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显微镜下减压联合前路 Zero-P 治疗颈椎病的早期临床疗效分析 *

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摘要 目的:探讨前路颈椎显微镜辅助下精准减压联合前路椎间隙 Zero-P 融合器置入治疗颈椎病的早期临床疗效。**方法:**回顾性分析 2016 年 6 月至 2018 年 1 月我院收治的 43 例颈椎病患者,处理节段共 73 个;患者均行显微镜辅助颈椎前路减压、髓核切除、Zero-P 置入融合内固定术。记录患者手术节段、手术时间,术中失血量及并发症。手术前,术后 1 个月、3 个月、6 个月、末次随访时的颈部及上肢疼痛视觉模拟评分（Visual Analogue Scale,VAS）、颈部日本骨科协会评分（Japanese Orthopedic Association,JOA)和颈椎残障功能指数(Neck Disability Index,NDI),并采用配对 t 检验对不同时间点的评分进行分析,评估临床疗效。并同期行颈椎 X 线、CT 及 MRI 检查,测量和评估椎间隙高度、颈椎 Cobb 角的改变情况和邻近节段异位骨化形成(Adjacent Level Ossification Development,ALOD)。**结果:**所有患者术后均获得随访,随访时间 12-18 个月,平均(14.9± 2.2)个月。平均手术时间(82.2± 20.9) min,失血量(91.5± 33.7) mL;未发生神经和血管损伤等严重并发症。与术前相比,患者术后 1 个月、3 个月、6 个月及末次随访时的 VAS 评分、JOA 评分、NDI 评分、椎间隙高度及 Cobb 角均明显改善,差异有统计学意义(P<0.05)。但术后随访时间点比较,差异无统计学意义(P>0.05)。术后出现轻度吞咽困难 2 例,中度和重度吞咽困难各 1 例。随访期间,所有患者均获椎间骨性融合,未发生 Zero-P 融合器松动、滑脱或断裂,椎体未出现继发性骨折。**结论:**显微镜辅助颈椎前路椎间盘切除、Zero-P 融合器置入治疗颈椎病,能够精准的去除神经脊髓组织的压迫,术后短期和中期临床疗效良好,同时显微镜下止血、术中出血少;视野清晰、手术安全性高。

关键词:显微镜;零切迹融合器(Zero-P);颈椎病;临床疗效

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Early Clinical Efficacy Analysis of Microsurgical Decompression Combined with Anterior Zero-P in the Treatment of Cervical Spondylosis*

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ABSTRACT Objective: To evaluate the early clinical effect of anterior cervical decompression assisted by microscope combined with Zero-P fusion device in anterior intervertebral space in the treatment of cervical spondylosis. **Methods:** From June 2016 to January 2018, 43patients with cervical spondylosis in our hospital were retrospectively studied, with a total of 73 segments. Microscopically assisted anterior cervical decompression, nucleus pulposus removal, zero-p fusion and internal fixation were performed in all patients. Operative segments, operative time, intraoperative blood loss and complications were recorded. Additionally, the Visual analogue scale (VAS), Japanese orthopaedic association score (JOA) and cervical disability function index (NDI) before operation, 1 month, 3 months, 6 months and the last follow-up after operation were used to evaluate the clinical efficacy. Paired t test was used to analyze the scores at different time points.Meanwhile, cervical X-ray, CT and MRI examinations were performed simultaneously to measure and evaluate the height of intervertebral space, changes of cervical Cobb Angle and Adjacent segmental Ossification Development (ALOD). **Results:** All patients were followed up postoperatively for 12-18 months, with(14.9± 2.2) months on average. with operation time of(82.2± 20.9) min on average, and blood loss of(91.5± 33.7) mL. No serious complications such as nerve and blood vessel injury occurred.VAS score, JOA score, NDI score, intervertebral height and Cobb Angle of the patients at 1, 3, 6 months after operation and the last follow-up were significantly improved compared with those before operation, and the differences were statistically significant (P<0.05). However, there were no statistically significant relationship between eachpoint (P>0.05). Mild dysphagia occurred in 2 cases, moderate dysphagia and severe dysphagia in 1 case respectively. During the follow-up period, all patients were provided with intervertebral osseous fusion without any loosening, slipping or fracture of zero-p fusion cage or secondary vertebral fracture. **Conclusions:** The anterior cervical discectomy assisted by the microscope and the zero-p fusion device implantation for the treatment of cervical spondylosis can accurately remove the compression of the neurospinal cord tissue, with good clinical efficacy in the short and medium term after the operation, as well as hemostasis

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under the microscope and less intraoperative bleeding.Clear vision and high safety.

Key words: Microscope; Zero-profile fusion device(Zero-P); Cervical spondylosis; Clinical efficacy

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前言

颈椎前路椎间盘切除融合术(Anterior Cervical Discectomy Fusion, ACDF)在 20 世纪 50 年代首次被报道,后被认为治疗颈椎病的经典外科治疗方法[1,2]。目前,自体骨或钛网植骨椎间融合结合前路钢板固定已广泛的应用于临床。考虑到独立的融合器或钛笼与植入物下沉的高发生率相关,会导致继发性后凸,外科医生更倾向于放置钛板内固定以确保稳定性,并预防随后的内置物相关并发症,包括脱位和假关节[3,4]。然而,前路钛板内固定的副作用,如软组织损伤和吞咽困难,仍然是不可避免的,尤其是当患者颈椎需要前路多节段融合固定时;以及前置钛板需椎体前方广泛剥离、导致邻近节段退变加速[5,6]。鉴于此,美国食品和药物管理局于 2008 年开发了一种新的零切迹颈椎椎间融合器(Zero-Profile,Zero-P, Synthes, Swiss),并批准用于治疗颈椎退行性疾病患者。在该系统中,在假体的前部附着一个设计好的带有四个角度控制的螺钉轨迹的板,其中螺钉可以通过端板进入椎体。整个装置可植入椎间隙,提供足够的稳定性,避免植入物与椎前软组织接触,降低内置物所致的并发症及邻近节段退变[7]。而颈椎手术显微镜减压的引入,可进一步提高术者对局部组织的分辨能力,降低组织损伤,更彻底地清除致压组织,充分减压,同时更好保护硬脊膜及脊髓[8]。本研究通过回顾分析我院行显微镜辅助下颈椎前路切开探查、髓核摘除、Zero-P 融合器置入融合内固定术患者的相关资料,分析显微精准减压联合 Zero-P 治疗颈椎病的有效性。

1 资料与方法

1.1 纳入及排除标准

纳入标准:① 临床症状表现为严重的颈部疼痛伴或不伴有上肢根性症状或出现行走不稳,走路有踩棉花感,双手持物及精细活动能力减退;并经过严格保守治疗三个月无效;② 影像学资料提示责任节段位于 C3/4~C6/7 之间;③ 患者症状、体征及影像学检查是一致的。

排除标准:① 颈椎肿瘤、脊柱感染以及类风湿性关节炎、神经退行性疾病;② 患有颈椎先天性畸形、颈椎骨折脱位、发育性颈椎管狭窄、后纵韧带骨化不能通过前路完全切除等疾病;③ 其它严重的全身性疾病或难以耐受手术。

1.2 一般资料

回顾性分析 2016 年 6 月至 2018 年 1 月我院收治的 43 例颈椎病患者,处理节段共计 73 个;其中单节段 16 例,双节段 20 例,三节段 7 例;男性 25 例,女性 18 例;年龄 31-76 岁,平均(55.3± 11.3)岁;病变节段:C3/4 10 例,C4/5 19 例,C5/6 30 例,C6/7 14 例。均采用显微镜辅助下颈椎前路切开探查、髓核摘除、Zero-P 融合器置入融合内固定术(显微镜,Carl Zeiss 公司;Zero-P,Debuy,美国)。

1.3 手术方法

患者在气管插管下进行全身麻醉,采取仰卧位,肩部垫高以暴露手术区域。C 型臂体位定位标记,常规消毒铺巾。自患者颈前右侧做横向手术切口,经食管气管鞘与颈动脉鞘间做钝性分离至椎体前方,C 型臂透视确定责任节段,撑开椎间隙;显微镜调整术区距离及目距,镜下切除责任节段的椎间盘,并刮除上下椎体软骨,刮匙及椎板咬骨钳充分去除残余的椎间盘和椎体后缘增生的骨赘,完整切除后纵韧带暴露至硬膜膨隆,显微镜对于出血点给予双及电凝止血,并可观察到硬膜内脊髓漂动状态。并用神经剥离子探查椎体后缘与硬膜外间隙有无残留的髓核组织,以达到彻底充分精准减压。使用合适的零切迹椎间融合器模具进行试模,并且将适当类型的 Zero-P 装置植入自体或同种异体骨,将 Zero-P 插入椎间隙并确认 Zero-P 的深度,依次沿着 Zero-P 螺口方向将锁定螺钉拧入椎体,冲洗,放置负压引流管,并关闭切口。附典型病例见图 1。

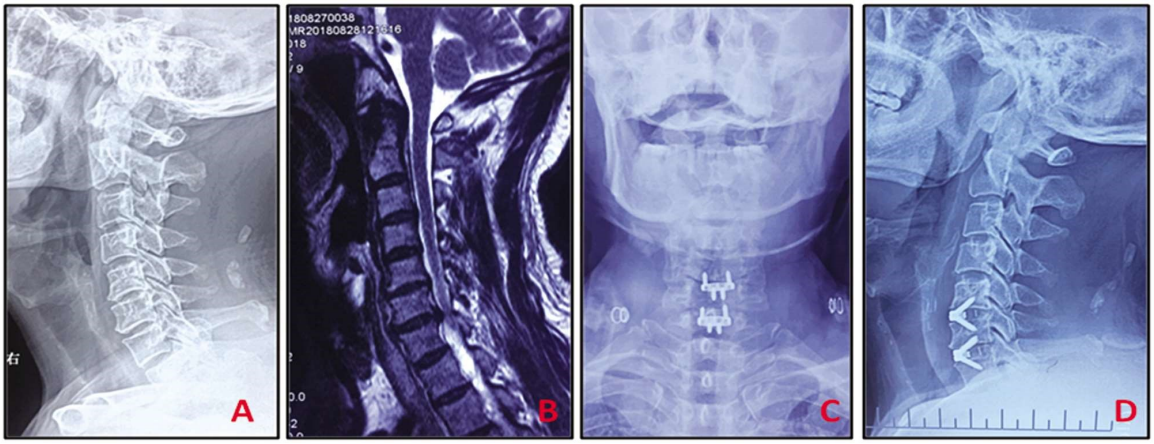

图 1 显微镜下减压联合前路 Zero-P 治疗颈椎病

Fig.1 Treatment of cervical spondylosis by Microsurgical decompression combined with anterior Zero-P

A 69-year-old man. The preoperative X-ray imaging (A) showed cervical degeneration. Sagittal magnetic resonance imaging T2 (B) showed spinal cord compression secondary to disc herniation in C5/6 and C6/7, and the intervertebral disc height was lost. At the 12 months' follow-up, the X-ray imagings (C,D) showed improvement of the cervical lordosis and disc height, the Zreo-P implants were stable, and the operative segment had no abnormal activity.

1.4 术后处理

术后常规给予抗生素预防感染,激素、甘露醇给予神经消肿,甲钴胺肌注营养神经治疗。手术后 1 天给予复查颈椎 X 线正侧位;2 天允许患者戴费城颈围下地行走活动,应用 4 周。所有患者至少随访 1 年,定期复查。

1.5 观察指标

收集的数据包括手术时间、术中失血量、并发症、临床和影像学表现。术前行颈椎 X 线、CT、MRI 检查。术后常规行颈椎 X 线片。手术前,手术后 1 个月、3 个月、6 个月及末次随访时进行临床及影像学评估。使用图像存档和通信系统(PACS)成像系统测量放射学结果。

临床疗效评价:对患者手术前、手术后 1 个月、3 个月、6 个月及末次随访时进行 VAS 评分、JOA 评分及 NDI 评分; 记录手术时间、失血量。术后并发症吞咽困难采用 Bazaz 分级评定[9](表 1)。

表 1 Bazaz 吞咽困难分级系统

Table 1 Bazaz Grading System for Dysphagia

Severity	Liquid	Solid
None	None	None
Mild	None	Rare
Moderate	None or rare	Occasionally
Severe	None or rare	Frepuent

影像学评价: 手术后 1 个月、3 个月、6 个月及末次随访时采集颈椎正侧位 X 线片,手术后 6 月行颈椎 CT 检查。

颈椎生理曲度(Cobb 角):中立位颈椎侧位 X 线片测量 C2 椎体下终板切线和 C7 椎体下终板切线的夹角(图 2)。

椎间隙高度(disc height,DH):手术后中立位颈椎 X 线侧位片,测量椎间隙前缘高度与椎间隙后缘高度的平均值。

邻近节段退变的 X 线片评估: 采集颈椎正位和侧位 X 线片,采用 Kellgren 椎间盘退变分类[10]评价方法评估邻近节段退变(表 2)。

1.6 统计方法

采用 SPSS 21.0(SPSS,USA)软件进行统计学分析,并对上述数据进行 t 检验,$P<0.05$ 为差异有统计学意义。

2 结果

2.1 术中情况

所有患者均接受了由同一位有经验医师进行的显微镜辅助 ACDF 术式的手术。手术时间 50~120 min,平均为(82.2± 20.9)min;术中失血量 40~200 mL,平均为(91.5± 33.7)mL;术中均无血管、神经损伤;所有切口均 I 甲愈合。

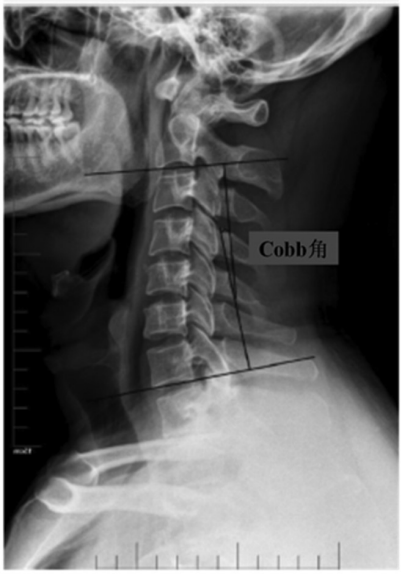

图 2 颈椎 Cobb 角:C2 椎体下终板切线与 C7 椎体下终板切线的夹角

Fig.2 Cervical Cobb angle :The angle constructed by lines the tangent line to the lower endplate of C2 and C7 vertebral body on the neutral standing lateral cervical X-ray.

表 2 Kellgren 分类标准

Table 2 Kellgren classification standard

Grade	X-ray imaging performance
0	Joint space is normal without osteophytes
1	Suspected narrowing of joint space,there may be osteophytes
2	Suspected narrowing of joint space,There are prominent osteophytes
3	Joint space narrowing is defined, with sclerosing changes, and moderate amount of osteophytes
4	Significant narrowing of joint space, severe sclerotic changes, and numerous osteophytes

Note: level 0 means no degeneration; Level 1-2 indicates mild degeneration; Level 3 indicates moderate degeneration; Level 4 represents severe regression.

2.2 临床疗效

术后患者均获得随访,随访时间 12-18 个月,平均(14.9± 2.2)个月。患者 VAS 评分从术前(6.33± 1.60)分下降至末次随访时(1.02± 0.67)分;JOA 评分从术前(10.58± 2.85)分改善至

末次随访时(15.81± 0.96)分;差异有统计学意义(P<0.05)。NDI评分从术前(30.95± 9.91)分下降至末次随访时(10.09± 3.12)分;差异有统计学意义(P<0.05)。

并发症分析:1 例患者术后出现声音嘶哑，并给予神经营养及雾化对症治疗,2 周后恢复。根据 Bazaz 吞咽困难评分,2 例患者(4.65%)出现轻度吞咽困难,1 周后逐渐消失。1 例患者(2.32%)术后出现中度吞咽困难,经对症治疗后 1 个月消失。1 例患者(2.32%)术后出现重度吞咽困难,为三节段患者,考虑术中食管牵拉较久所致,1 月后转为中度不适,后逐渐恢复正常。围术期无感染、死亡病例;无脑脊液漏、食管漏、气管损伤、颈前异物感及融合器松动病例。

2.3 影像学评估

术后 X 线评价结果显示,椎间隙高度从术前(5.14± 0.72)mm 提高至末次随访时（6.65± 0.98)mm；差异有统计学意义(P<0.05)。颈椎 Cobb 角从术前平均(9.34± 2.59)° 提高至末次随访时(15.16± 1.63)°;差异有统计学意义(P<0.05)。然而,术后各随访时间点无统计学差异(P>0.05) ,术后 6 个月 CT 成像评价结果显示,患者均获得椎间骨性融合(100%)。Zero-P 融合器未发生松动、滑脱或断裂,椎体没有出现继发性骨折。

表 3 Zero-P 术后患者临床疗效及影像学评估

Table 3 Evaluation of clinical outcome and imaging data in patients after Zero-P

Outcomes	Preoperative	1 month	3 month	6 month	Last Follow-Up
JOA score	10.58± 2.85	14.53± 1.05*	15.35± 1.02*	15.40± 0.95*	15.81± 0.96*
VAS score	6.33± 1.60	1.58± 0.85*	1.21± 0.74*	1.05± 0.72*	1.02± 0.67*
NDI score	30.95± 9.91	14.49± 5.15*	11.35± 3.67*	10.26± 3.26*	10.09± 3.12*
DH(mm)	5.14± 0.72	6.85± 1.04*	-	-	6.65± 0.98*
Cobb angle(°)	9.34± 2.59	16.30± 1.74*	15.72± 1.86*	15.21± 1.68*	15.16± 1.63*

Note: Data are expressed as x± SD; * denotes significant difference from preoperative.

表 4 Zero-P 术后患者吞咽困难及 ALOD 发生率

Table 4 Incidence of dysphagia and ALOD in patients after Zero-P

Outcome	Dysphagia				ALOD				
	None	Mild	Moderate	Severe	0	1	2	3	4
1 week	39	2	1	1	86	0	0	0	0
1 month	42	0	1	0	86	0	0	0	0
3 month	43	0	0	0	84	2	0	0	0
Last Follow-Up	0	0	0	0	83	2	1	0	0
N(%)		4(9.30)					3(3.61)		

Note: ALOD: Adjacent-Level Ossification Development.

3 讨论

3.1 颈椎病的手术治疗

颈椎病是由颈椎间盘退变和继发性颈椎组织病变,刺激或压迫周围的颈神经根、脊髓、椎动脉或交感神经而引起的一系列临床表现。颈椎病患者轻则感到头、颈、肩及臂部疼痛、麻木,重则肢体软弱无力,甚至出现大小便障碍及瘫痪[11]。对于症状严重经严格保守治疗后无明显缓解的患者，通常进行手术治疗,其手术方式包括前路、后路和前后路联合,前路手术方式主要有颈椎前路椎间盘切除减压融合术(Anterior cervical discectomy and fusion,ACDF),椎体次全切减压植骨融合术(Anterior cervical corpectomynd fusion,ACCF）和人工颈椎间盘置换术(Artificial cervical disc replacement,ACDR)3 种方式,而 ACDF 是一种完成神经脊髓减压、重建椎间高度和颈椎前凸的成熟治疗方法,被脊柱外科医生和患者的广泛所接受[12]。虽然使用自体髂骨可以提供坚固的骨融合,但供骨区域的并发症包括神经损伤、血肿形成、感染和疼痛的发生率仍然不容忽视。为了在临床工作中避免这些问题，人们研发了各种各样的融合器装置,并逐渐取代自体髂骨的融合，逐渐成为 ACDF 患者的主要选择[3]。单纯融合器置入辅助 ACDF 已被证明是一种安全有效的方法。但是,单纯融合器的置入后期下沉的发生率较高,继发性后凸畸形,长期可能导致邻近的颈椎节段疾病。放置前钛板可以防止 cage 下沉,降低假关节风险,增加稳定性,保持颈椎正常的生理曲度[4]。虽然目前的前路钢板的设计经过多年的改进,但与前路钢板相关的并发症并不少见。Li[13]报道如果使用前路钛板固定,相邻节段退变的发生率更高,相反如果不使用钛板的 ACDF 可以降低邻近节段退行性变的发生率。此外,安装钛板需要更大的手术范围。这将增加软组织损伤的可能性,特别是对于长节段的患者。大量临床报告显示使用前路钛板时,术后吞咽困难的发生率增加;慢性吞咽困难的患病率超过 2 个月的仍存在的发生率为 3%-21%,钛板内固定物直接刺激食道通常被认为是一个重要因素。因此低切迹及光滑轮廓钛板被认为是降低 ACDF 术后吞咽困难发生率的重要因素[14]。很多文献报道显示颈椎行 ACDF 手术后的吞咽困难发生率为 2%-67%[15]。我们的研究表明，颈椎前路 Zero-P 融合器置入吞咽困难的发生率为 9.30%,持续时间短,术后 1 月仅有 1 例的轻度的吞咽

困难,3 月随访时完全消失。此结果与 Yong[16]所报道的结果相一致,且明显的低于钛板融合器组。这是由于 Zero-P 融合器装置只是占据椎间盘空间,不超过椎体前缘,避免的内固定物与食管、气管及周围软组织的直接接触,降低了术后吞咽困难的发生率。

3.2 Zero-P 与前路钛板融合器治疗颈椎病的比较

传统的颈椎钛板融合器固定可提高融合率,维持或改善颈椎矢状面对齐和稳定性,降低移植物下沉和退出的风险。然而,在过去的几年里,Zero-P(ACDF 的一个独立装置)已经被开发出来,目的是减少与传统颈椎前板相关的发病率,同时保持前板椎间支架的优点。该装置由放射性聚醚醚酮聚合物装置和一个小的不透明的钛板组成,钛板被纳入椎间隙。此外,还有 4 颗螺钉用于 1 级锁紧机构的内固定。既往的研究证实,Zero-P 具有与传统的钛板融合器结构相同的融合率和生物力学稳定性。此外,两种方法都纠正了颈椎后凸畸形并改善了颈椎的序列[7,17]。在本研究中,使用 Zero-P 融合器的 ACDF 患者,JOA 评分、VAS 评分、NDI 评分、C2-C7 Cobb 角、DH 高度均有显著改善。而且手术后 6 个月的 CT 影像学检查均显示骨性融合。这些结果令人满意并且与先前的研究结果相一致,说明采用 Zero-P 融合器的 ACDF 或传统的颈椎钛板融合器的 ACDF 均是早期治疗颈椎病的有效治疗方法。此外,我们认为 Zero-P 融合器操作简单,手术时间较短及失血量较少。既往研究结果表明,颈椎前路钛板融合器术后 ALOD 的发生率显著增加[5,6],这是由于椎体前纵韧带的广泛剥离及钛板上下缘位置距离融合节段上下两个椎间隙的距离较近(<5 mm)所致。而在本研究中,使用 Zero-P 融合器行 ACDF 手术的患者,术后 ALOD 的发病率仅为 3.61%,此结果与 Yong[16]所报道的结果相一致,且明显的低于钛板融合器组。这是由于 Zero-P 融合器置入时仅操作与间盘平面,无需对椎前前纵韧带广泛剥离,不会靠近邻近椎间隙,可以有效地避免对邻近节段及颈部组织结构的骚扰,减少邻近节段异位骨化的形成。

3.3 显微镜结合 Zero-P 治疗颈椎病的优点

近年来,随着微创脊柱的发展,颈椎病的治疗更加的趋于微创化、精准化。20 世纪 70 年代,Williams[18]等就提出了将显微镜技术应用到脊柱疾病的手术治疗当中。1975 年,Hankinson[19]首次将显微镜应用到颈椎前路椎间盘切除术中,并取得了良好的临床效果;指出显微镜辅助下颈椎前路的解剖结构更加清楚,减压及止血更充分。Huang[20]等通过病例资料回顾分析研究表明,显微镜辅助颈椎前路手术,可有效的减少术中失血量,缩短手术时间,显著降低术后并发症(吞咽困难、异位骨化)的发生率;它与传统直视下的颈椎前路手术具有相同的临床效果。显微镜辅助颈椎前路手术,可以扩大术者及助手的手术视野,目镜在同轴光源下能够提供三维立体成像,并且可以放大 4-8 倍,使术者能够清楚的分辨后纵韧带、硬膜及硬膜外静脉丛等神经组织结构,在执行彻底减压的同时确保操作的安全。此外,显微镜辅助的颈椎前路手术可以充分解除椎体后缘骨赘对脊髓的脊神经的压迫,对椎管内的出血点辨识度增加,双极电凝止血更方便。并能够清晰的镜下看见硬膜的膨起及脊髓的波动,做到充分彻底精准的减压。显著提高颈椎前路手术的优良率,是一种安全、有效的手术治疗方法。文献研究报道[21]显微镜下颈椎前路手术的优良率为 90%,硬脑膜撕裂、椎间盘感染或脊髓和神经根损伤的并发症发生率 < 2%,再手术率为 5%;并且在显微镜下进行手术并不会增加颈椎前路手术感染的风险。我们的研究表明,显微镜辅助下 Zero-P 用于 ACDF 的临床和影像学初步疗效满意,镜下减压更加精准及彻底,Zero-P 融合器操作简便,稳定性可靠,术后并发症少。显微镜下减压联合前路 Zero-P 置入 ACDF 术可作为治疗颈椎疾病的有益补充。然而,这项研究也存在一定局限性,样本数量少,随访时间短,没有随机对照研究;早期颈椎及肢体功能的改善效果明显,远期的临床疗效需要进一步长期的随访及多中心大样本的系统研究。我们将继续观察这些患者,来证实我们在本研究中得到的结果。

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