢椎椎弓根置钉中的优势和安全性。**方法:**回顾性分析我院我科自 2016.09 至 2018.09 因颈椎病入院并行颈后路手术且行寰枢椎椎弓根置钉的共计 58 例。按照是否使用 3D 打印技术制作的标杆性导板而将其分为实验组及对照组。实验组(28 例)在导板辅助下进行置钉,而对照组(30 例)则采用常规的徒手置钉。比较两组患者的置钉手术时间,透视次数,出血量,置钉的准确性,两组患者的术后及术后半年的疼痛评分(VAS)及日本骨科协会颈椎功能评分(JOA)评分。**结果:**所有患者均随访半年以上。两组患者在出血量指标的比较中未发现统计学差异($P>0.05$)。实验组的透视次数及手术时间均显著少于对照组,其准确度在显著优于对照组($P<0.05$)。两组患者在疼痛评分及功能评分的比较中均未发现显著性差异($P>0.05$)。**结论:**与传统常规手术技术相比,使用 3D 打印技术标杆性导板能有效的降低透视次数和手术时间,提高置钉的准确性,且不增加风险,具有很好的安全性。在临床中可进一步的进行推广。

关键词:导板;椎弓根螺钉;3D 打印

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Clinical Application of a Novel 3D Printed Drill Guide Template in Atlantoaxial Pedicle Screw Placement*

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ABSTRACT Objective: To investigate the reliability of using the template with guide rods for atlantoaxial pedicle screw placement, and to compare the clinical outcomes of atlantoaxial pedicle screw placement by using the novel 3D printed template and by the conventional method. **Methods:** From 2017.09 to 2018.09, 58 patients diagnosed as cervical spondylotic disease were retrospectively analyzed. All the patients were divided into two groups by different surgery types. 28 patients underwent surgery using a novel 3D printed drill guide template (experimental group), while 30 patients underwent surgery by conventional method (control group). The clinical outcomes were evaluated by operation time, intraoperative blood loss, frequency of fluoroscopy in surgery, screw placement accuracy. Japanese Orthopaedic Association (JOA) score of cervical neurological function, and visual analogue scale (VAS) of pain were used for comparisons between the two groups. **Results:** All the patients underwent successful 6 months completed follow-up. The experimental group had similar results in blood loss, pre-and postoperative JOA scores and VAS scores, and improvement rate of JOA score with those in control group($P>0.05$). The intraoperative fluoroscopy frequency and operation time was significantly lower in the experimental group ($P<0.05$), and the screw placement accuracy was significantly higher in the experimental group than those in control group ($P<0.05$). **Conclusions:** Comparing the conventional method, using the novel drill guide template can result in lower intraoperative fluoroscopy frequency and higher screw placement accuracy without increasing the risk, which could be further promoted in clinic.

Key words: Drill guide template; Pedicle screw; 3D printing

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前言

随着社会的发展,特别是工作、生活方式的改变,颈椎病目前已经成为常见的脊柱疾病^[1]。尽管保守治疗目前已经能够产

生良好的治疗效果,但仍有相当一部分患者需要行手术治疗^[2]。颈椎病的手术治疗方式主要分为前路手术和后路手术两大类(还有前后路联合手术),尽管对手术方式的选择目前仍有争议^[3],但不可否认的是颈椎后路手术能够取得较为良好的治疗

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效果。在颈椎后路手术中,钉棒的置入是必不可少的。常见的钉棒置入方式是采用侧块螺钉的置入方法,但对于寰枢椎来讲,由于特有的解剖结构和血管神经分布特点,椎弓根置钉更为安全和有效^[6]。但是,寰枢椎结构复杂,尤其是其后方与延髓直接毗邻,一旦出现置钉失误往往引发灾难性的后果,因此,寰枢椎的椎弓根置钉问题一直是脊柱外科医生所关注的焦点和热点^[5]。

3D 打印技术是目前在临床中广为流行的数字技术^[6],这种方法通过事先获取患者的骨骼基本 CT 信息和资料,导入电子计算机后通过软件进行重建,在电脑上按照患者的实际骨骼情况个性化的设计穿刺的进针点和及进针角度,在后方的椎板及棘突、关节突位置按照上述指标设计出含有进针点及角度的导板。在手术中将软组织剥离干净后把导板放置在椎板之上。便可以起到极大的导向作用^[7]。同时,我们为了防止通道的滑移以及体位的变化,特意将不同的导板进行了改良,在原有基础上增加了标杆和定位孔,手术剥离后首先进行定位孔的确定和固定,然后进行导板的固定。从而极大的提高了置钉的准确性和安全性。现将其临床使用情况报道如下。

1 资料和方法

1.1 研究对象

我们将 2016.09-2018.09 于我科住院,诊断为颈椎病并符合纳入及排除标准的共计 58 例患者纳入本次研究,并行回顾性分析。按照手术方式的不同,将其共分为实验组和对照组。实验组患者采用 3D 打印标杆型导板辅助的办法进行置钉,而对照组则采用传统的徒手置钉的方法对寰枢椎进行置钉。实验组中,男性患者与女性患者分别为 16 例与 12 例,对照组中的其比例则为 19 例与 11 例。实验组中患者的年龄分布为 51.2 ± 17.8 岁,对照组中的年龄分布则为 52.6 ± 15.9 岁。两组的年龄、性别等一般性资料经比较未见到显著统计学差异 ($P > 0.05$),具有可比性。

本次研究的纳入和排除标准如下:纳入标准^[8]:① 经过结合患者的症状、体征及影像学资料,均诊断为颈椎病;② 均接受单一的后路全椎板减压手术,且置钉方式为颈 2- 颈 7。排除标准^[8]:① 术前影像学资料显示椎弓根直径过小不能置钉者;② 颈椎合并有滑脱、骨折、肿瘤及其他疾病者;③ 患者合并严重的骨质疏松等全身系统性疾病者;④ 随访不完善者。

1.2 方法

1.2.1 手术方法 所有纳入本次研究的患者均由同一团队完成手术。患者全身麻醉满意后,采用俯卧位,头部加以固定后进行常规消毒铺单。取正中切口,逐层切口皮肤、皮下组织、浅筋膜、深筋膜并将椎体后方附着肌肉及软组织剥离干净。充分显露椎板、棘突及关节突、侧块。实验组手术前将打印好的标杆性

导板消毒。术中首先找到术前设计的定位点,将导板中的定位点与患者实际定位点想吻合,并进行初步固定。此时标杆通道所在的位置即为进针点和进针方向。使用开口器或者超声骨刀钻破椎板的骨皮质,然后使用手钻进行进一步的深入,探针证实无误后,给予放置定位针。使用 C 型臂进行术中透视,证实无误后将定位针取出放置 3.5 mm 的椎弓根螺钉。对照组则采用传统的徒手进针方式,将手术区域充分暴露后,按照骨性标志点进针,内倾角及头倾角均采用 25° 左右。探针证实无误后放置定位针进行定位透视,C 型臂透视无误后,取出定位针,拧入椎弓根螺钉。所有患者均采用经 2- 颈 7 的钉棒置入方法。颈 2 及颈 7 采用椎弓根钉,颈 3-6 则采用侧块螺钉的置入办法。

1.2.2 3D 打印导板的制作 实验组患者均行颈椎 CT 薄层扫描,将 CT 数据刻盘以后导入电子计算机的 Mimics 软件。通过确定灰度值范围,建立蒙皮,从冠状、横断及矢状位确定具体位置,然后重建颈椎 3D 模型,将颅底及寰椎、颈 3 椎体和相应的部分进行去除,重建出单独的枢椎 3D 模型。在软件中的 Medcad 模块中,建立虚拟进针通道,一般直径设立为 3 mm。进针点一般选择为侧块的内上方,内倾及头倾角设立为 25° 左右。在建立的过程中,同时观察椎动脉是否有高跨现象。然后将设计好的相关数据导入到 3-matic 软件,并进行必要的修饰和增厚。按照之前的数据确定定位点和固定点。完善最终的导板、导杆及通道。最后将所有的数据导入 Preform 软件,通过 3D 打印机进行打印。

1.2.3 评价方法 通过术中记录的手术时间、透视次数、出血量对两组患者进行比较。采用 Lu^[9]的置钉准确度来对置钉的准确程度进行评价(共分为 0 级 -3 级四个等级,0 级最好,3 级最差。疼痛评价指标则使用公认的 VAS^[10] (Visual Analogue Scale)标准进行评估(10 分越高,代表疼痛最重,0 分最低,表示无任何疼痛)。功能评价则使用 JOA^[11] (Japanese Orthopaedic Association Scores)标准对患者的主观症状、临床症状、日常生活受限程度、膀胱功能等进行相应评估(最高为 29 分,分数越高代表功能越好)。

1.3 统计学分析

使用 SPSS 19.0 根据不同的样本类型采用不同的检验方法,计数资料采用卡方检验,计量资料采用 t 检验,以 $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 手术时间、出血量及透视次数的比较

本次研究显示,实验组患者在出血量的指标中与对照组并无统计学差异($P > 0.05$)。而在手术时间及透视次数的比较中,实验组患者显著优于对照组($P < 0.05$)。见表 1。

表 1 两组患者手术中各指标的比较($\bar{x} \pm s$)

Table 1 The comparison of operation scores between two groups ($\bar{x} \pm s$)

	Observe group	Control group	P
Blood loss(mL)	381.45 $\pm$ 62.24	377.36 $\pm$ 54.88	<0.05
Operation time(min)	164.32 $\pm$ 22.8	184.3 $\pm$ 46.2	>0.05
X ray time	3.41 $\pm$ 0.62	4.86 $\pm$ 0.89	>0.05

2.2 两组患者的疼痛及功能评分评估

实验结果显示。两组患者在手术前的疼痛及功能评分均无

显著性差异。在手术后其评分较前均有显著改善。两组患者间在术后未见显著差异。见表 2。

表 2 两组患者的 VAS 和 JOA 评分比较($\bar{x} \pm s$)Table 2 The VAS and JOA scores before and after the operation between two groups ($\bar{x} \pm s$)

	Observe group	Control group	P
VAS			
Before operation	6.42± 0.84	6.40± 0.81	>0.05
After operation	2.25± 0.27 *	2.27± 0.22 *	>0.05
JOA			
Before operation	11.52± 1.13	11.44± 1.42	>0.05
After operation	14.48± 2.05 *	14.51± 2.16 *	>0.05

Note: * $P<0.05$, compared with before treatment.

2.3 两组患者螺钉准确度的比较

我们将观察组和对照组两组患者的枢椎的螺钉的准确度

进行比较。结果发现,观察组患者的螺钉准确度显著优于对照组。相比具有统计学差异。 $(P<0.05)$,见表 3。

表 3 两组患者的螺钉准确度比较情况($\bar{x} \pm s$)Table 3 The Accuracy scores of screw between two groups ($\bar{x} \pm s$)

Groups	0	1	2	3
Observe group	53	3	0	0
Control group	49	7	3	1

3 讨论

颈椎病是常见的脊柱退行性疾病^[12]。患者多伴有局部的疼痛不适,单侧或者双侧上肢的麻木,下肢的无力及“踩棉花感”等症状。颈椎病常根据其具体症状及影像学特点分为局部型、神经根型、脊髓型和其他型三大类。大部分颈椎病患者经系统正规的治疗后可得到很好的治疗效果,但仍有不少患者需行手术治疗才能彻底获得治愈^[13]。颈椎病的手术治疗可大体分为前路手术、后路手术及前后路手术三大类。尽管目前手术入路的选择仍有较大争议,但后路手术能够取得很好的治疗效果,尤其是对于后方压迫为主患者及多节段突出患者更是如此^[14]。而不论是哪种后路手术,由于稳定性的需要,钉棒的置入都是必须的。

由于颈椎基本的解剖学特点^[15],颈 3- 颈 6 的椎体一般采用侧块螺钉的置入方式。此方法的操作较为直接简单,相对安全并能起到良好的固定效果和力学满足^[16]。一方面是这三个椎体的侧块相对较小且短。置入的螺钉很难起到很好的力学效果。并且寰枢椎周围毗邻静脉丛及神经,一旦出现置钉的失误很容易造成非常恶劣的严重后果。因此,对于寰枢椎及颈 7 椎体,常规选择椎弓根的置入方式。但不可否认的是,寰枢椎解剖情况非常复杂,且直径较小,并且常常由于增生蜕变导致解剖标志很难判断。因此,寰枢椎的椎弓根钉置入一直以来都是脊柱外科技术的难点^[17]。

为了提高寰枢椎椎弓根钉置入的准确性,确保手术的安全顺利进行。国内外众多学者进行了多年的努力^[18,19]。例如计算机导航技术已被证实能有效的提高置钉的准确性,使得其安全性大幅度上升^[20]。但是计算机导航技术有其自身的缺陷与不

足^[21,22]:1.成本过于昂贵,整个设备及配套的软件需要极大的经济投入。2.总体技术掌握难度大,学习曲线长,需要耗费较大精力和时间去掌握。3.该技术要求患者的机体保持绝对静止,一旦出现位置的变化,需再次重新定位。也因此,导航技术很难获得很好的临床运用。

3D 打印技术是另外一种被证明在置钉过程中能够取得良好切实效果的技术^[23]。此项技术利用将术前获得的 CT 数据导入电子计算机,使用专用软件进行患者骨骼结构的重建及手术过程的模拟^[24]。确定最佳的进针点及进针方向后,使用虚拟的通道暂时替代螺钉。以此为依据,建立通道,并建立能够与棘突、椎板紧密相连的导板。最后将所有数据导入 3D 打印机,最终获得带有穿刺通道的 3D 打印导板。在手术时,将附着于椎板及棘突的所有软组织及肌肉清理干净后,将已消毒好的导板进行附着,从而完成置钉过程。此方法已被证实能有效的提高置钉的准确性,降低风险,显著提高准确度^[25]。并且相对于导航技术,此方法耗费经费明显较少,在一般的医院即可开展,且数据处理及软件操作等技术经简单的培训后即可熟练掌握,因此,在临床应用中具有更好的可行性。

但我们在使用通道型导板时发现了一个缺陷,那就是由于体位改变或者软组织剥离不干净,会导致导板中的通道与实际位置发生偏移,从而造成置钉的失败。有学者提出扩大导板的面积来保证其准确度的建议^[26]。但此方法会造成软组织剥离区域的进一步增加,从而加大了出血,延长了手术时间并增加了手术风险。

所以,我们在通道型 3D 打印导板的基础上,总结我们之前的临床经验,设计了标杆型 3D 打印导板^[1]。与常规导板不同在于,我们将导航技术与 3D 打印技术相结合,事先在电子计

算机与患者机体间找到两个标志点。手术时,先在患者机体中找到此标志并进行导板的固定。然后利用通道来进行椎弓根钉的置入。此外,此种通道还能术者多提供 2 个标志点,一旦出现置钉的失败,在进行螺钉的调整时,能够为术者提供更为明显的调整依据,从而有效的减少手术时间与透视次数。本次研究结果也充分证实了此项技术的优势。在我们的实验中我们发现,在手术时间,透视次数,螺钉的准确性等指标中,3D 打印导板技术均显示了显著的优势。且对患者的疼痛及功能不造成负面影响。

当然,3D 打印导板技术并不是万能的,也会出现置钉的失误^[27,28]。其主要原因可大体总结为以下几点^[29,30]:第一,CT 获取的数据存在一定的误差,从而导致构建的骨骼数据与机体的实际情况存在差异。继而导致通道的设计出现异常,最终引放置钉的失败。因此,在 CT 数据获取时,一定要密扫+薄扫。第二,在术区的暴露过程中,很难将软组织和机体完全清除干净,而我们在电子计算机虚拟过程中是完全将软组织去除的,从而导致了放置导板时并不能实现完美的吻合。第三,患者在手术过程中的体位与做 CT 检查时的体位不可能完全一致,从而导致导板的放置失败。第四,尽管我们已对导板进行了固定,但很难保证完全固定的实现,导板与椎体之间的微动依然会导致通道的放置出现偏差。但无论如何,3D 打印导杆型导板能够有效的提高椎弓根钉置入的准确性,显著的降低手术时间及出血量,提高手术安全性,且投入相对较低,有良好的前景和临床可行性。在临床工作中可进一步的进行推广。

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