临床论著

单节段颈前路椎间融合术后 ROI-C 融合器沉降的相关因素分析

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【摘要】目的:分析采用 ROI-C 行颈前路单节段椎间盘切除减压融合(anterior cervical discectomy and fusion, ACDF)术后融合器沉降的相关因素。**方法**:回顾总结采用 ROI-C 行单节段 ACDF 治疗颈椎间盘退变性疾病的 83 例患者资料。记录患者年龄、性别、手术节段、吸烟史及骨密度检查结果。在术前颈椎侧位 X 线片上测量颈椎整体曲度(cervical alignment, CA)、融合节段角度(segmental angle, SA)、椎间隙前高度(anterior disc height, ADH)和椎间隙后高度(posterior disc height, PDH)。将随访的中立位颈椎侧位 X 线片与术后即刻比较, ADH 或 PDH 丢失>2mm 判定为融合器沉降, 分入沉降(subsidence)组(S 组, 22 例), 并记录沉降的部位; ≤2mm 分入未沉降 (nonsubsidence) 组 (N 组, 61 例)。应用独立样本 t 检验 χ^2 检验对以上参数行组间比较, 采用多变量 Logistic 回归分析单节段 ACDF 术后 ROI-C 沉降的危险因素。将危险因素进一步分组使用 χ^2 检验计算似然比(likelihood ratio, LR)进行评价。**结果**:单节段 ACDF 术后 ROI-C 沉降发生率为 26.5%(22/83), 其中陷入椎体前方终板者占 63.6%(14/22)。S 组、N 组年龄分别为 59.86±12.11 岁、52.77±10.34 岁, 差异有统计学意义 (P=0.010); 性别、吸烟史、手术节段和骨密度均无统计学差异(P>0.05)。S 组术前的 CA、SA、ADH 分别为-0.800°±5.637°、0.432°±2.162°和 3.768±1.210mm, N 组分别为 4.893°±5.718°、1.198°±1.826°和 5.066±1.257mm, 两组比较差异有统计学意义(P<0.001, P=0.031 和 P<0.001), 两组的 PDH 差异无统计学意义(P=0.092)。多变量 Logistic 回归分析显示术前 CA 和年龄是 ROI-C 沉降的危险因素(P=0.014 和 P=0.038)。根据术前 CA 情况将患者分为术前 CA 后凸(CA<0°)和前凸(CA≥0°)组, 根据术前年龄将患者分为<60 岁和≥60 岁组, χ^2 检验显示术前 CA 后凸和 60 岁以上病例 ROI-C 沉降概率分别比前凸和 60 岁以下病例高 12.5 倍和 4.5 倍(LR=12.529, P<0.001; LR=4.454, P=0.030)。**结论**:术前 CA 后凸和年龄 60 岁以上是单节段 ACDF 术后 ROI-C 沉降的危险因素。选择 ROI-C 行单节段 ACDF 治疗颈椎间盘退变性疾病时应考虑这两项因素的影响。

【关键词】颈前路椎间盘切除减压融合术; 椎间融合器; 沉降; 颈椎曲度
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Risk factors for postoperative subsidence of ROI-C in single-level anterior cervical discectomy and fusion/LI Guo, WU Jianfeng, HUANG Wending//Chinese Journal of Spine and Spinal Cord, 2016, 26 (12): 1063-1069

【Abstract】Objectives: To investigate and analyze the risk factors for postoperative subsidence of RIO-C in single-level anterior cervical discectomy and fusion (ACDF). **Methods:** Eighty-three patients who underwent single-level ACDF with ROI-C for cervical degenerative disc disease were included in this retrospective study. The factors such as age, sex, operative level, smoking history, bone mineral density (BMD), and preoperative sagittal cervical alignment (CA), operated segmental angle (SA), anterior/posterior disc height (ADH/PDH) in the lateral radiographs of cervical spine were collected. Patients were categorized into subsidence group(S group, n=22) and nonsubsidence group(N group, n=61) based on the loss of the disc height for 2mm. These clinical and radiographic factors were compared between two groups by using independent sample t-test or Chi-square test. Risk factors for postoperative subsidence of ROI-C in single-level ACDF were analyzed by multivariate Logistic regression. The likelihood ratios (LR) of risk factors were obtained by using χ^2 test on the basis of a cutoff. **Results:** Subsidence occurred in 22(26.5%) of 83 patients.

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The incidence of subsidence into the anterior endplate was 63.6%(14/22). Mean age was 59.86±12.11 and 52.77±10.34 years(P=0.010) in group S and group N, while gender, surgery level, smoking history, BMD showed no significant differences between group S and group N (P>0.05). A significant difference was found with respect to preoperative CA, SA and ADH in group S compared with group N(P<0.001, P=0.031 and P<0.001, respectively), whereas there was no significant difference in PDH(P=0.092). Multivariate Logistic regression analysis revealed that the preoperative CA(P=0.014) and age(P=0.038) affected subsidence. The patients in each group were assigned to kyphotic or lordotic subgroup and senior or junior subgroup according to cervical alignment cutoff of 0 degree and age cutoff of 60 years respectively. The risk of ROI-C subsidence in the kyphotic subgroup was 12.5-fold greater than that in the lordotic subgroup (LR=12.529, P<0.001). The patients older than 60 years were 4.5-fold more likely to display subsidence than those younger than 60 years(LR=4.454, P=0.030). **Conclusions:** In single-level ACDF with ROI-C, the risk factors affecting postoperative cage subsidence are preoperative CA of kyphosis and age older than 60 years. The data suggest that spinal surgeons should cautiously consider the preoperative CA and/or age when deciding on the ROI-C for single-level ACDF to treat patients with degenerative disc disease.

【Key words】 Anterior cervical discectomy and fusion; Stand-alone cage; Postoperative subsidence; Cervical alignment

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前路颈椎间盘切除减压植骨融合术(anterior cervical discectomy and fusion,ACDF)是治疗颈椎间盘退变性疾病的标准术式。椎间融合器可以防止植骨块塌陷，减少取骨处并发症和简化手术程序[1,2],但融合器沉降是常见的并发症,可导致融合节段和颈椎整体曲度改变[3]。ACDF 术后融合器沉降与患者临床特质、所选融合器的材料和形态、手术操作及融合节段稳定性等因素相关[4-6]。联合使用前路钛板可减少融合器沉降的发生率,但其存在应力遮挡不利骨融合，加速邻近节段退变和食道、气管并发症多的不足,以及内固定失败风险[7,8]。为避免前路钛板的不足,近年来自身带有增加椎间稳定性装置的融合器开始应用于临床,随访发现仍有部分病例发生术后融合器沉降。本研究回顾总结我院 2011 年 5 月~2014 年 6 月采用 ROI-C 行单节段 ACDF 治疗退变性颈椎椎间盘疾病的 83 例患者的临床资料，探讨术后 ROI-C 沉降的相关因素。

1 资料与方法

1.1 一般资料

2011 年 5 月~2014 年 6 月在我院因颈椎间盘退变性疾病采用 ROI-C 行前路单节段 ACDF 手术治疗的患者 96 例。排除后纵韧带骨化症、合并外伤史和无法完成 X 线测量的 C7/T1 患者 13 例。共纳入 83 例患者,其中男 48 例,女 35 例,年龄 35~81 岁 (54.65±11.27 岁)。随访 26~42 个月(34.6±6.2 个月)。术前全部患者行颈椎正侧位 X 线片和 MRI 检查。

1.2 手术方法

全麻下进行手术,取仰卧位,用软枕垫高肩部使颈部适度后伸。经颈部右侧横切口,牵开内脏鞘和血管鞘显露椎间隙前缘,C 型臂 X 线机透视确认手术间隙。用 Caspar 撑开器适度撑开待减压椎间隙,切开椎前筋膜和前纵韧带,切除纤维环和髓核组织,刮除椎体后缘增生骨赘,用薄型椎板咬骨钳向上下椎体后缘及侧方扩大潜行减压，最后切除后纵韧带,彻底解除脊髓和神经根压迫。减压后用刮匙轻柔刮除软骨终板至骨性终板中央部可见点状渗血,避免损伤骨性终板。参考术前测量相邻椎间隙的均值，选择较之增加 0.5~1.5mm 高度和适合椎间隙宽度的 ROI-C 融合器。拆除撑开器,台下助手适度牵引头部，将填塞适量自体髂骨的 ROI-C 置入，使其前缘距离椎体前缘不超过 1mm，再利用撑开臂适当加压数次使置入 ROI-C 适应减压椎间隙的形态。经 C 型臂 X 线机透视确认位置满意后,先后轻叩尾侧和头侧自稳嵌片,完成固定。冲洗伤口,放置负压引流管,逐层关闭切口。术后颈托固定 8 周。

1.3 观察指标

记录患者年龄、性别、吸烟史、手术节段及骨密度结果信息。术后 1 周内、2 个月、3 个月和 6 个

月摄片复查,之后每 6 个月随访 1 次。采用 syngo fastView 软件(德国西门子公司)读取患者术前中立位颈椎侧位 X 线片,使用 Cobb 法测量颈椎整体曲度(cervical alignment,CA),为 C2 与 C7 椎体下终板连线的垂线之间夹角;融合节段角度(segmental angle,SA),为手术节段的上位椎体上终板连线垂线与下位椎体下缘终板连线的垂线之间的夹角,前凸角度用正值表示,后凸角度用负值表示。阅读放大 250%的颈椎侧位 X 线片(DICOM 格式)并测量手术椎间隙前高度(anterior disc height,ADH)和后高度(posterior disc height,PDH),分别为手术节段上位椎体前下顶点与下位椎体的前上顶点和上位椎体后下顶点与下位椎体后上顶点之间的距离(图 1)。随访的颈椎侧位 X 线片与术后即刻比较,ADH 或 PDH 丢失>2mm 者,判定为融合器沉降,分入沉降(subsidence)组(S 组),记录沉降部位;≤2mm 分入未沉降(nonsubsidence)组(N 组)。

1.4 统计学方法

使用 SPSS 20.0 进行相关数据处理分析。计数资料采用频数表示,进行 χ^2 检验分析;计量资料采用均数±标准差($\bar{x}\pm s$)表示,采用独立样本 t 检验比较;对有统计学意义的变量进一步采用多变量 Logistic 回归分析;将危险因素再次分组,使用 χ^2 检验计算似然比(likelihood ratio,LR)进行评价。P<0.05 为差异有统计学意义。

2 结果

患者均完成 2 年以上随访,ROI-C 沉降发生率为 26.5%(22/83),其中陷入椎体前方终板患者占 63.6%(14/22,图 2),陷入后方终板患者占 22.7%(5/22),前后方终板皆有者占 13.6%(3/22)。S 组有 4 例、3 例和 15 例分别于术后 3 个月、6 个月和 1 年出现融合器沉降。S 组与 N 组平均年龄差异有统计学意义(P=0.010);两组患者性别、吸烟史、手术节段和 BMD 均无统计学差异(表 1)。S 组术前 CA、SA、ADH 与 N 组比较有统计学差异(P<0.001、P=0.031 和 P<0.001),而两组术前 PDH 差异无统计学意义(P=0.092,表 2)。多变量 Logistic 回归分析显示,术前 CA 和年龄与 ROI-C 沉降存在显著相关性(P 分别为 0.014 和 0.038),术前 SA 和术前 ADH 与 ROI-C 沉降无相关性(P 分别为 0.184 和 0.057,表 3)。根据术前 CA 情况将患者分为术前 CA 后凸(CA<0°)和前凸(CA≥0°)组,根据术前年龄将患者分为<60 岁和≥60 岁组,统计结果显示术前 CA 后凸和≥60 岁病例的 ROI-C 沉降发生概率分别比前凸和<60 岁病例高 12.5 倍和 4.5 倍(LR=12.529,P<0.001 和 LR=4.454,P=0.030,表 4)。

3 讨论

融合器沉降(cage subsidence,CS)是指融合器进入弹性模量相对较低的椎体内的现象,是单独使用融合器的 ACDF 术后常见并发症。CS 程度与融合器-椎体之间弹性模量差及其所受应力成正比,而与融合器和相邻终板的接触面积成反比。随着融合器广泛应用,其制作材料和外形设计不断改进和完善,旨在促进椎间融合及减少沉降率。从早期的金属融合器到现今临床最常使用的复合材料融合器,它们弹性模量逐渐减小趋于接近人

图 1 颈椎侧位 X 线片上影像学测量 **a** CA,颈椎整体曲度,为 C2 与 C7 椎体下终板连线的垂线之间的夹角,前凸角度用正值表示,后凸角度用负值表示 **b** SA,融合节段角度,为上位椎体上终板连线和下位椎体下缘终板连线的垂线之间的夹角 **c** ADH 和 PDH 分别表示手术椎间隙前高度和后高度

Figure 1 Radiological measurements on lateral cervical X-ray film **a** CA was defined as the angle between perpendicular line of inferior endplate of C2 and C7. The positive values denoted as lordosis and negative values denoted as kyphosis **b** SA was defined as the angle between perpendicular line of superior endplate of cranial vertebrae and inferior endplate of caudal vertebrae **c** ADH and PDH represented anterior disc height and posterior disc height of the fused level

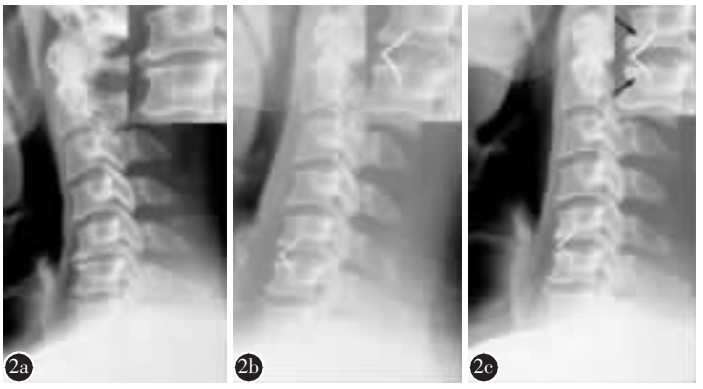

图 2 患者男,64 岁,神经根型颈椎病,采用 ROI-C 行 C5/6 节段 ACDF 治疗 **a** 术前颈椎侧位 X 线片示颈椎整体曲度(CA)存在-13.4°后凸角,C5/6 节段椎间隙前高度(ADH)为 2.3mm **b** 术后 2 个月颈椎侧位 X 线片示 C5/6 节段 ADH 恢复满意,CA 有所恢复,仍有-5.6°后凸 **c** 术后 7 个月颈椎侧位 X 线片示 ROI-C 沉降入上位椎体前下角内,ADH 减少 2mm。右上角放大图见 C5 椎体前下角出现骨质硬化表现,ROI-C 嵌片周围见透亮影改变(箭头所示)和内部植骨有吸收的迹象,提示此处应力集中和 ROI-C 固定嵌片松动

Figure 2 A 64 years old male patient with cervical spondylotic radiculopathy, who underwent C5/6 ACDF with ROI-C **a** On lateral cervical film, the patient's preoperative CA and anterior disc height(ADH) in C5/6 segment were -13.4 degrees and 2.3 millimeters respectively **b** At 2 months after surgery, there were still -5.6 degrees in the CA despite good restoration of ADH in the operated segment **c** At 7 months follow-up, the subsidence of ROI-C into the anteroinferior endplate of C5 vertebrae and decline by 2mm in C5/6 ADH was seen on the lateral cervical film. The sclerosis change in anteroinferior aspect of C5 vertebrae was noted, the radiolucent zone(arrow mark) around anchored clips of ROI-C in the adjacent vertebrae and resorption of bone graft inside the cage in the inset of magnified view of the operated segment, which implied stress concentration on this region and loosening of ROI-C anchored clips

表 1 S 组与 N 组一般资料对比

Table 1 Comparison of general information between 2 groups

	S组 Group S	N组 Group N	*P*值 *P* value
例数 *n*	22	61	
性别(男/女) Gender(male/female)	13/9	35/26	0.889
年龄(岁) Age(year)	59.86±12.11	52.77±10.34	0.010
手术节段 Operation level			
C3/4	2	2	0.744
C4/5	5	14	
C5/6	12	37	
C6/7	3	8	
吸烟史 Smoking history			
吸烟 Smoker	7	20	0.934
不吸烟 Nonsmoker	15	41	
骨密度 Bone mineral density			
T 值≤-1 T score ≤-1	9	13	0.074
T 值>-1 T score >-1	13	48	

表 2 S 组与 N 组影像学测量参数对比

Table 2 Comparison of radiological measurements between 2 groups

	S组(*n*=22) Group S	N组(*n*=61) Group N	*P*值 *P* value
术前 CA(°) Preoperative cervical alignment	-0.800±5.637	4.893±5.718	<0.001
术前 SA(°) Preoperative segmental angle	0.432±2.162	1.198±1.826	0.031
术前 ADH(mm) Preoperative anterior disc height	3.768±1.210	5.066±1.257	<0.001
术前 PDH(mm) Preoperative posterior disc height	3.777±0.969	4.597±1.075	0.092

表 3 单节段 ACDF 术后 ROI-C 沉降因素的 Logistic 回归分析结果

Table 3 Result of Logistic regression for ROI-C subsidence after single level ACDF

	OR Odds ratio	95%可信区间 95% confidence interval	*P*值 *P* value
年龄(岁) Age(year)	1.101	1.005~1.207	0.038
术前 CA Preoperative cervical alignment	3.774	1.600~12.997	0.014
术前 SA Preoperative segmental angle	1.232	0.584~2.597	0.184
术前 ADH Preoperative anterior disc height	1.053	0.903~1.196	0.057

体骨组织[9]。头侧具有凸起结构的解剖型楔形融合器较以往的圆柱形融合器更加适合椎间隙的形态,可增加与终板的接触面积,能够均匀分布和传

表 4 不同术前颈椎曲度和年龄的患者术后 ROI-C 沉降发生情况的比较

Table 4 Comparison of ROI-C subsidence between the patients with different preoperative CA and age

	S组 Group S	N组 Group N	χ^2 值 χ^2 value	*P*值 *P* value	LR Likelihood ratio
术前颈椎曲度前凸 Preoperative cervical lordotic alignment	10	52	13.546	<0.001	12.529
术前颈椎曲度后凸 Preoperative cervical kyphotic alignment	12	9			
年龄<60 岁 Age<60 years	12	48	4.705	0.030	4.454
年龄≥60 岁 Age≥60 years	10	13			

递椎间应力，有助于促进植骨组织生长和椎间融合[10]。

ACDF 联合前路钛板可以增加节段稳定性和改善颈椎曲度，还能够减少融合节段的应力，降低 CS 发生率，但存在椎前组织副损伤和加速邻近节段退变的不足[11,12]。零切迹设计的 ROI-C 巧妙地将嵌片置入椎体内部，可以增加融合节段的稳定性，避免了前路钛板的缺点。临床实践证明应用 ROI-C 的 ACDF 术式是安全、有效和微创的治疗措施[8,13,14]，但也存在一定的沉降率。有文献[13,15]报道单节段使用 ROI-C 的沉降率在 0~61%，本研究的 ROI-C 沉降发生率为 26.5%(22/83)。与传统的融合器相比，自稳双锚定嵌片设计可防止 ROI-C 在椎间隙内移位，理论上还可增加融合器与相邻椎体的结合力，迄今尚无 ROI-C 置入后颈椎稳定性变化的生物力学和临床研究报道。ROI-C 双锚定嵌片具有相对稳定作用，相似设计理念的 Zero-P 融合器采用锁定螺钉以绝对稳定的方式增加融合节段的稳定性。Scholz 等[16]通过体外生物力学实验证实单节段 ACDF 使用 Zero-P 可以提供同前路钛板相似的稳定性。Lee 等[17]比较单独使用传统融合器、联合前路钛板和 Zero-P 的单节段 ACDF 的临床疗效，发现 Zero-P 固定的稳定性优于单独使用传统融合器，而差于联合前路钛板固定。我们观察到 S 组有 5 例椎体内的 ROI-C 嵌片周围出现透亮区提示假体松动，说明由于应力增加 ROI-C 嵌片固定的稳定性呈现下降的表现。由此可见，ROI-C 固定嵌片的稳定性是有一定限度的。本研究旨在阐明 ROI-C 沉降的危险因素，为选择合适的融合固定方式治疗颈椎间盘退变性疾病提供依据。

Fujibayashi 等[18]发现使用钛合金融合器治疗的所有病例术后早期都存在 1~2mm 沉降。Barsa 等[19]和 Lee 等[20]观察到 CS 于手术半年后多不再发展。Hakało 等[21]通过动物力学实验总结 CS 过程包括初期融合器与椎间隙互相调整适应的快速发展阶段和之后的融合器缓慢沉降阶段。融合器与终板结合使应力均衡分布标志着初期阶段的结束，而第二阶段则终止于椎体间形成足以承担和传递应力的骨性融合。从时间点上看，椎间获得骨性融合是 CS 的终结点，适应性沉降则是椎节融合过程的必经环节。有学者[22]认为 CS 是椎间融合的不利因素。有些矛盾的是，Pechlivanis 等 [23]和 Klingler 等[24]却发现椎间融合组病例较未融合组伴有更大程度的 CS。也有学者认为 CS 可增加移植骨和相邻椎体骨小梁的接触而促进椎间融合，因此置入融合器的位置及植骨的质和量是 CS 的相关因素[6,24,25]。此外，过度撑开椎间隙，损伤或去除融合器相邻骨性终板，粗暴强行置入融合器也是 CS 的术中危险因素[26]。颈椎终板的生物力学强度自头侧向尾侧呈递减趋势，由中央至外周逐渐增大[5]，而终板承载应力则随着椎体向下移行逐渐增加。正是考虑到 CS 的术中危险因素和颈椎终板的力学特点，我们在术中仔细刮除软骨终板，尽量保留骨性终板完整性，确定 ROI-C 型号时去除 Caspar 撑开器，台下助手牵引颈部使融合间隙和其他椎间盘均匀受力后轻柔置入合适的 ROI-C，并将融合器尽量靠近椎体前缘。

椎间盘、骨和韧带组织退变可导致颈椎曲度变化，甚至由生理性前凸发展成后凸畸形，颈椎力线移至椎体前方又可加速退变。ACDF 治疗颈椎退变性疾病能够恢复和保持矢状位生理性前凸是减少融合器沉降和获得满意疗效的重要因素。ACDF 术后颈椎曲度变化的生物力学机制尚不清楚。Klingler 等[24]应用融合器行单节段 ACDF 发现术后 CA 改善程度和 SA 改善程度存在正相关的

线性关系。Chien 等[27]发现连续双节段 ACDF 的病例术后 CA 平均有 25%的恢复，而单节段 ACDF 术后 CA 恢复不明显。我们的病例中可以观察到部分病例置入 ROI-C 使得 ADH 恢复后 SA 即刻得到矫正，CA 随之也有不同程度的恢复，而颈椎曲度仍未恢复到生理性前凸的病例多出现 CS。这种现象的原因可能是由于退变导致椎间隙发生结构性改变，尤其 ADH 变低无法匹配 ROI-C 前高后低的解剖型前凸角度而出现 ROI-C 与相邻终板的前半部分紧密接触，而与终板后半部分接触面积较少。加之颈椎曲度后凸致颈椎轴向力线前移使得 ROI-C 前部应力集中。这些可能是 CS 多发生在终板前部的原因。由此可见，单节段 ACDF 术前准确评价颈椎曲度改变和认识术后颈椎曲度变化的规律是选择最优手术方式的先决条件。

CS 不但造成椎间高度丢失和神经根管容积变小，还能导致融合节段前凸角度减小，甚至出现 SA 和 CA 后凸，使融合节段应力集中，加速邻近椎节退变。Lee 等[20]通过平均 21.3 个月的随访发现，单节段 ACDF 的 CS 病例的颈部和臂部疼痛评分结果均比未沉降者差。长期来看，CS 可能影响治疗效果，但是这种负性关系并未得到广泛的证实。Wu 等[28]报道 CS 者长期疗效同未沉降者相比并无明显差别，指出恢复和维持颈椎前凸曲度才是获得优良治疗结果的保证。

综上所述，ROI-C 的固定嵌片是相对稳定的固定装置，可增加融合节段的稳定性。术前 CA 后凸和年龄 60 岁以上是单节段 ACDF 术后 ROI-C 沉降的危险因素。选择 ROI-C 行单节段 ACDF 治疗颈椎间盘退变性疾病时应考虑这两项因素的影响。

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消息

《中国脊柱脊髓杂志》2017 年出刊计划

为了更好地实现学术期刊服务于学术交流与传播的目标，也为了给作者、读者提供一个深入探讨学术问题的平台，本刊 2017 年针对脊柱脊髓领域内的一些学术焦点、热点，将以专刊（专题）形式登载相关学术专题内容的稿件，为读者全面展示该专题最新学术成果和研究进展。

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