

· 临床研究 ·

脊柱侧凸数字导航模板的准确性与安全性的病例对照研究

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【摘要】 目的:设计新型脊柱侧凸个体化数字导航模板(简称导板)并在手术中应用,评价其置钉准确性和安全性。**方法:**2013年12月至2014年12月,对10例脊柱侧凸病例(观察组)进行CT扫描,应用计算机软件进行模型重建、模拟置钉和导板设计;应用快速成型技术制造导板;在手术中应用导板辅助置钉,记录其出血量、手术时间、术前与术后血肌酐含量变化、置钉相关并发症发生情况,术后CT扫描明确螺钉位置并进行分级,评价置钉准确率,并与同期行徒手置钉的10例脊柱侧凸病例(对照组)进行对比。观察组包括特发性侧凸5例,先天性侧凸5例;男3例,女7例;年龄4~18岁,平均11.9岁;主弯Cobb角 42.1° ~ 78.4° ,平均 54.9° 。对照组包括特发性侧凸5例,先天性侧凸5例,男2例,女8例;年龄6~17岁,平均12.6岁;主弯Cobb角 38.2° ~ 93.4° ,平均 56.6° 。**结果:**观察组置钉167枚,其中I级138枚(82.6%),II级25枚(15.0%),III级4枚(2.4%),无IV级螺钉;穿破皮质29枚(17.4%),可接受螺钉163枚(97.6%)。对照组置钉165枚,其中I级98枚(59.4%),II级39枚(23.6%),III级21枚(12.7%),IV级7枚(4.2%);穿破皮质67枚(40.6%),可接受螺钉137枚(83.0%)。两组病例置钉分级、穿破皮质比例、可接受螺钉比例均有差异($Z=-5.013, P=0.000; \chi^2=9.347, P=0.002; \chi^2=20.242, P=0.000$)。Cobb角矫正率[(74.1 ± 10.0)% vs (69.7 ± 17.6)%,出血量(455 ± 447) ml vs (415 ± 389) ml,手术时间(163.5 ± 53.7) min vs (164.0 ± 48.7) min,术前与术后3d血Cr变化(-5.3 ± 3.2) vs (-3.4 ± 3.1) $\mu\text{mol/L}$,差异均无统计学意义($t=0.696, P=0.496; t=0.214, P=0.833; t=0.022, P=0.983; t=1.375, P=0.192$)。两组均未见与置钉相关的并发症。**结论:**应用个体化数字导航模板辅助脊柱侧凸术中椎弓根螺钉置入,准确性较徒手置钉明显提高,且安全性良好。

【关键词】 脊柱侧凸; 外科手术, 计算机辅助; 椎弓根螺钉; 病例对照研究

DOI: 10.3969/j.issn.1003-0034.2015.10.015

Case-control study on accuracy and safety of patient-specific drill-guide templates used in scoliosis cases ZHANG Yu-peng, SHI Ya-min, WANG Hua-dong, and HOU Shu-xun. Department of Orthopaedics, the First Hospital Affiliated to the General Hospital of PLA, Beijing 100048, China

ABSTRACT Objective: To evaluate the accuracy and safety of pedicle screw insertion with the aid of novel patient-specific drill-guide templates in scoliosis cases. **Methods:** Ten patients with scoliosis were selected to participate in the research (the observation group) from December 2013 to December 2014. The data was obtained from CT scanning, and put into the computer to perform reconstruction of spine, simulation of pedicle screw insertion, and design of patient-specific drill-guide templates with software. The templates were made with rapid prototyping technique. After sterilization, the templates were used to aid the pedicle screw insertion intraoperatively. The blood loss, operation duration, change of creatinine level pre-and post-operation, and complications related to pedicle screw insertion were recorded. The location of pedicle screws were graded so as to evaluate the accuracy. A comparative study was then performed with the data of ten scoliosis cases operated with free-hand method during the same period (control group). There were 5 cases of idiopathic scoliosis and 5 cases of congenital scoliosis in the observation group, including 3 males and 7 females. Their average age was 11.9 years old (ranged, 4 to 18 years old), and the average Cobb angle of main curve was 54.9° (ranged, 42.1° to 78.4°). There were also 5 cases of idiopathic scoliosis and 5 cases of congenital scoliosis in the control group, including 2 males and 8 females. Their average age was 12.6 years old (ranged, 6 to 17 years old), and the average Cobb angle of main curve was 56.6° (ranged, 38.2° to 93.4°). **Results:** A total of 167 pedicle screws were inserted intraoperatively, with 138 screws (82.6%) in grade I, 26 screws (15.0%) in grade II, 4 screws in grade III (2.4%), but no screws in grade IV according to the CT image. There were 29 (17.4%) screws perforated, and 163 (97.6%) screws could be accepted. In the control group, a total of 165 pedicle screws were inserted intraoperatively, with 98 screws (59.4%) in grade I, 39 screws (23.6%) in grade II, 21 screws in grade III (12.7%), and 7 screws in grade IV

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(4.2%). There were 67 (40.6%) screws perforated, and 137 (83.0%) screws could be accepted. The grade distribution of screw position, ratio of perforated and accepted screws were significantly different between the two groups respectively ($Z=-5.013, P=0.000; \chi^2=9.347, P=0.002; \chi^2=20.242, P=0.000$). The correction rate of Cobb angle were (74.1±10.0) % vs (69.7±17.6) %; blood loss were (455±447) ml vs (415±389)ml; operation duration were (163.5±53.7) min vs (164.0±48.7) min; and the changes of creatinine level pre-and post-operatively were (-5.3±3.2) μmol/L vs (-3.4±3.1) μmol/L; all above data had no significant differences respectively ($t=0.696, P=0.496; t=0.214, P=0.833; t=0.022, P=0.983; t=1.375, P=0.192$). There were no complications related to pedicle screw insertion in each group. **Conclusion:** The novel patient-specific drill guide template can be used to assist the insertion of pedicle screws in scoliosis cases with much higher accuracy than that of freehand method and fair safety.

KEYWORDS Scoliosis; Surgery, computer-assisted; Pedicle Screw; Case-control studies

Zhongguo Gu Shang/China J Orthop Trauma, 2015, 28(10): 945-950 www.zggszz.com

由于椎弓根螺钉具有三柱固定、为脊柱提供即刻牢固固定、矫形力量强大、可大幅度提高融合率等优势,已在脊柱外科手术中得到广泛应用^[1]。尽管置钉技术日益成熟,且总体来讲安全性较好,但对于经验较少的年轻医生来说,准确置钉仍是一大挑战,置钉失误及与其相关的并发症仍时有发生^[1-2]。对于脊柱畸形病例,由于其解剖结构变异较多,徒手置钉更显复杂,并且 T₄-T₉ 节段由于距脊髓和主动脉距离均较短,安全区域范围最小,置钉要求更高。尽管有学者认为应用个体化数字导航模板(以下简称导板)可以显著提高脊柱侧凸手术置钉准确率,但并未对其准确性与安全性进行对比研究,难以明确其相对传统置钉方法的优势^[3]。自 2013 年 12 月至 2014 年 12 月设计了对照试验,将导板辅助置钉与徒手置钉进行对比,报告如下。

1 资料与方法

1.1 一般资料

经医院伦理委员会批准,选取拟行手术的脊柱侧凸病例 20 例并分为观察组与对照组(各 10 例),征得其本人及家属同意并签署知情同意书(非随机对照)。其中,观察组包括特发性侧凸 5 例,先天性侧凸 5 例;男 3 例,女 7 例;年龄 4~18 岁,平均(11.9±4.2)岁。对照组包括特发性侧凸 5 例,先天性侧凸 5 例,男 2 例,女 8 例;年龄 6~17 岁,平均(12.6±3.8)岁。观察组主弯 Cobb 角为 42.1°~78.4°,平均

(54.9±12.1)°,对照组主弯 Cobb 角为 38.2°~93.4°,平均(56.6±20.7)°。两组年龄、性别比例、侧凸类型构成及主弯 Cobb 角差异无统计学意义(表 1),固定方式均采用全椎弓根螺钉,术中均未行截骨。

1.2 研究方法

1.2.1 观察组操作流程 拍摄脊柱全长正侧位、左右侧屈位 X 线片,测量 Cobb 角,进行分类、分型,确定拟固定节段。用 Philips 128 排螺旋 CT 对拟固定节段脊柱进行连续扫描,患者取仰卧位。扫描条件:电压 120 kV,电流 30 mA,层厚 0.67 mm,层距 0.67 mm,512×512 矩阵。将扫描获得的 CT 容积图像数据以 DICOM 格式导入 Mimics 17.0 软件。进行图像分割,将各节段单独分离出来并进行 3D 模型重建;如遇较复杂畸形,多节段发生骨性融合,则视为同一节段。模拟置钉:放置虚拟螺钉,在冠状位、矢状位和轴位上进行调整,以使螺钉达到理想位置,并在三维视图上进一步微调,以兼顾螺钉位置和连接棒的安装。将上述各节段模型及虚拟螺钉导入 3-Matic 9.0 软件;在脊柱后方相应骨性结构进行标记,提取拟置钉区域棘突根部、椎板后方、横突周围的解剖形态,并与虚拟螺钉通道组合,添加方框结构(围绕并避开棘突尖部)和连接杆,得到虚拟导板。与器械厂家合作,制作与上述导板相配套的金属套筒及钻头。以光敏树脂为材料,通过 Form1+光固化快速成型机(美国 Formlabs 公司)制作导板。将导板进行

表 1 两组脊柱侧凸患者术前临床资料比较

Tab.1 Comparison of clinical data between observation group and control group of patients with scoliosis

组别	例数	性别(例)		年龄($\bar{x}\pm s$, 岁)	侧凸类型(例)		术前 Cobb 角($\bar{x}\pm s$, °)
		男	女		先天性	特发性	
观察组	10	3	7	11.9±4.2	5	5	54.9±12.1
对照组	10	2	8	12.6±3.8	5	5	56.6±20.7
检验值	-	-	-	$t=0.932$	-	-	$t=0.228$
P 值	-	0.652	-	0.364	0.385	-	0.822

注:“-”表示用 Fisher 确切概率法,无统计值

Note: ‘-’ means there is no statistical value due to the using of Fisher exact probability test

低温等离子消毒,金属套筒及螺钉等常规高压蒸汽灭菌,进行术中应用。逐层显露术野,确定拟手术节段。将导板置于相应节段后方,助手把持导板,置入金属套筒,由术者用电钻进行钻孔,置入螺钉,进行矫形。

1.2.2 对照组操作流程 对照组根据 C 形臂 X 线透视确定手术节段。用电钻钻孔,置入导针,透视下校正导针位置,然后依次用电钻置入术前选择好的螺钉,再次用 C 形臂 X 线正侧位透视确认位置,其余操作同观察组。

1.3 观察项目与方法

术后拍摄 X 线片并行 CT 扫描,评价螺钉在椎弓根内的位置,记录所有穿破椎弓根皮质的螺钉数目、方向,按照 Lu 等^[3]的方法测量穿透距离并评价螺钉等级:Ⅰ级,螺钉完全在椎弓根内;Ⅱ级,螺钉穿出椎弓根壁<2 mm;Ⅲ级,螺钉穿出椎弓根壁≥2 mm 且<4 mm;Ⅳ级,螺钉穿出椎弓根壁≥4 mm。Ⅰ级、Ⅱ级为可接受螺钉,Ⅲ级、Ⅳ级螺钉为不可接受螺钉。比较两组病例螺钉置入准确度差异。

记录所有患者 Cobb 角矫正率、手术时间、出血量、术中和术后出现的血管、神经、内脏损伤等并发症,统计术前与术后 3 d 血肌酐(Cr)变化情况。比较两组病例上述指标的差异。

1.4 统计学处理

应用 SPSS 17.0 软件进行统计学处理。定量资料用均数±标准差($\bar{x} \pm s$)表示,年龄、术前 Cobb 角、Cobb 角矫正率、手术时间、出血量、血 Cr 变化用两样本均数的 t 检验;性别和侧凸类型比较用 Fisher 确切概率法;螺钉分级比较用秩和检验;穿破皮质螺钉和可接受螺钉的比较用 Pearson 卡方检验。 $P < 0.05$ 为差异有统计学意义。

2 结果

观察组置钉 167 枚(T₁-L₅),其中Ⅰ级 138 枚(82.6%),Ⅱ级 25 枚(15.0%),Ⅲ级 4 枚(2.4%),无Ⅳ级螺钉;穿破皮质 29 枚(17.4%),可接受螺钉 163 枚(97.6%)。对照组置钉 165 枚(T₂-L₅),其中Ⅰ级 98 枚(59.4%),Ⅱ级 39 枚(23.6%),Ⅲ级 21 枚(12.7%),

Ⅳ级 7 枚(4.2%),穿破皮质 67 枚(40.6%),可接受螺钉 137 枚(83.0%)。两组病例置钉分级、穿破皮质比例、可接受螺钉比例均有明显差异($Z = -5.013, P = 0.000; \chi^2 = 9.347, P = 0.002; \chi^2 = 20.242, P = 0.000$)。

观察组与对照组 Cobb 角矫正率[(74.1±10.0)% vs (69.7±17.6)%],出血量[(455±447) ml vs (415±389) ml],手术时间[(163.5±53.7) min vs (164.0±48.7) min],术前与术后 3 d 血 Cr 变化[(-5.3±3.2) μmol/L vs (-3.4±3.1) μmol/L] 差异均无统计学意义(见表 2)。两组均未见与置钉相关的并发症。观察组典型病例见图 1。

3 讨论

3.1 置钉准确度分析

目前多采用徒手置钉,螺钉误置率为 6.8%~34.8%,由于评价标准不同,各研究数据差异较大,但多数意见认为,脊柱畸形病例采用徒手置钉并不可靠^[4-7]。本研究中,对照组置钉准确率与上述结果一致。同时,观察组的可接受螺钉比例远高于对照组,而穿破皮质螺钉比例远低于对照组,说明导板辅助置钉的准确率远高于徒手置钉。

目前欧美发达国家较为流行的计算机辅助导航技术,按照 2 mm 标准(即穿破皮质 2 mm 以内视为置钉准确),可使置钉准确率达 95%以上^[8-10]。并且有研究发现,即便对于非脊柱畸形病例,应用术中 CT 导航仍有高达 8.97%的螺钉需要调整^[11]。而本研究中,观察组置钉准确率可与术中 CT 导航辅助置钉相比,进一步证明了导板辅助置钉的准确度。

在脊柱畸形手术中应用导板技术的报道较少,并且未见导板与其他方法置钉的病例对照研究。Lu 等^[3]报道应用导板辅助脊柱侧凸椎弓根螺钉置入,98.2%的螺钉完全在椎弓根内,而全部螺钉均未突破皮质超过 2 mm,显示了非常高的置钉准确率,然而笔者并未与同期应用徒手置钉的病例进行对比。本研究数据略低于上述报道,但穿破皮质小于 2 mm 的螺钉比例仍达 97.6%,说明导板设计的准确度较好。同时,本研究在软件设计时对部分虚拟置钉进行了微调,以兼顾螺钉位置和连接棒的安装问题,可能

表 2 两组脊柱侧凸患者置钉准确率与安全性对比

Tab.2 Comparison of the accuracy and safety between observation group and control group of patients with scoliosis

组别	例数	Cobb 角矫正率($\bar{x} \pm s, \%$)	手术时间($\bar{x} \pm s, \text{min}$)	出血量($\bar{x} \pm s, \text{ml}$)	Cr 变化($\bar{x} \pm s, \mu\text{mol/L}$)	螺钉分级(枚)				穿破皮质螺钉(枚)	可接受螺钉(枚)
						Ⅰ级	Ⅱ级	Ⅲ级	Ⅳ级		
观察组	10	74.1±10.0	163.5±53.7	455±447	-5.3±3.2	138	25	4	0	29	163
对照组	10	69.7±17.6	164.0±48.7	415±389	-3.4±3.1	98	39	21	7	67	137
检验值	-	$t=0.696$	$t=0.022$	$t=0.214$	$t=1.375$	$Z=-5.013$				$\chi^2=9.347$	$\chi^2=20.242$
P 值	-	0.496	0.983	0.833	0.192	0.000				0.002	0.000

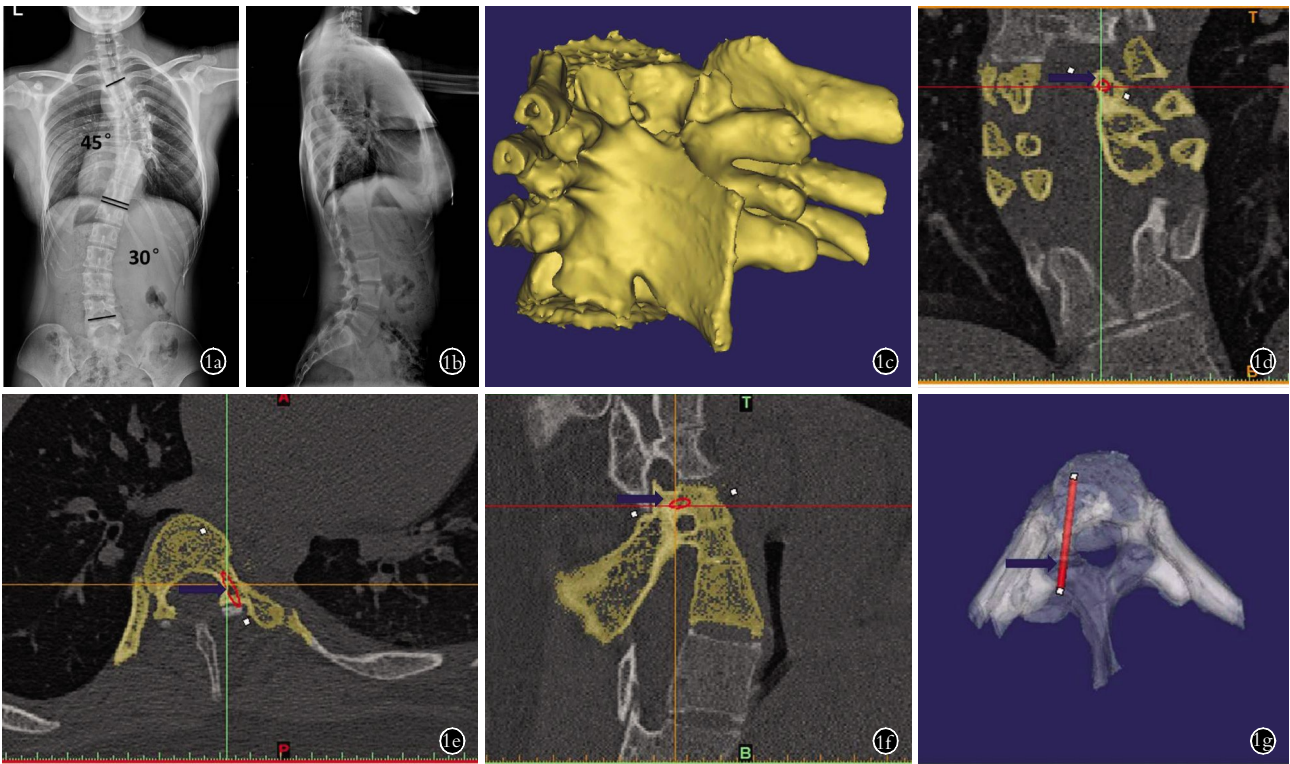


图 1 患者,女,14 岁,先天性脊柱侧凸 **1a.** 脊柱全长正位 X 线片显示 T₆-T₇ 和 T₇-T₈ 未分节,主弯 Cobb 角 45° **1b.** 侧位 X 线片显示胸椎前凸 **1c.** CT 扫描后,应用软件将每个节段独立分割并行三维重建,本例 T₇-T₈ 节段因未分节,视为同一节段进行设计 **1d, 1e, 1f, 1g.** 进行模拟置钉,分别在冠状位(1d)、轴位(1e)及矢状位(1f)上调整虚拟螺钉位置,并在三维视图(1g)上进一步确认,其中虚拟螺钉为红色,蓝色箭头所示为虚拟螺钉位置

Fig.1 A 14 years old girl with congenital scoliosis **1a.** AP view of the spine revealed the failure of segmentation of T₆-T₇ and T₇-T₈ vertebrae, and the Cobb angle of main curve was 45° **1b.** Lateral view of the spine showed lordosis of thoracic spine **1c.** Segmentation and 3D reconstruction of each single vertebrae was performed with software. In this case, T₇-T₈ were treated as one level as the failure of segmentation **1d, 1e, 1f, 1g.** Simulation of pedicle screw insertion was performed in coronal (1d), axial (1e) and sagittal (1f) view, which was confirmed in 3D view (1g). The virtual screw was marked red, which was indicated with blue arrow

也对置钉准确性造成一定影响。

3.2 误差分析

由于脊柱侧凸病例骨性结构复杂,且侧凸弧顶椎弓根与硬膜、神经根和胸膜距离均较近,故显露时需较为谨慎,避免伤及上述结构而出现并发症。但导板技术是基于椎体后方无软组织的假定情况,其准确度很大程度上取决于其与骨性结构的贴附紧密程度,这就要求术者尽可能彻底清理导板覆盖范围的软组织。因此,术野显露应当由具备一定脊柱畸形手术经验的医生来进行,这样才能保证一方面不伤及重要结构,另一方面尽可能将导板覆盖范围的软组织清理干净。然而在实际手术中,软组织并不能完全清理,这样可能对置钉准确率造成影响。

在整个流程中,CT 数据采集、计算机设计、快速成形机制造和术中应用均会存在一定误差。虽然 CT 数据采集时患者为仰卧位,术中各节段相互位置关系会发生改变,但因导板均以单节段设计或者未分节的多节段椎体设计为基础,不会因术中体位变化

而受到干扰。为了尽量减少导板制造误差,本研究采用了目前精确度较高的光固化成型方法(精度可达 0.025 mm),可最大限度降低材料误差。同时,由经验丰富的医师进行术野显露。而应用导板辅助置钉,仍有 17.4% 的螺钉穿出皮质,说明软组织尚存在一定误差。为了明确数字导板技术实际应用中的误差,有学者在 32 具尸体标本上进行 C₁ 和 C₂ 椎弓根螺钉置钉,将术后实际螺钉进钉点和角度与术前设计的理想进钉点和角度进行对比,其进钉点误差为 0.01~0.20 mm,角度误差平均为 0.12°,说明其误差在可接受范围内,且低于计算机导航系统^[12]。但对于脊柱侧凸的定量误差研究未见报道。下一步的研究中,应当将术前设计的进钉点及角度与术后实际的参数进行对比,以评定误差,以此为基础完善导板设计。

3.3 安全性分析

本研究中,观察组与对照组在出血量、手术时间和置钉相关并发症方面均无显著差异,说明与徒手置钉相比,导板辅助置钉并不增加出血量和手术时



图 1 患者,女,14岁,先天性脊柱侧凸 **1h.** T₇ 左侧及 T₉ 双侧虚拟螺钉置钉完毕,蓝色箭头所示为螺钉位置 **1i, 1j, 1k.** 制作虚拟导板,提取脊椎背面解剖信息,生成底板(1i);围绕虚拟螺钉生成置钉通道(1j);将底板与置钉通道组合,并添加方框(黄色箭头所示)和连接杆(红色箭头所示),生成虚拟导板(1k) **1l.** 术前行快速成型机制造导板,术中将其放置在相应节段脊椎后方,在通道辅助下进行钻孔和置钉 **1m.** 术后正位 X 线片示冠状面矫正效果良好 **1n.** 术后侧位 X 线片示原有的胸椎前凸得到部分矫正 **1o.** 术后 CT 显示 T₇ 左侧螺钉完全在椎弓根内 **1p.** 术后 CT 显示 T₉ 双侧螺钉均在椎弓根内

Fig.1 A 14 years old girl with congenital scoliosis **1h.** Simulation of screw placement was performed. The left virtual screw of T₇ and bilateral virtual screws of T₉ were indicated with blue arrow **1i, 1j, 1k.** Generation of virtual template. Dorsal anatomic information of the vertebrae was obtained, and then used to generate the base of template(1i). Screw tunnel was obtained surrounding the virtual screw(1j). The base and tunnel was combined, added with a box(yellow arrow) and three connectors(red arrows), then the virtual template was obtained(1k) **1l.** Template was made by rapidform machine preoperatively, and then placed on the corresponding part of the vertebrae to aid drilling and placement of the screw intraoperatively **1m.** Postoperative AP X-ray showed a favorable result on coronal plane **1n.** Postoperative lateral X-ray revealed partial correction of the lordosis of the thoracic spine **1o.** CT showed the left screw of T₇ was in the pedicle completely **1p.** CT showed the bilateral screws of T₉ were both in the pedicle

间,且因置钉准确率高,无置钉相关并发症。

有报道指出,光敏树脂材料可能有潜在的细胞毒性,对肾功能造成影响^[13]。为了避免其对人体可能的影响,课题组设计了专用配套工具,在使用时置于导板通道内,并通过锤击将其固定于原位,这样既避免钻孔时将材料碎屑带入骨内,又增强了钻孔时的稳定性。术前与术后血 Cr 变化情况也与对照组无明显差异,说明此种设计对肾功能无明显影响,安全性

较好。目前未见其他类似报道。

本研究的不足之处是,由于受到伦理限制,无法进行完全随机对照,并且样本量较小,可能给结论带来一定偏差。在今后的工作中,应当一方面扩大临床应用例数,另一方面进行动物实验,定量评价导板置钉的误差。

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(收稿日期: 2015-09-01 本文编辑: 王宏)

更正启事

由于作者提供图片的疏忽和编校过程中的失误, 2015 年第 7 期 651 页刊出的文章“体外 IL-1 β 诱导股骨头建立软骨退变模型”的图 5 刊出有误, 现更正如下。由此给读者带来不便, 敬请谅解。

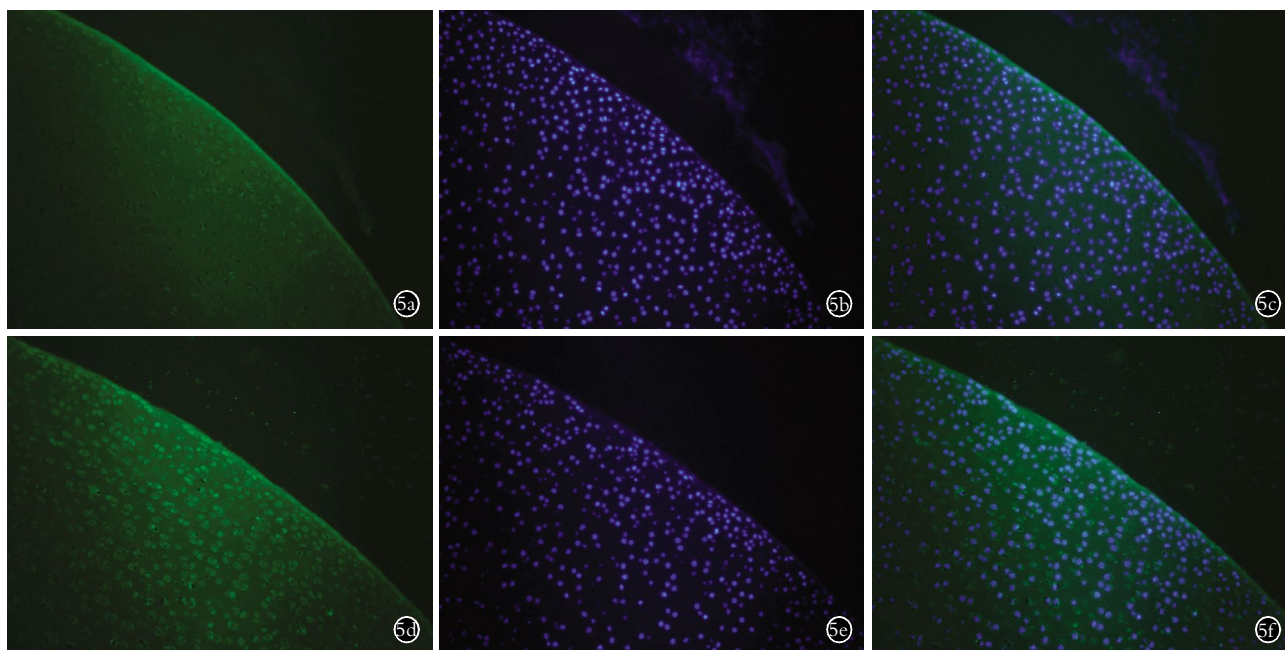


图 5 免疫荧光检测 ADAMTS5 表达(200 \times) 5a. 正常组的 ADAMTS5 免疫染色 5b. 细胞核 DAPI 染色 5c. 正常组的 ADAMTS5 免疫染色和细胞核 DAPI 染色的重叠 5d. IL-1 β 干预的 ADAMTS5 免疫染色 5e. 细胞核 DAPI 染色 5f. IL-1 β 干预的 ADAMTS5 免疫染色和细胞核 DAPI 染色的重叠

Fig.5 Immunofluorescence staining of ADAMTS5 (200 \times) 5a. The expression of ADAMTS5 in the control group 5b. Nuclei staining in the control group 5c. The merge of fig. 5a and 5b 5d. The expression of ADAMTS5 in the experimental group 5e. Nuclei staining in the experimental group 5f. The merge of fig. 5d and 5e