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在线全文

腰椎后路融合术中皮质骨轨迹螺钉和传统椎弓根螺钉的临床效果比较*

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【摘要】 目的 比较皮质骨轨迹螺钉和传统椎弓根螺钉在腰椎后路融合中的临床效果。**方法** 回顾性分析本院2016年1月–2019年1月经过手术治疗的腰椎退变患者，符合入组条件的患者共123例，按不同术式分组，按照年龄、性别、融合节段数进行匹配，其中传统椎弓根螺钉（traditional pedicle screws, PS）组63例，皮质骨轨迹螺钉（cortical bone trajectory screws, CBTS）组60例。对两组的结局指标进行比较。主要结局指标为围术期情况（包括手术时间、术中估计失血量、住院时间）、视觉模拟量表（visual analog scale, VAS）评分、Oswestry功能障碍指数（Oswestry Disability Index, ODI）评分、椎体间融合率，次要结局指标为术后首次活动时间、并发症发生率。分别在术前和术后1周、1个月、3个月和12个月以及末次随访评估VAS评分和ODI评分。术后1年、2年和末次随访时评估椎体间融合率。**结果** CBTS组与PS组相比较，手术时间〔（142.8±13.1）min vs.（174.7±15.4）min，P<0.001〕、住院时间〔（9.5±1.5）d vs.（12.0±2.0）d，P<0.001〕和术中估计失血量〔（194.2±38.3）mL vs.（377.5±33.1）mL，P<0.001〕均减少。两组间比较，术后1周和术后1个月CBTS组腰痛的VAS评分低于PS组，术后1个月CBTS组的ODI评分低于PS组，差异均有统计学意义（P<0.05）；术后各时点两组下肢痛的VAS评分、椎体间融合率之间的差异无统计学意义。各组内比较，相比于术前，CBTS组、PS组术后各时点的背痛VAS评分、下肢痛VAS评分、ODI评分均降低，差异均有统计学意义（P<0.05）。CBTS组与PS组相比较，术后首次活动时间、总体并发症发生率差异无统计学意义。**结论** 在腰椎后路融合手术中，CBTS技术在椎体间融合率、疼痛缓解、功能改善及并发症发生率等方面取得和PS技术同样效果，且能显著缩短手术时间和住院时间，减少失血量。

【关键词】 皮质骨轨迹螺钉 椎弓根螺钉 后路腰椎融合术 临床效果

Comparison of Clinical Effects of Cortical Bone Trajectory Screws and Traditional Pedicle Screws in Posterior Lumbar Fusion

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【Abstract】 Objective To compare the clinical effects of cortical bone trajectory screws and traditional pedicle screws in posterior lumbar fusion. **Methods** A retrospective study was conducted to analyze lumbar degeneration patients who underwent surgical treatment at our hospital between January 2016 and January 2019. A total of 123 patients who met the inclusion criteria were enrolled. The subjects were divided into two groups according to their surgical procedures and the members of the two groups were matched by age, sex, and the number of fusion segments. There were 63 patients in the traditional pedicle screws (PS) group and 60 in the cortical bone trajectory screws (CBTS) group. The outcomes of the two groups were compared. The primary outcome measures were perioperative conditions, including operation duration, estimated intraoperative blood loss (EBL), and length-of-stay (LOS), visual analog scale (VAS) score, Oswestry Disability Index (ODI) score, and interbody fusion rate. The secondary outcome measures were the time to postoperative ambulation and the incidence of complications. VAS scores and ODI scores were assessed before operation, 1 week, 1 month, 3 months, and 12 months after operation, and at the final follow-up. The interbody fusion rate was assessed in 1 year and 2 years after the operation and at the final follow-up. **Results** The CBTS group showed a reduction in operation duration ([142.8±13.1] min vs. [174.7±15.4] min, P<0.001), LOS ([9.5±1.5] d vs. [12.0±2.0] d, P<0.001), and EBL ([194.2±38.3] mL vs. [377.5±33.1] mL, P<0.001) in comparison with the PS group. The VAS score for back pain in the CBTS group was lower than that in the PS group at 1 week and 1 month after operation and the ODI score in the CBTS group was lower than that in the PS group at 1 month after operation, with the differences being statistically significant (P<0.05). At each postoperative time point, the VAS score for leg pain and the interbody fusion rate did not show significant difference between the two groups. The VAS score for back and leg pain and the ODI score at each time point after operation in both the CBTS group and the PS group were significantly lower than those before operation (P<0.05). No significant difference was found in the time to postoperative ambulation or the overall complication incidence between the two groups. **Conclusion** The CBTS technique could significantly shorten the

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operation duration and LOS, reduce EBL, and achieve the same effect as the PS technique does in terms of intervertebral fusion rate, pain relief, functional improvement, and complication incidence in patients undergoing posterior lumbar fusion.

【Key words】 Cortical trajectory pedicle screw Pedicle screw Posterior lumbar fusion Clinical efficacy

椎弓根螺钉(traditional pedicle screws, PS)广泛用于腰椎管狭窄、腰椎滑脱、脊柱侧弯等疾病的治疗,是当前脊柱内固定的金标准[1-3]。PS的稳定性大部分通过与皮质骨的接触获得,小部分通过与松质骨的接触获得[4]。研究发现,在骨质疏松的椎体中,PS的固定强度明显降低[5-6]。为了解决这一问题,SANTONI等[7]于2009年提出一种新的皮质骨轨迹螺钉(cortical bone trajectory screws, CBTS),该螺钉通过扩大与皮质骨的接触面积而获得更大的固定强度[8-9]。此外,由于CBTS的进钉点更靠近后正中线,减少了术中软组织剥离,降低了出血量[10]。目前,CBTS用于腰椎融合术的相关报道较少,且存在病例数少、随访时间短、研究间结论不一致等情况[11-13]。而脊柱融合手术的中长期效果是评估手术是否成功的关键指标。本研究通过迄今为止随访时间最长的队列研究,旨在比较PS和CBTS在腰椎后路融合中的中期临床效果,为临床应用提供参考。

1 对象与方法

1.1 研究对象

本研究纳入了2016年1月–2019年1月在成都市中西医结合医院确诊并进行手术的123例腰椎退变患者。纳入标准:①使用CBTS或PS进行腰椎后路融合手术;②年龄>40岁;③诊断为腰椎间盘突出、腰椎管狭窄、腰椎滑脱。排除标准:①既往腰椎手术史;②腰椎骨折;③脊柱侧弯畸形;④随访时间小于2年。根据患者术式不同分为CBTS组和PS组,并按照年龄、性别、融合节段数进行匹配,最终纳入123例患者,其中CBTS组60例,PS组63例。本研究获得成都市中西医结合医院伦理委员会的批准,伦理批准号2020年ZXKT第008号。

1.2 手术方法

所有手术均由我院两位具有高级职称的脊柱外科医师完成,两位医师从事腰椎融合手术一线临床工作时间均超过15年。

1.2.1 CBTS组手术方法

全身麻成功后,术区常规消毒铺巾。取后正中长约5 cm切口,暴露椎板至关节突内缘并确定椎间隙。经上关节突中心的垂线与横突下缘下方1 mm水平线的交点为进钉点,1.5 mm磨钻开孔突破表层皮质,用直径2.5 mm、长度2.5 cm的限深电钻以尾倾25°、内倾15°建立钉道,探查内壁完整性,植入4枚CBTS;切除棘突及上位椎体下关节突以及下位椎体部分上关节突、双侧相应椎板至椎弓根内缘、黄韧带,以及摘除突出的椎间盘组织,扩大双侧侧隐窝及神经根管,解除神经根及硬膜囊压迫,冲洗、止血,清除椎间隙内髓核、纤维环及软骨终板。椎体间植骨融合内固定。X线透视确认内固定物位置后,冲洗切口,止血,放置负压引流管,逐层缝合切口。

1.2.2 PS组手术方法

全身麻醉成功后,术区常规消毒铺巾。取后正中长约5 cm的纵向切口,暴露椎板及关节突,以人字嵴顶点为椎弓根进针点并制备钉道,植入螺钉;切除上位椎体棘突、椎板下半,切除增生的黄韧带和骨赘,椎管及神经根管减压;椎体间植骨融合、内固定,透视确定钉棒及融合器位置后;冲洗、止血、放置引流管,逐层缝合切口。

1.3 术后处理

术后24 h应用抗生素预防伤口感染,并根据引流量情况拔除引流管。拔除引流管后指导患者佩戴腰围进行下地活动。

1.4 效果评价和随访

基线比较两组的术前一般资料,包括年龄、性别、诊断、手术节段、骨质疏松患病率及随访时间。

主要结局指标为比较两组的围术期情况(包括手术时间、术中估计失血量、住院时间)、视觉模拟量表(visual analog scale, VAS)评分、Oswestry功能障碍指数(Oswestry Disability Index, ODI)评分、椎体间融合率。次要结局指标为围术期情况(术后首次活动时间)、并发症发生率。

疼痛的评估采用VAS评分系统(0~10分),0分代表完全无痛,10分代表难以忍受的最剧烈的疼痛,分别在术前和术后1周、1个月、3个月和12个月以及末次随访进行评估。

功能的评估采用ODI评分(0%~100%),数值越大,功能越差,分别在手术前和术后1个月、6个月和12个月以及末次随访进行评估。

椎体间融合率的比较采用Bridwell标准判断[14],该标准分为Ⅰ~Ⅳ级,其中Ⅰ~Ⅱ级认为是达到椎间融合,于术后1年、2年和末次随访时进行评估。

1.5　统计方法

定量数据以$\bar{x}\pm s$表示，对定性资料采用频数(构成比或率)进行统计描述。定量资料的组间比较采用两个独立样本t检验或方差分析，对定性资料的组间比较采用卡方、校正卡方或Fisher确切概率法。$P<0.05$为差异有统计学意义。

2　结果

2.1　基线比较

共计123例符合标准的患者纳入本回顾性研究，其中CBTS组60例，PS组63例，两组间年龄、性别、手术节段数目、随访时间、骨质疏松患病率、诊断分布等基线情况的差异均无统计学意义。见表1。

表 1　两组患者基线比较

Table 1　Comparison of the baseline data of the two groups of patients

Index	CBTS group (n=60)	PS group (n=63)	P
Mean age/yr., $\bar{x}\pm s$	60.8±9.8	62.1±6.7	0.391
Sex/case (%)			0.547
Male	28 (46.7)	26 (41.3)	
Female	32 (53.3)	37 (58.7)	
Diagnosis/case (%)			0.970
Stenosis	32 (53.3)	33 (52.4)	
Spondylolisthesis	12 (20.0)	12 (19.0)	
Disc herniation	16 (26.7)	18 (28.6)	
No. of segments/case (%)			0.964
1	54 (90.0)	56 (88.9)	
2	4 (6.7)	5 (7.9)	
3	2 (3.3)	2 (3.2)	
Osteoporosis/case (%)	12 (20.0)	17 (26.9)	0.401
Follow-up/month, $\bar{x}\pm s$	53.7±6.3	52.7±6.7	0.366

CBTS: cortical bone trajectory; PS: pedicle screws.

2.2　围术期指标

见表2。CBTS组的手术时间、术中估计失血量、住院时间均短于PS组，差异有统计学意义($P<0.001$)。CBTS组术后首次活动时间短于PS组，但差异无统计学意义。

表 2　两组围术期情况比较

Table 2　Comparisons of perioperative conditions between the CBTS and the PS groups

Index	CBTS group (n=60)	PS group (n=63)	P
Operative time/min, $\bar{x}\pm s$	142.8±13.1	174.7±15.4	<0.001
EBL/mL, $\bar{x}\pm s$	194.2±38.3	377.5±33.1	<0.001
LOS/d, $\bar{x}\pm s$	9.5±1.5	12.0±2.0	<0.001
POD of ambulation/h, $\bar{x}\pm s$	27.6±6.4	29.3±7.1	0.158

LOS: length-of-stay; EBL: estimated blood loss; POD: postoperative day.

2.3　疼痛评分

见表3。两组间比较，术后1周和1个月，CBTS组腰痛的VAS评分低于PS组，差异均有统计学意义($P=0.048$，$P=0.038$)；术后各时点两组下肢痛的VAS评分之间的差异无统计学意义。组内比较，相比于术前，两组术后各时点的背痛VAS评分和下肢痛VAS评分均降低，差异均有统计学意义($P<0.05$)。

表 3　两组疼痛和功能比较

Table 3　Comparisons of VAS and ODI scores between the CBTS and the PS groups

Index	CBTS group (n=60)	PS group (n=63)	P
VAS score for leg pain			
Preoperative	5.4±1.3	5.8±1.7	0.152
1 week postoperation	3.4±1.2*	3.8±1.4*	0.073
1 month postoperation	2.8±0.9*	3.0±1.0*	0.170
3 months postoperation	2.1±1.0*	2.3±0.9*	0.423
12 months postoperation	1.6±0.9*	1.5±0.8*	0.429
VAS score for back pain			
Preoperative	6.6±1.5	6.4±1.7	0.447
1 week postoperation	3.8±1.4*	4.3±1.6*	0.048
1 month postoperation	2.7±1.2*	3.2±1.3*	0.038
3 months postoperation	2.2±1.0*	2.5±1.2*	0.093
12 months postoperation	1.6±0.9*	1.8±0.8*	0.163
ODI/%			
Preoperative	50.7±6.1	52.6±7.6	0.136
1 month postoperative	36.5±6.3*	38.9±6.5*	0.040
6 months postoperation	28.4±6.1*	30.5±6.3*	0.062
12 months postoperation	22.5±5.5*	23.4±5.2*	0.346
Last follow-up	17.6±4.3*	17.3±4.8*	0.701

VAS: visual analog scale; ODI: Oswestry Disability Index. * $P<0.05$, vs. preoperative findings within the group. The data were presented as $\bar{x}\pm s$.

2.4　ODI评分

见表3。相比于术前，术后各时点两组的ODI评分均降低，且差异均有统计学意义($P<0.05$)。术后1个月，CBTS组的ODI评分低于PS组，差异有统计学意义($P=0.040$)。

2.5　椎体间融合率

CBTS组和PS组的所有病例均进行了单个椎间融合器植入。术后各时点，两组间的椎体间融合率差异无统计学意义。见表4。图1示CBTS组患者影像检查结果，图2

表 4　两组椎体间融合率比较

Table 4　Comparisons of fusion rate between the CBTS and the PS groups

Fusion rate	CBTS group (n=60)	PS group (n=63)	P
One-year follow-up/case (%)	49 (81.7)	53 (84.1)	0.812
Two years follow-up/case (%)	53 (88.3)	58 (92.1)	0.553
Last follow-up/case (%)	56 (93.3)	61 (96.8)	0.592

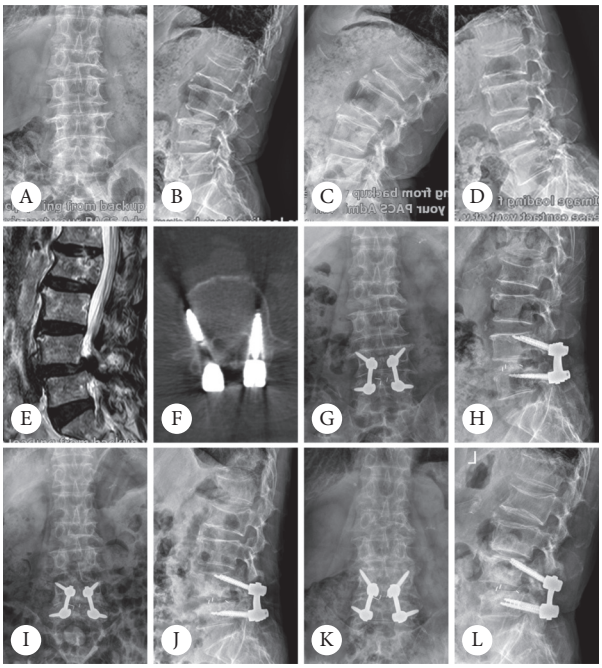

图 1 CBTS组80岁男性患者。术前正侧位（A～B）及过伸过屈位X线（C～D）提示腰4/5层面腰椎滑脱，术前矢状位MRI（E）提示腰椎管狭窄；术后3 d轴位CT（F）提示钉道方向由内向外；术后3个月正侧位X线（G～H）提示内固定在位，钉道由尾侧向头侧；术后24个月正侧位X线（I～J）和术后48 个月正侧位X线（K～L）示内固定位置良好

Fig 1 An 80-year-old male patient in the CBTS group. Preoperative anteroposterior and lateral X-ray images (A and B) and flexion-extension X-ray images (C and D) showed lumbar spondylolisthesis at L4-5. Sagittal images of MRI (E) pre-operation showed lumbar spinal canal stenosis. Transverse images of CT (F) 3 days post-operation showed medio-lateral trajectory of CBTS screws. Anteroposterior and lateral X-rays 3 months post-operation (G and H) showed the internal fixation in good position and a superiorly directed track in the sagittal plane. Anteroposterior and lateral X-rays 24 months (I and J) and 48 months (K and L) post-operation showed internal fixation in good position

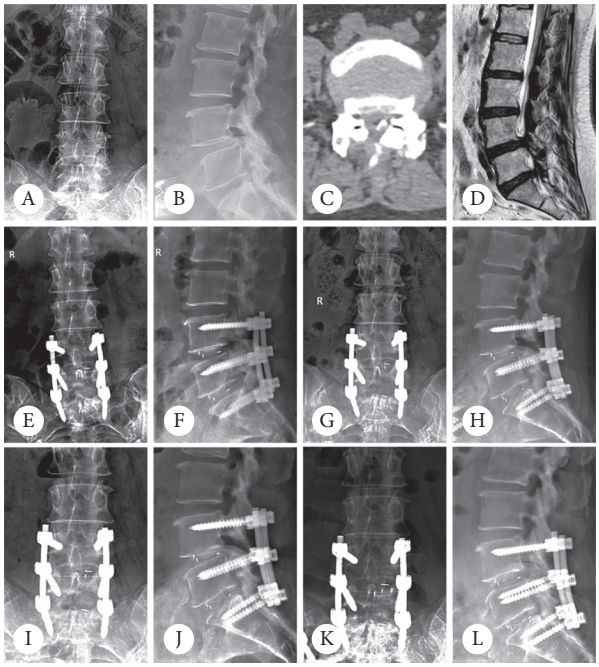

图 2 PS组61岁女性患者。术前正侧位X线（A～B）未见腰椎滑脱。术前轴状位CT（C）、矢状位MRI（D）提示腰椎管狭窄。术后3个月（E～F）、术后12个月（G～H）、术后36个月（I～J）、术后60个月（K～L）正侧位X线未见内固定失效

Fig 2 A 61-year-old female patient in the PS group. Preoperative anteroposterior and lateral X-ray images (A and B) showed no lumbar spondylolisthesis. Preoperative transverse images of CT (C) and sagittal images of MRI (D) showed lumbar spinal canal stenosis. Anteroposterior and lateral X-rays 3 months (E and F), 12 months (G and H), 36 months (I and J) and 60 months (K and L) post-operation showed internal fixation in good position

示PS组影像学检查结果。

2.6 并发症

见表5。两组总体并发症发生率、早期手术相关并发症发生率、晚期手术相关并发症〔症状性临近节段病变(adjacent segment disease, ASD)〕发生率差异均无统计学意义。CBTS组中2例(3.3%)的患者出现症状性ASD，其中1例患者进行翻修手术。PS组中5例(7.9%)的患者出现症状性ASD，其中3例患者进行翻修手术。

表 5 两组患者手术相关并发症比较

Table 5 Comparisons of surgery-related complications between the CBTS and the PS groups

Complication	CBTS group (n=60)	PS group (n=63)	P
Early complications/case (%)	5 (8.3)	7 (11.1)	0.764
Dural laceration	2 (3.3)	2 (3.2)	
Misplacement of screws	0	1 (1.6)	
Symptomatic hematoma	1 (1.7)	1 (1.6)	
Superficial wound infection	2 (3.3)	2 (3.2)	
Deep wound infection	0	1 (1.6)	
Late complication*/case (%)	2 (3.3)	5 (7.9)	0.258
Total/case (%)	7 (11.7)	12 (19.0)	0.322

ASD: adjacent segment disease. * Symptomatic ASD.

3 讨论

使用PS进行的经后路腰椎融合在临床上广泛用于治疗腰椎退变性疾病。但PS应用于低骨量的椎体时容易出现内固定失效，且置钉时需要局部广泛的软组织剥离而加重局部软组织损伤、增加出血量[15-16]。近年来出现的CBTS螺钉有望克服上述缺点。首先，CBTS螺钉通过增大与皮质骨的接触面积，增大了螺钉对于拔出力和剪切力的抵抗性，进而降低螺钉再发生松动的概率 。其次，

CBTS螺钉通过比PS更靠中线的进钉点，减少了术中椎旁肌的剥离、降低了失血量[17]。此外，CBTS螺钉的在横断面上从内向外、在矢状面上由尾侧向头侧的钉道方向理论上能够降低神经损伤的风险[18]。

疼痛和功能受限是患者就诊的主要原因。本研究中，CBTS组和PS组术后均获得了明显的疼痛缓解和功能改善，且改善效果随着随访时间的延长，更加明显。CBTS组因为术中软组织损伤少，术后1周和1个月时腰痛VAS评分更低，术后1个月时ODI评分更低。这与LEE等[19]的研究相似。

更短的手术时间、更少的出血量和住院时间对于加速患者的康复和节约医疗资源大有裨益。本研究发现CBTS组的术中出血量、手术时间、住院时间均明显低于PS组。有研究发现CBTS组的手术时间和住院时间均明显短于PS组[20-21]。LEE等[19]发现CBTS组的手术时间较PS组短，但两组的住院时间无差异。MARUO等[22]发现CBTS组和PS组的手术时间无差异。造成上述研究结果差异的原因可能是作为一种全新的技术，CBTS技术存在学习曲线。CHANG等、HU等[23-24]发现CBTS组的术中估计失血量明显少于PS组。这或可归因于CBTS组术中较少的软组织剥离及更短的手术时间。

椎体间融合率是衡量腰椎融合手术长期效果的关键指标。本研究发现，CBTS组在术后1年、2年和末次随访时的椎体间融合率与PS组比较差异无统计学意义，这和SAKAURA等[25]研究结果相似。

降低手术相关的并发症对于改善患者的满意度至关重要。本研究发现两组间的总体并发症发生率、术中并发症发生率和远期并发症发生率差异无统计学意义。本研究中没有发现内固定的失效。这与SNYDER等、HOFFMAN等[26-27]的报道结果相似。本研究中未发现螺钉松动，但LIU等[28]均报道了两组均发生了螺钉松动，且PS组的螺钉松动率更高。上述结果的差异可能来源于手术熟练程度、否使用椎间融合器、所选患者的体型是否过度肥胖等[29]。

本研究有一定的局限。首先是样本量较小，这会影响对低概率事件的判断。其次，患者相对年轻，骨质疏松症的发病率较低，这在理论上会降低CBTS螺钉相对于PS的生物力学优势。最后，本研究为回顾性研究，限制了指标数据收集的种类。因此，未来需要选用骨质疏松发病率高的老年病例进行前瞻性、大样本的随机对照研究来比较CBTS螺钉和PS的临床使用效果。

综上，CBTS组和PS组在椎体间融合率、疼痛缓解、功能改善和并发症等方面结果相同，但是CBTS组在手术时间、术中出血、住院时间方面具有显著优势。

*　　*　　*

作者贡献声明　张学磊负责论文构思、经费获取、调查研究、初稿写作和审读与编辑写作，顾祖超负责论文构思、研究方法和审读与编辑写作，张宇负责初稿写作和审读与编辑写作，李果负责论文构思、调查研究、监督指导、初稿写作和审读与编辑写作。所有作者已经同意将文章提交给本刊，且对将要发表的版本进行最终定稿，并同意对工作的所有方面负责。

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