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·临床研究·

经椎弓根动态固定术与髓核摘除术治疗腰椎间盘突出症的中长期临床疗效分析

房 朗[1],宋 磊[1],罗 磊[2],张承旻[1],赵 晨[2],张泽桐[1],罗 飞[1],侯天勇[1],周 强[1,2] (1.陆军军医大学第一附属医院骨科,重庆 400038;2.重庆医科大学附属第三医院骨与创伤中心,重庆 401120)

[摘 要] **目的** 通过前瞻性研究评估经后路椎弓根动态固定术与单纯髓核摘除术治疗单节段腰椎间盘突出症的中长期临床疗效。**方法** 选取陆军军医大学第一附属医院2012年7月至2014年8月收治的104例腰椎间盘突出症患者,其中19例因未能完成随访剔除本研究,最终85例纳入本研究。根据患者术式选择分为动态组44例和单摘组41例,术后随访5年以上。比较2组患者临床评估指标(VAS、ODI)、影像学评估指标(腰椎活动度、椎间隙高度)及并发症(手术节段腰椎间盘突出复发、腰椎不稳、螺钉松动及伤口感染)情况。**结果** 动态组在末次随访时VAS及ODI优于单摘组($P<0.05$)。末次随访时动态组椎间隙高度下降约12.75%,单摘组下降24.17%,2组比较差异有统计学意义($P<0.05$)。患者腰椎整体活动度术前与术后组内比较差异无统计学意义($P>0.05$),2组间比较差异也无统计学意义($P>0.05$);动态组手术节段末次随访时保留(4.05±0.79)°的活动度,约为术前活动度的45.30%,末次随访时邻近节段活动度与术前比较差异无统计学意义($P>0.05$)。动态组无腰椎间盘突出复发,单摘组复发5例,其中4例行保守治疗,1例再次手术。动态组未出现腰椎失稳病例,单摘组有3例失稳病例,其中1例因手术节段滑脱,出现腰痛及下肢神经症状再次手术,2例因无症状随访观察;2组均未出现螺钉松动及伤口感染病例。**结论** 经椎弓根动态固定术中长期临床疗效优于单纯髓核摘除术,能更好地维持椎间隙的高度,减少手术节段的复发和腰椎不稳的发生。

[关键词] 腰椎间盘突出症;髓核摘除术;经椎弓根动态固定;Dynesys系统

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Long-term prospective control study of transpedicle dynamic stabilization and discectomy in the treatment of lumbar disc herniation

FANG Lang[1],SONG Lei[1],LUO Lei[2],ZHANG Cheng-min[1],ZHAO Chen[2],ZHANG Ze-tong[1],LUO Fei[1],HOU Tian-yong[1],ZHOU Qiang[1,2] (1. Department of Orthopedics, First Affiliated Hospital of Army Medical University, Chongqing 400038, China; 2. Department of Orthopedics and Trauma, Third Affiliated Hospital of Chongqing Medical University, Chongqing 401120, China)

Abstract: Objective A prospective control study was conducted to evaluate the clinical and imageological outcomes of transpedicle dynamic stabilization and discectomy in the treatment of single segment lumbar disc herniation. **Methods** Totally 104 patients of lumbar disc herniation who were admitted into the first affiliated hospital of the Army Medical University from July 2012 to August 2014 were selected.

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[通信作者] 周 强,E-mail:zq_cyf3@163.com

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Among them, 19 patients were excluded from this study due to failure to complete the follow-up, and 85 patients were finally included in this study. The 85 patients were divided into the dynamic group (44 cases) and the discectomy group (41 cases) according to their choice of operation method, and they were followed-up for 5 years at least. The clinical assessment indicators (VAS and ODI), imageological assessment indicators (lumbar mobility and intervertebral height) and complications (recurrence of lumbar disc herniation at the surgical segment, lumbar instability, screw loosening and wound infection) of the two groups were compared and analyzed. **Results** The VAS and ODI scores of the dynamic group at the last follow-up were better than those of the discectomy group ($P<0.05$). At the last follow-up, the intervertebral height of the dynamic group decreased by about 12.75% while the discetomy group decreased by about 24.17%, and the difference was statistically significant ($P<0.05$). There was no statistically significant difference between the preoperative and postoperative lumbar mobility of the total lumbar in both of the two groups ($P>0.05$), and there was no statistical significance between the two groups ($P>0.05$). At the last follow-up, the range of motion of the operative segment in the dynamic group remained (4.05 ± 0.79) degrees, about 45.30% of the preoperative range of motion. Compared with that before surgery, there was no satatistically significant difference in the range of motion of the adjacent segment at the last follow-up ($P>0.05$). There was no recurrence of lumbar disc herniation in the dynamic group, while there were 5 cases in the discectomy group, among which 4 cases received conservative treatment and 1 case underwent reoperation. There was no patient of lumbar instability in the dynamic group, and there were 3 cases in the discetomy group. One of them had a second operation due to low back pain and radiculopathy caused by spondylolisthesis, and the other two cases were followed up for no symptoms. There was no patient of screw loosening and wound infection in the two groups. **Conclusion** The long-term clinical effect of transpedicle dynamic stabilization is better than that of discetomy, and it can better maintain the height of intervertebral space and reduce the recurrence of operative segment and lumbar instability.

Keywords: lumbar disc herniation; discectomy; transpedicle dynamic stabilization; Dynesys system

腰椎间盘突出症是骨科的常见病、多发病,严重影响患者的生活质量[1]。目前腰椎间盘突出症的治疗方式主要包括保守治疗及手术治疗,保守治疗能缓解大多数患者的临床症状,经保守治疗无效或严重的腰椎间盘突出症则需要手术干预[2-3]。手术治疗中传统的髓核摘除术在临床上能有效缓解患者的腿痛症状,且费用相对便宜,临床上应用较广。但该术式也存在一些问题,比如手术节段突出复发率可高达7.1%~23%,手术节段腰椎会出现失稳,易发生各种综合原因引起的腰痛等问题[4-8]。经典的后路椎间融合术疗效确切,手术节段的复发率几乎为零,但也存在手术节段活动丧失、植骨不融合等并发症[9-11]。因此,腰椎动态固定的理念逐渐发展,既能分担腰椎手术节段的应力,限制腰椎的过度活动,又保留了手术节段的活动度。Dynesys 系统是目前临床上应用最为广泛的动态固定装置,有文献报道 Dynesys 治疗腰椎间盘突出症具有良好的效果,也有部分文献报道 Dynesys 手术与传统手术在治疗腰椎间盘突出症上没有明显的优势[12-13]。但上述文献报道多为短期的回顾性研究,循证医学证据等级较低。因此,本课题组通过前瞻性研究评估动态固定术与髓核摘除术治疗单节段腰椎间盘突出症的中长期临床疗效、影像学结果、腰椎间盘突出复发及手术节段腰椎不稳等并发症的发生情况,以期为临床提供更详实有效的参考依据。

1 资料与方法

1.1 临床资料

选择陆军军医大学第一附属医院 2012 年 7 月至 2014 年 8 月收治的 104 例腰椎间盘突出症患者为研究对象,其中 19 例因未能完成随访剔除本研究,最终 85 例单节段腰椎间盘突出症患者纳入本研究。本研究通过陆军军医大学第一附属医院伦理委员会的批准[伦理号:2012 年伦审科研第(14)号],并分别在中国临床试验注册中心(注册号:chiCTR-ONRC-12002280,2012-06-15)及 ClinicalTrials 国际临床试验中心(注册号 NCT02110186)进行注册。由经验丰富的脊柱外科医生告知经后路椎弓根动态固定术与单纯髓核摘除术的优缺点,患者自愿选择手术方式,分为动态组 44 例和单摘组 41 例。单摘组采取经后路单纯髓核摘除术,其中男 24 例,女 17 例,平均年龄(40.56 ± 11.15)岁。动态组采取经后路髓核摘除术联合椎弓根动态固定术,其中男 23 例,女 21 例,平均年龄(43.52 ± 8.5)岁。纳入标准:①诊断为单节段腰椎间盘突出症,且有明确的手术指征;②邻近节段无椎间盘突出;③年龄 18~60 岁;④签订临床试验知情同意书,接受髓核摘除或 Dynesys 动态固定手术。排除标准:①合并有其他腰椎疾病(如腰椎滑脱、腰椎感染、腰椎肿瘤等);②既往有腰椎手术史;③有精神疾病、化学物质依赖;④妊娠期妇女;⑤有其他严重系统疾病。本研究 2 组患者临床资料比较,差异无统计学意义($P>0.05$),具有可比性(表 1)。

表 1 患者临床资料比较

组别	n	年龄（岁）	男/女（例）	随访时间（月）	BMI（kg/m^2）	合并疾病[例(%)]		节段(例)	
						糖尿病	高血压	L_4/L_5	L_5/S_1
动态组	44	43.52±8.50	23/21	71.27±7.12	24.27±3.03	7(15.91)	7(15.91)	18	26
单摘组	41	40.56±11.15	24/17	70.44±6.40	23.54±2.84	4(9.76)	9(21.95)	15	26
P		0.171	0.562	0.574	0.257	0.398	0.476	0.683	

1.2 手术方法

所有患者采用常规静吸复合麻醉后置于俯卧位，选择后正中皮肤切口。动态组采用 Wiltse 入路置入螺钉，避免损伤关节囊[14]。Wiltse 入路从最长肌与多裂肌之间置入椎弓根螺钉，Wiltse 入路示意图见图 1。根据术前患者的临床表现、体征及影像学特点行单侧或双侧椎板间开窗减压，摘除突出及破碎的髓核组织。通过连接器将合适长度的间隔器分别置入双侧椎弓根螺钉之间，在保留腰椎生理前凸的情况下适当撑开椎间隙。双侧放置引流管后逐层缝合伤口。单摘组采用传统后正中入路，根据患者术前临床表现、体征及影像学特点行单侧或双侧椎板间开窗减压，摘除突出及破碎的髓核组织，在减压侧放置引流管后逐层缝合伤口。

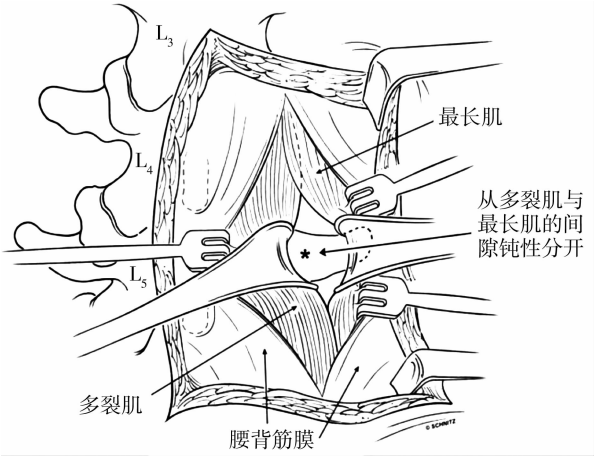


图 1 Wiltse 入路示意图

1.3 临床、影像学及并发症评估指标

所有患者随访 5 年以上，临床评估指标包括腰痛和腿痛的视觉模拟评分（VAS）、Oswestry 功能障碍指数（ODI）。影像学评估包括腰椎整体活动度、手术节段活动度、手术节段上一邻近节段活动度、手术节段椎间隙高度（腰椎侧位 X 射线片上手术节段椎间隙前缘高度与后缘高度的平均值）。并发症评估指标包括腰椎间盘突出症复发、手术节段腰椎不稳（在过伸过屈位时上下椎体水平位移 > 3 mm 或角度变化 L_5/S_1 > 15°、其余节段 > 10°）、螺钉松动及伤口感染情况。

1.4 统计学分析

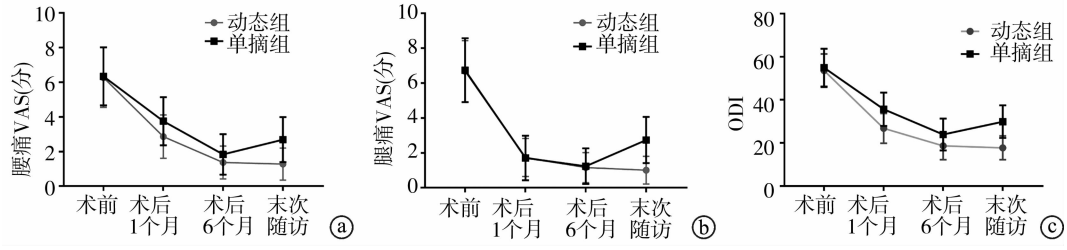
所有的数据分析均采用 SPSS 23.0 统计软件，术前对 2 组患者年龄、BMI、随访时间、腰腿痛 VAS、ODI 进行独立样本 t 检验。对 2 组患者性别比例、手术节段比例、合并高血压及糖尿病比例进行 χ^2 检验。对 2 组患者术前与术后腰腿痛 VAS、ODI、腰椎整体活动度、手术节段活动度、手术节段上一邻近节段活动度、手术节段椎间隙高度进行重复测量方差分析。检验水准为 $\alpha = 0.05$。$P < 0.05$ 为差异有统计学意义。

2 结果

2.1 临床结果

术后 1 个月、6 个月 2 组患者腰痛及腿痛 VAS 持续降低（$P < 0.05$）。末次随访时，动态组腰腿痛 VAS 较术后 6 个月无明显变化（$P > 0.05$），但单摘组腰腿痛 VAS 较术后 6 个月有所上升（$P < 0.05$）。单摘组术后腰痛 VAS 高于动态组，在术后 1 个月、6 个月及末次随访时差异均有统计学意义（$P < 0.05$），见图 2a。术后 1 个月及 6 个月2 组患者腿痛 VAS 比较差异无统计学意义（$P > 0.05$），末次随访时，单摘组患者腿痛 VAS 高于动态组，差异有统计学意义（$P < 0.05$），见图 2b。

术后 2 组患者 ODI 较术前均有明显改善（$P < 0.05$），动态组患者术后 1 个月、6 个月及末次随访时 ODI 均低于单摘组，差异有统计学意义（$P < 0.05$），见图 2c。



a：腰痛 VAS；b：腿痛 VAS；c：ODI

图 2 VAS 及 ODI

2.2 影像学结果

术前2组患者腰椎整体活动度、手术节段活动度及手术节段上一邻近节段活动度比较差异无统计学意义($P>0.05$)。术后6个月及末次随访时,2组患者整体活动度比较差异无统计学意义($P>0.05$)。动态组患者术后6个月手术节段活动度较术前明显减小($P<0.05$),末次随访时手术节段活动度较术后6个月减小,动态组手术节段末次随访时保留约(4.05±0.79)°的活动度,约保留术前活动度的45.30%($P<0.05$)。单摘组术后6个月、末次随访时手术节段活动度较前一随访时间点均增加,但与术前相比差异无统计学意义($P>0.05$)。动态组手术节段上一邻近节段活动度术后6个月、末次随访时较前一随访时间点均增加,但与术前相比差异无统计学意义($P>0.05$);单摘组上一邻近节段活动度术后6个月、末次随访时较前一随访时间点均减小,但与术前相比差异无统计学意义($P>0.05$),见表2。

术前2组患者手术节段椎间隙高度比较差异无统计学意义($P>0.05$);术后1个月动态组患者手术节段椎间隙高度与术前比较,差异无统计学意义($P>0.05$),术后6个月时较术前下降约7.718%($P<0.05$),末次随访时椎间隙高度较术后6个月下降约5.495%($P<0.05$)。单摘组椎间隙高度在术后1个月、6个月、末次随访时椎间隙高度较前一随访时间点均下降,术后6个月较术前下降约17.763%,末次随访时较术后6个月下降约7.733%。末次随访时动态组手术节段椎间隙高度较术前下降约12.75%,单摘组椎间隙高度较术前下降约24.17%,2组比较差异有统计学意义($P<0.05$),见图3。

表2 患者腰椎活动度比较($\bar{x}\pm s$,°)

组别	n	腰椎整体活动度			手术节段活动度			上一邻近节段活动度		
		术前	术后6个月	末次随访	术前	术后6个月	末次随访	术前	术后6个月	末次随访
动态组	44	37.94±12.26	36.24±10.79	39.61±11.36	8.94±2.53	4.47±0.96	4.05±0.79	8.36±2.28	8.65±2.37	9.16±2.54
单摘组	41	38.49±11.32	37.67±10.85	38.70±12.49	8.73±2.87	8.89±2.98	9.59±3.05	8.41±2.43	8.29±2.39	8.15±2.47
P		0.830	0.544	0.726	0.721	0.000	0.000	0.922	0.488	0.067

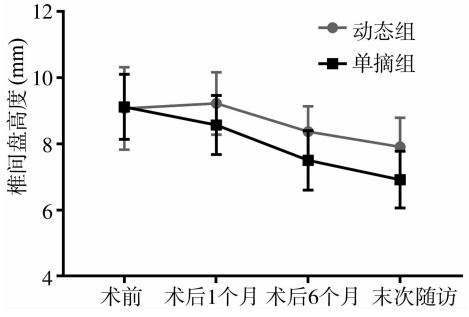


图3 手术节段椎间隙高度变化

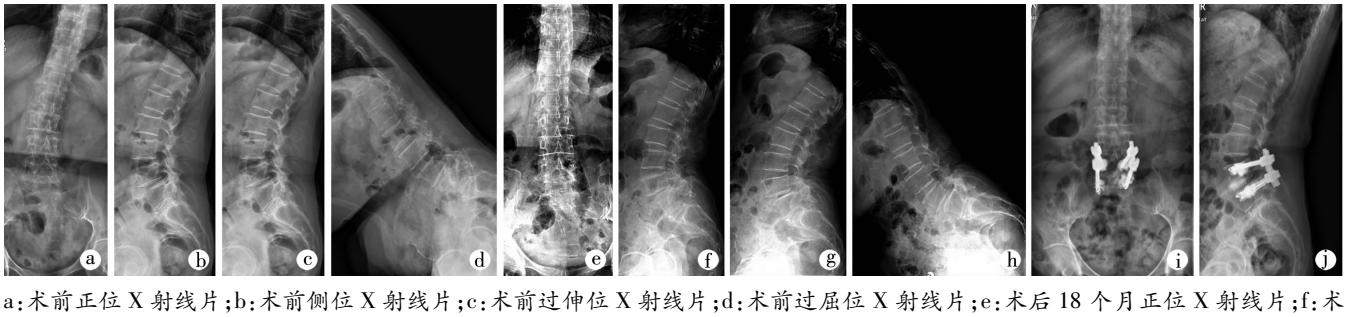
2.3 并发症

单摘组5例患者手术节段椎间盘突出复发,其中1例接受椎间融合手术后治愈,4例行保守治疗,症状缓解。动态组无椎间盘突出复发患者。单摘组末次随访时发现3例腰椎不稳,其中1例因腰椎滑脱出现腰痛及下肢神经症状行椎间融合手术,其余2例无腰痛症状予随访观察。动态组未发现腰椎不稳病例。2组均未出现伤口感染及螺钉松动病例。

2.4 典型病例

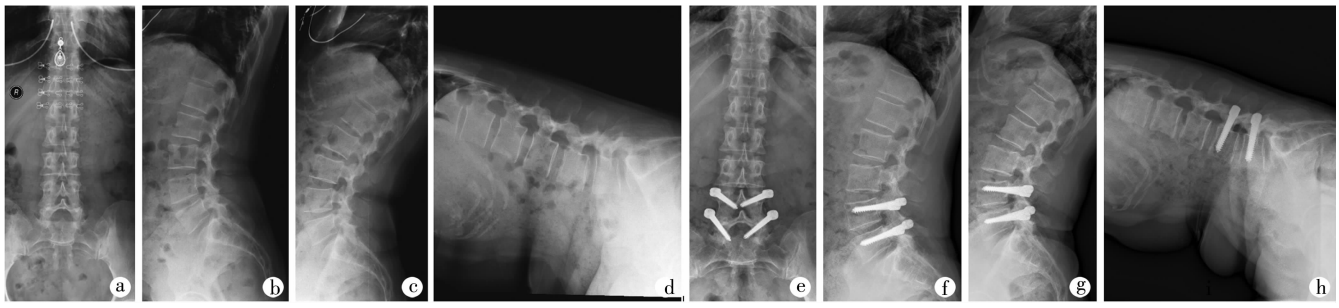
单摘组典型病例:患者,女,52岁,L_4/L_5腰椎间盘突出症,行L_4/L_5髓核摘除术。术后腰腿痛缓解。术后18个月再次出现腰腿痛,诊断为L_4/L_5椎体滑脱症(Ⅰ度退行性滑脱),行经后路L_4/L_5椎间融合术,术后症状缓解(图4)。

动态组典型病例:患者,女,46岁,诊断为L_4/L_5腰椎间盘突出症,行经后路L_4/L_5髓核摘除联合经椎弓根动态固定术,术后症状缓解,术后5年患者无腰腿痛症状(图5)。



a:术前正位X射线片;b:术前侧位X射线片;c:术前过伸位X射线片;d:术前过屈位X射线片;e:术后18个月正位X射线片;f:术后18个月侧位X射线片;g:术后18个月过伸位X射线片;h:术后18个月过屈位X射线片;i:融合术后正位X射线片;j:融合术后侧位X射线片

图4 单摘组典型病例影像资料



a:术前正位X射线片;b:术前侧位X射线片;c:术前过伸位X射线片;d:术前过屈位X射线片;e:末次随访正位X射线片;f:末次随访侧位X射线片;g:末次随访过伸位X射线片;h:末次随访过屈位X射线片

图5 动态组典型病例影像资料

3 讨论

腰椎间盘突出症发病率较高,影响患者的生活质量,手术治疗是解决腰椎间盘突出症症状的有效手段。髓核摘除术因价格便宜、创伤小、短期疗效佳在临床上应用广泛[15-16]。但髓核摘除术因破坏了腰椎固有结构,患者腰椎长期承受压力会出现腰椎不稳、慢性腰痛、腰椎间盘突出复发等问题[17]。Dynesys动态固定术因提供内固定系统,既稳定了手术节段,减轻了手术节段椎间盘压力,又避免了融合术后手术节段活动度的丢失[18]。理论上Dynesys动态固定术能解决髓核摘除术的上述问题,但缺少相关研究,特别是高等级的循证医学证据。

本研究证实,与单纯髓核摘除术相比,Dynesys动态固定术中长期临床疗效更好,具有较低的椎间盘突出复发率和手术节段不稳发生率。Aihara等[19]报道了一项髓核摘除术后5年的随访结果,患者再手术率为12.4%,常见的原因是手术节段椎间盘再次突出(7.01%)、手术节段不稳或滑脱(2.28%)。Daly等[20]提到,腰椎髓核摘除术是美国最为常见的脊柱手术,每年超过300 000例患者接受该手术,但是术后需严格限制腰椎的活动,以减少椎间盘的再次突出,延缓椎体不稳的进展。Dynesys动态固定术能够明显减少手术节段椎间盘的再次突出,并保持手术节段腰椎的稳定性,患者可早期进行功能锻炼,不必过于限制腰椎活动及日常活动,能更快地恢复工作,更好地生活,并保持积极的心态。

本研究证实Dynesys动态固定术后短期内能够维持甚至提高手术节段椎间隙的高度,但术后6个月手术节段椎间隙高度较术前有所下降,下降幅度约7.718%,末次随访时椎间隙高度与术后6个月比较有轻微下降,下降幅度平缓,末次随访时椎间隙高度较术后6个月下降约5.495%,较术前下降约12.75%。单摘组术后末次随访时较术前下降约24.17%,2组差异明显。由此我们认为,Dynesys动态固定术与髓核摘除术相比,能够延缓椎间隙高度的下降,从而相对地维持椎间隙的高度。在术后6个月后,Dynesys动态组椎间隙高度下降缓慢,而单摘组椎间隙术后则持续性下降,下降幅度明显。有研究证实椎间隙高度的维持与腰痛呈负相关[21-23]。Lidar等[21]的一项前瞻性研究证实,病态性肥胖的患者通过外科减肥手术后因体重减轻,椎间隙高度增加,患者轴向及根性腰痛大幅度减轻,生活质量得以提高。因此,我们推断术后5年单摘组腰腿痛VAS与ODI增加与椎间隙高度下降有着一定的关系。

腰椎融合术后手术节段上一邻近节段活动度会增加,与邻椎病的发生密切相关,本研究证实,在末次随访时动态组手术节段上一邻近节段活动度较术前增大,但差异无统计学意义,单摘组手术节段上一邻近节段活动度与术前比较差异也无统计学意义。Wu等[24]的一项平均随访50.3个月的腰椎融合与Dynesys动态固定术的回顾研究证实,Dynesys动态固定手术节段上一邻近节段活动度增大,但融合组手术节段上一邻近节段活动度比Dynesys组增加更多。Han等[25]的一项至少随访4年的回顾性研究的结果表明,Dynesys动态固定术与融合术相比在预防邻椎病上并无优势。本研究Dynesys动态固定术手术节段在末次随访时保留约(4.05±0.79)°的活动度,在末次随访时未出现邻椎病的情况,可能与本组患者术前邻近节段无椎间盘突出有关,是否对邻近节段有保护作用我们之后将继续观察并与单节段融合术对比。

综上所述,Dynesys动态固定术的中长期临床疗效优于髓核摘除术,既解决了髓核摘除术后复发及术后手术节段不稳的问题,又能维持椎间隙的高度,与髓核摘除术相比具有较大的优势,在患者经济条件允许的情况下,是一个比较好的选择。虽然现阶段学术界对腰椎动态固定有一定的争议,但这只是现阶段动态固定技术存在的一些不足,动态固定术的理念是超前的,

可重建腰椎的功能,如同关节置换一样,重建了关节功能,最终将被大众所接受。

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