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## 脊髓型颈椎病前路减压两种固定融合方法比较

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**摘要:** [目的] 比较零切迹自稳型颈椎融合器 (zero notch self stabilizing cervical fusion cage, ROI-C) 与钛板-融合器 (plate-cage, PC) 颈椎前路减压融合术 (anterior cervical decompression and fusion, ACDF) 治疗脊髓型颈椎病 (cervical spondylotic myelopathy, CSM) 的临床效果。[方法] 2021年1月—2022年7月就诊于本院的CSM患者112例, 抽签法随机分为两组, 其中56例采用ROI-C的ACDF, 另外56例采用PC内固定。比较两组围手术期、随访及影像学资料。[结果] ROI-C组手术时间[(105.8±24.6) min vs (128.2±30.5) min, P<0.001]、术中出血量[(26.0±4.3) ml vs (31.0±5.8) ml, P<0.001]、术后下地行走时间[(1.3±0.4) d vs (1.6±0.5) d, P<0.001]及早期并发症发生率(7.1% vs 26.8%, P=0.006)均显著优于PC组。两组恢复完全负重活动时间差异无统计学意义(P>0.05)。随时间推移, 两组JOA、NDI评分及椎体束征均显著改善(P<0.05)。术后3个月ROI-C组NDI评分[(18.6±4.2) vs (20.8±4.5), P=0.009]显著优于PC组, 其他相应时间点, 两组间上述指标的差异均无统计学意义(P>0.05)。影像方面, 与术前相比, 末次随访时两组颈椎前凸角、最小椎管矢状径均显著增加(P<0.05), 而颈椎ROM显著减小(P<0.05)。对应时间点, 两组上述影像学指标的差异均无统计学意义(P>0.05)。至末次随访时, 融合器下沉两组间差异无统计学意义(12.5% vs 3.6%, P=0.164)。[结论] 两种固定融合方法的ACDF的临床结果近似, 相比之下, ROI-C手术创伤小, 早期并发症发生率低, 早期临床结果优于PC。

**关键词:** 脊髓型颈椎病, 颈前路减压融合术, 零切迹自稳型颈椎融合固定, 钛板-笼架融合固定

中图分类号: R681.55

文献标志码: A

文章编号: 1005-8478 (2024) 09-0801-07

**Comparison of two instrumented fusion techniques in anterior cervical decompression and fusion for cervical spondylotic myelopathy // GAO Jun-wei, SHEN Qing-feng, XIA Ying-peng. Department of Spinal Surgery, People's Hospital of Tianjin City, Tianjin 300000, China**

**Abstract:** [Objective] To compare the clinical outcomes of anterior cervical decompression and fusion (ACDF) with zero notch self-stabilizing cervical fusion cage (ROI-C) versus titanium plate-cage system (PC) for cervical spondylotic myelopathy (CSM). [Methods] A total of 112 patients who admitted to our hospital for CSM from January 2021 to July 2022 were included into this study and randomly divided into two groups by lottery. Among them, 56 patients received ROI-C, while the other 56 patients received PC as instrumented fusion implant in ACDF. The perioperative period, follow-up and imaging data of the two groups were compared. [Results] The ROI-C group proved significantly superior to the PC group in terms of surgery time [(105.8±24.6) min vs (128.2±30.5) min, P<0.001], intraoperative blood loss [(26.0±4.3) ml vs (31.0±5.8) ml, P<0.001], time to resume postoperative walking [(1.3±0.4) days vs (1.6±0.5) days, P<0.001] and the incidence of early complications (7.1% vs 26.8%, P=0.006). There was no significant difference in time to return full weight-bearing activities between the two groups (P>0.05). The JOA and NDI scores, as well as pyramidal tract sign were significantly improved in both groups over time (P<0.05). The NDI score in ROI-C group was significantly better than that in the PC group 3 months postoperatively [(18.6±4.2) vs (20.8±4.5), P=0.009], which became not statistically significant since then between them (P>0.05). In addition, there were no statistically significant differences in the JOA score and pyramidal tract sign between the two groups at any time points accordingly (P>0.05). In terms of imaging, compared with pre-operation, the cervical lordosis angle and minimum sagittal spinal canal diameter were significantly increased in both groups at the last follow-up (P<0.05), while the cervical ROM was significantly decreased (P<0.05). At the corresponding time point, there were no statistically significant differences in the above imaging indexes between the two groups (P>0.05). At the last follow-up, there was no statistically significant difference between the two groups in term of fusion subsidence (12.5% vs 3.6%, P=0.164). [Conclusion] The clinical outcomes of ACDF with both the instrumented-fusion methods were similar. In contrast, the ROI-C had less surgical trauma and lower inci-

dence of early complications, and better the early clinical consequences over the PC.

**Key words:** cervical spondylotic myelopathy, anterior cervical decompression and fusion, zero notch self-stabilizing cervical fusion cage, titanium plate and cage system

脊髓型颈椎病（cervical spondylotic myelopathy, CSM）典型特征为脊髓损害或缺血，致使脊髓功能异常，引发行走不稳、肢体感觉障碍等症状，重者可能瘫痪，为临床症状最重的颈椎病类型，一旦确诊需及时手术治疗<sup>[1, 2]</sup>。颈前路减压融合术（anterior cervical decompression and fusion, ACDF）被称为颈椎病治疗的“金标准”，通过对突出椎间盘、骨赘直接减压，恢复颈椎生理曲度等能减轻相关症状<sup>[3]</sup>。既往多采取钛板-融合器系统（plate-cage, PC）用于ACDF干预，但PC操作相对繁琐，术后易出现吞咽困难等系列并发症<sup>[4]</sup>。为减少手术并发症，提高患者安全性和舒适度，零切迹自稳型颈椎融合器（zero notch self stabilizing cervical fusion cage, ROI-C）于临床中逐渐开展，通过独特的双锁片结构保证融合的稳定性，融合率高，同时操作中解剖显露范围小，手术创伤小，且对患者食管等组织影响不大，术后吞咽困难发生风险小<sup>[5, 6]</sup>。有研究称，ROI-C与前路PC内固定治疗ACDF效果均明显，但ROI-C能显著降低术后吞咽困难的发生率<sup>[7]</sup>。姚晓玲等<sup>[8]</sup>研究表明，零切迹颈前路椎间融合内固定器能明显改善CSM患者神经症状，减少术后吞咽困难及邻近椎间盘退变发生，但融合器下沉风险较大。目前，关于ROI-C用于治疗CSM的研究不少，但是能否完全取代PC内固定尚存在争议，且多为回顾性研究，前瞻性研究相对少。故本研究行随机对照试验，分析ROI-C用于CSM患者ACDF治疗的临床疗效，为ROI-C临床应用提供一定的参考，报道如下。

## 1 资料与方法

### 1.1 纳入与排除标准

纳入标准：(1) 经临床、影像学等检查证实为单节段或双节段CSM；(2) 年龄40~77岁；(3) 保守治疗2个月效果不理想或无效；(4) 有ACDF适应证，且均为初次手术。

排除标准：(1) 合并胸腰椎疾病；(2) 存在感染、免疫、凝血或中枢神经系统疾病；(3) 既往有颈椎手术史；(4) 因严重内科疾病等不耐受手术者；(5) 先天性颈椎畸形、肿瘤、重度骨质疏松症者；(6) 对研究涉及到的材料有过敏史者。

### 1.2 一般资料

本研究为前瞻性随机对照试验，2021年1月—2022年7月本科收治的CSM患者共112例符合上述标准，纳入本研究。采用抽签法随机将患者分为ROI-C组与PC组，每组56例。两组患者一般资料见表1，两组患者年龄、性别、病程、BMI、累及节段数等一般资料比较差异无统计学意义( $P>0.05$ )。本研究经医院伦理委员会批准，患者均知情同意。

表1. 两组患者术前一般资料比较  
Table 1. Comparison of preoperative general data between the two groups

指标	ROI-C组 (n=56)	PC组 (n=56)	P值
年龄(岁, $\bar{x} \pm s$ )	56.5±9.1	56.1±9.2	0.829
性别(例, 男/女)	28/28	32/24	0.449
病程(月, $\bar{x} \pm s$ )	14.8±4.0	15.2±4.7	0.629
BMI(kg/m <sup>2</sup> , $\bar{x} \pm s$ )	22.6±1.8	23.1±2.0	0.167
累及节段数(节, $\bar{x} \pm s$ )	2.0±0.5	2.2±0.7	0.085

### 1.3 手术方法

ROI-C组：患者取仰卧位，垫高肩背。均在右侧胸锁乳突肌前缘做5cm左右横行切口，在颈动脉血管鞘与内脏鞘间钝性分离，尽量不或少刺激颈动脉窦；常规显露至椎体前方，C形臂X线机透视下定位，经由椎间撑开器将病变椎体间隙撑开，摘除髓核、软骨终板，借助磨钻、咬骨钳处理椎体后缘骨赘。探查后纵韧带，将其增生/骨化组织切除，保留椎体骨性终板。彻底减压后，依据椎间隙大小选择合适型号的ROI-C融合器试模，将其置入椎间隙。明确型号后取出试模，将同种异体骨碎填充到ROI-C融合器后植入椎间隙；经由嵌片打入器分别将预弯的双侧椎间桥形固定嵌片打入上、下椎体。C形臂X线机透视下可见嵌片位置满意，椎间隙间零切迹。双节段者，相同流程对第2个椎间隙操作。

PC组：彻底减压操作同上。减压后椎间隙试模，明确高度合适后将同种异体骨植入。C形臂X线机透视下可见椎间融合器位置满意，椎间撑开器取出，依据减压范围取合适长度钛板放到椎体前缘，行开路、钻孔，旋入14mm钛板锁定螺钉，将钛板固定在椎体，C形臂X线机透视下可见钛板螺钉位置合适。

术后依据两组患者引流量确定拔管时间（术后24 h 内引流量<10 ml 便可拔管），依据情况对症处理，颈托固定6~8周。

#### 1.4 评价指标

记录围手术期资料，包括手术时间、切口总长度、术中失血量、透视次数、下地行走时间、切口愈合及手术相关早期并发症。采用恢复完全负重活动时间、颈椎功能障碍指数（neck disability index, NDI）<sup>[9]</sup>、日本骨科协会评分（Japanese Orthopedic Association scores, JOA）<sup>[10]</sup>、椎体束征及随访过程中相关事件发生情况。行影像学检查，测量两组患者颈椎前凸角（C<sub>2-7</sub> Cobb 角）、颈椎整体活动度（range of motion, ROM）及责任段最小椎管矢状径。

#### 1.5 统计学方法

采用 SPSS 24.0 软件进行统计学分析。计量资料满足正态分布时以  $\bar{x} \pm s$  表示，组内多个时间点比较行单因素方差分析，整体行重复测量方差分析；两组组间比较行独立 *t* 检验。计数资料行  $\chi^2$  或连续性校正  $\chi^2$  检验。等级资料两组比较采用 Mann-Whitney U 检验，组内比较采用 Friedman 检验。*P*<0.05 为差异有统计学意义。

## 2 结果

### 2.1 围手术期情况

两组患者均成功结束手术，术中无脊髓损伤、大血管损伤等并发症发生，两组患者围手术期资料见表2。ROI-C 组手术时间、术中失血量及术后下地行走时间均显著优于 PC 组 (*P*<0.05)，两组切口总长度、术中透视次数与住院时间的差异均无统计学意义 (*P*>0.05)。两组患者术后切口均甲级愈合，无切口感染发生。ROI-C 组术后发生声音嘶哑1例，吞咽困难3例，早期并发症发生率7.1% (4/56)；PC 组术后声音嘶哑、吞咽困难分别发生5例、10例，早期并发症发生率26.8% (15/56)，ROI-C 组术后早期并发症发生率显著低于 PC 组 (*P*=0.006)。针对并发症，保守治疗7 d 后均可进食流食，术后4周声音嘶哑症状缓解，ROI-C 组术后3个月无吞咽困难症状，PC 组术后3个月仍有3例轻度吞咽困难，术后半年吞咽均恢复正常。

### 2.2 随访结果

所有患者均获1年以上随访，平均随访时间(17.0±5.0)个月。随访过程中，两组患者均无症状加重，无再次翻修手术发生。

表2. 两组患者围手术期资料与比较

Table 2. Comparison of perioperative data between the two groups

指标	ROI-C 组 (n=56)	PC 组 (n=56)	<i>P</i> 值
手术时间 (min, $\bar{x} \pm s$ )	105.8±24.6	128.2±30.5	<0.001
切口总长度 (cm, $\bar{x} \pm s$ )	4.4±0.5	4.3±0.6	0.340
术中失血量 (ml, $\bar{x} \pm s$ )	26.0±4.3	31.0±5.8	<0.001
透视次数 (次, $\bar{x} \pm s$ )	3.0±0.5	3.2±0.6	0.058
下地行走时间 (d, $\bar{x} \pm s$ )	1.3±0.4	1.6±0.5	<0.001
切口愈合 (例, 甲/乙/丙)	56/0/0	56/0/0	ns
住院时间 (d, $\bar{x} \pm s$ )	7.5±1.7	8.2±2.1	0.055

两组随访结果见表3。两组恢复完全负重活动时间差异无统计学意义 (*P*>0.05)。两组术后3个月、末次随访 JOA、NDI 评分及椎体束征均较术前显著改善 (*P*<0.05)；术前两组上述指标的差异均无统计学意义 (*P*>0.05)，术后3个月 ROI-C 组 NDI 评分显著低于 PC 组 (*P*<0.05)，末次随访时两组 NDI 评分的差异无统计学意义 (*P*>0.05)，术后相应时间点，两组 JOA 评分及椎体束征的差异均无统计学意义 (*P*>0.05)。

### 2.3 影像评估

两组影像评估结果见表4。与术前相比，末次随访时两组颈椎前凸角、最小椎管矢状径均显著增加 (*P*<0.05)，而颈椎 ROM 显著减小 (*P*<0.05)。对应时间点，两组上述影像学指标的差异均无统计学意义 (*P*>0.05)。典型病例影像见图1、2。

至末次随访时两组患者均无螺钉松动、嵌片或钛板断裂发生，融合间隙均达到骨性融合。至末次随访时，ROI-C 组融合器下沉7例(12.5%)，PC 组融合器下沉2例(3.6%)，但两组差异无统计学意义 (*P*=0.164)。

## 3 讨论

近年来探寻新型内固定融合器成为脊柱外科研究的重点，保留 ACDF 优点的同时避免其不足，满足“微创化”需求<sup>[11, 12]</sup>。零切迹融合器符合上述需求，有 ROI-C、Zero-P、Zero-P VA 等多种类型<sup>[13, 14]</sup>，其中 ROI-C 应用相对多，具有直接减压、恢复颈椎生理曲度、减轻轴性疼痛等优点<sup>[15, 16]</sup>。随着仪器更新、外科医师熟悉且掌握疾病，ROI-C 手术适应证不断增加，目前可能适用于全部可行 ACDF 者，其禁忌证包括严重骨质疏松、先天性颈椎管狭窄等<sup>[17]</sup>。

表3. 两组患者随访指标比较

Table 3. Comparison of follow-up indexes between the two groups

指标	时间点	ROI-C组 (n=56)	PC组 (n=56)	P值
恢复完全负重活动时间 (d, $\bar{x} \pm s$ )		84.6±15.0	90.0±17.5	0.082
NDI评分 (分, $\bar{x} \pm s$ )	术前	30.2±5.6	29.6±6.0	0.585
	术后3个月	18.6±4.2	20.8±4.5	<b>0.009</b>
	末次随访	11.2±2.3	12.0±2.6	0.087
<i>P</i> 值		<0.001	<0.001	
JOA评分 (分, $\bar{x} \pm s$ )	术前	7.8±1.7	8.0±2.0	0.570
	术后3个月	12.4±2.6	11.5±2.3	0.055
	末次随访	14.6±2.8	14.0±2.5	0.234
<i>P</i> 值		<0.001	<0.001	
椎体束征 (例, -/+//++)	术前	19/21/16	18/21/17	0.812
	术后3个月	26/19/11	23/20/13	0.542
	末次随访	32/18/6	29/19/8	0.520
<i>P</i> 值		<0.001	0.022	

表4. 两组患者影像资料 ( $\bar{x} \pm s$ ) 与比较Table 4. Imaging data ( $\bar{x} \pm s$ ) and comparison between the two groups

指标	时间点	ROI-C组 (n=56)	PC组 (n=56)	P值
颈椎前凸角 (°)	术前	13.6±4.2	14.1±3.8	0.510
	末次随访	22.3±3.8	21.8±3.4	0.465
	<i>P</i> 值	<0.001	<0.001	
颈椎ROM (°)	术前	50.6±6.3	49.9±6.5	0.564
	末次随访	45.0±5.5	43.2±5.0	0.073
	<i>P</i> 值	<0.001	<0.001	
最小椎管矢状径 (mm)	术前	9.6±1.0	9.3±1.3	0.369
	末次随访	16.7±2.5	16.0±2.4	0.134
	<i>P</i> 值	<0.001	<0.001	

张伟等<sup>[7]</sup>通过回顾性研究发现，相比常规融合器、钢板，ROI-C用于颈椎前路手术能明显缩短手术时间及住院时间、减少术中失血量，本研究与之部分相符。这可能与ROI-C操作简单，仅需安装固定嵌片，进而手术时间显著短，同时可减少暴露及拧入操作，创伤小，可减少出血有关。本研究中，ROI-C组术后下地行走时间比PC组显著短，而住院时间差异无统计学意义，这可能是因为ROI-C操作相对术后引流量少，可尽早拔管，便于患者更早地下地行走，虽然手术相关指标可能缩短住院时间，但患者机体恢复、经济问题等其他因素也可影响之。本研究中，ROI-C组术后吞咽困难发生比例比PC组显著低，与相关报道一致<sup>[18, 19]</sup>。究其原因：ROI-C零切迹能尽可能不或少刺激食管，且该系统操作显露范围相对小，手术时间短，术中牵拉食管、椎前软组织很

轻，故能明显减少术后吞咽困难发生。随访上，本研究两组患者术后NDI评分、JOA评分及椎体束征较术前均显著改善，提示ROI-C或PC内固定ACDF治疗CSM均能改善颈脊髓神经功能及颈椎功能障碍，这一结果与张俊辉等<sup>[20]</sup>报道一致。与之不同的是，本研究发现ROI-C组术后3个月NDI评分比PC组显著低，可见ROI-C相比PC内固定能进一步改善患者术后短期脊髓神经及颈椎功能，这可能与ROI-C相对“微创化”、术后早期并发症少等有关，而两组末次随访上述评分对比差异均无统计学意义，与相关报道一致<sup>[21, 22]</sup>。

夏毕成等<sup>[23]</sup>研究表明，ROI-C与PC在改善颈椎病患者颈椎前凸角、椎间隙高度上效果相当。有报道称零切迹组术后颈椎前凸角、椎前软组织厚度与PC组对比差异显著，前者术后融合器沉降比例比PC

显著高<sup>[24]</sup>；姚晓玲等<sup>[8]</sup>调查显示，Zero-P VA术后30个月患者融合器下沉比例高达24%。可见临床需重视零切迹融合器下沉问题。本研究中，两组术后3个月、末次随访颈椎前凸角、最小椎管矢状径较术前均显著改善，且两组间对比差异无统计学意义，与相关研究结果相符<sup>[21, 23]</sup>，提示ROI-C与PC内固定治疗均能获得良好的颈椎生理曲度恢复，影像学疗效类

似。本研究中，ROI-C与PC患者术后颈椎ROM均有丢失，这可能与两者均为前路手术有关。另外，末次随访时ROI-C组融合器下沉比例比PC组高，但无统计学差异，这与姚晓玲等<sup>[8]</sup>报道不符。分析可能原因：样本量少；融合器下沉与颈椎整体曲度有关，而组间颈椎整体曲度对比差异不大<sup>[25]</sup>。



图1. 患者男性，50岁，CSM，行ROI-C的ACDF术。1a: 术前MRI可见C<sub>5/6</sub>、C<sub>6/7</sub>节段脊髓压迫；1b: 术后MRI可见C<sub>5/6</sub>、C<sub>6/7</sub>节段脊髓压迫解除；1c: 术后2 d X线片见ROI-C位置良好；1d: 术后9个月X线片见C<sub>5/6</sub>骨性融合，C<sub>6/7</sub>间隙下沉。

Figure 1. A 50-year-old male received ACDF with ROI-C for CSM. 1a: Preoperative MRI showed spinal cord compression at C<sub>5/6</sub> and C<sub>6/7</sub> levels; 1b: Postoperative MRI showed proper relief of spinal cord compression at C<sub>5/6</sub> and C<sub>6/7</sub> segments; 1c: X-ray 2 days after surgery showed ROI-C implant in good position; 1d: X-rays 9 months after surgery revealed C<sub>5/6</sub> bone fusion, whereas C<sub>6/7</sub> subsided in some extent.

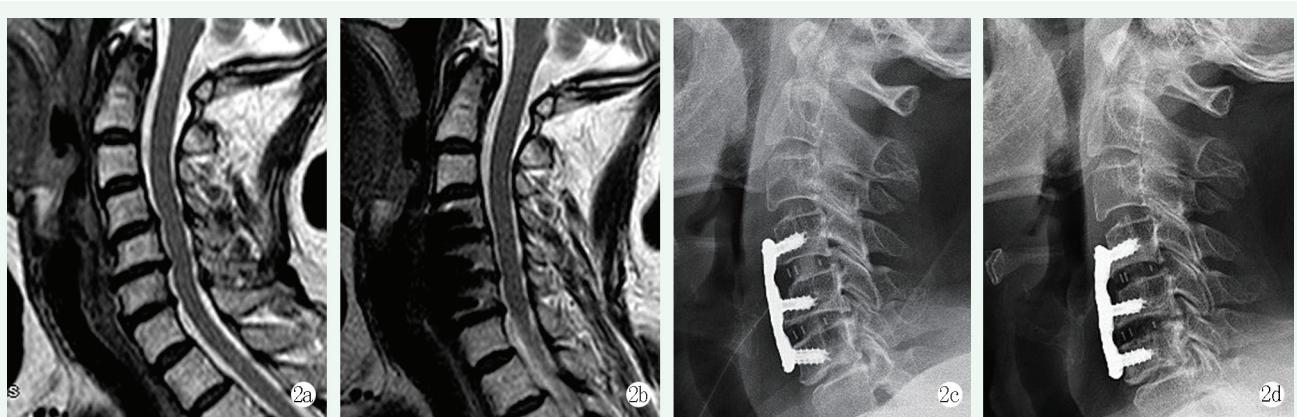


图2. 患者女性，66岁，CSM，行PC内固定的ACDF术。2a: 术前MRI可见C<sub>4/5</sub>、C<sub>5/6</sub>节段脊髓压迫；2b: 术后MRI可见C<sub>4/5</sub>、C<sub>5/6</sub>节段脊髓压迫解除；2c: 术后2 d X线片可见PC内置物位置良好；2d: 术后1年X线片可见C<sub>4/5</sub>骨性融合，C<sub>5/6</sub>间隙下沉。

Figure 2. A 66-year-old female underwent ACDF with cage-plate for CSM. 2a: Preoperative MRI showed spinal cord compression at C<sub>4/5</sub> and C<sub>5/6</sub> levels; 2b: Postoperative MRI revealed the spinal cord decompressed at C<sub>4/5</sub> and C<sub>5/6</sub> levels; 2c: X-ray 2 days after surgery showed that the titanium plate-cage implants in good position; 2d: X-ray 1 year postoperatively showed C<sub>4/5</sub> bone fusion and C<sub>5/6</sub> subsided slightly.

综上所述，ROI-C行ACDF治疗CSM的效果与PC相当，ROI-C在减少手术创伤、早期并发症、改善短期颈椎功能障碍上有优势。本研究不足：样本量较少且随访时间相对短；未对比ROI-C对不同病变节段CSM的治疗效果，尚需进一步研究。

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(收稿:2023-08-21 修回:2023-12-13)

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(本文编辑: 闫承杰)