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聚丙烯补片材料在腹股沟疝修补中的临床应用研究 *

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摘要 目的：采用生物材料补片进行修补，加强腹壁薄弱区域实现功能重建，分析该方法治疗腹股沟疝的临床疗效。**方法：**选择我院收治的无嵌顿性择期腹股沟疝手术患者 30 例，随机分为传统修补组与生物补片修补组。比较患者的围手术期指标(手术时间、出血量、住院时间、术后下地活动时间、镇痛药物应用例数)、临床疗效，通过随访比较术后 1 个月、3 个月、6 个月患者的 VAS 评分及主观满意度，记录切口感染及其他并发症的发生情况。**结果：**所有患者均顺利完成手术，并完成半年以上随访。研究组的手术时间、术中失血量、住院时间、术后下地活动时间、镇痛药物应用均明显短于或低于对照组(P<0.05)。两组患者术后 1 个月、3 个月、6 个月的 VAS 评分、主观满意度均较术前显著降低(P<0.05)，但两组之间相比差异无统计学意义(P>0.05)。**结论：**采用生物补片材料修补腹股沟疝的手术创伤较小且患者恢复期短，近期疗效及安全性与传统手术相当。

关键词：腹外疝；聚丙烯补片；疝修补；围手术期；临床疗效

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Research on the Clinical Application of Polypropylene Patch Material in the Treatment of Inguinal Hernia*

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ABSTRACT Objective: To analyze the clinical effect of the repair of inguinal hernia with biomaterial patch to strengthenthe reconstruction of the weak abdominal wall on the inguinal hernia. **Methods:** Thirty patients with non strangulated inguinal hernia who were treated in our hospital were randomly divided into the traditional repair group and the biological patch repair group according to the patients' wishes. The clinical curative effect was compared between the two groups. The patients were followed up for 1 month, 3 months and 6 months after operation. The VAS score and subjective satisfaction were recorded, and incision infection and other complications were recorded. **Results:** All patients were successfully completed the operation, and more than six months' follow-up. The operation time, intraoperative blood loss, length of hospital stay, time of postoperative ground movement, analgesic drug use were significantly shorter or lower than those of the control group (P<0.05). The VAS score and subjective satisfaction of both groups were significantly lower than those before operation (P<0.05), but there was no significant difference between the two groups (P>0.05). **Conclusions:** There was less surgical trauma and shorter recovery period in biological patch repair group, but the safety and short-term effects were comparable with the traditional surgery.

Key words: Abdominal external hernia; Polypropylene patch; Hernia repair; Perioperative period; Clinical efficacy

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前言

腹股沟疝是常见的普外科临床疾病，中老年患者人的发病率较高，传统手术采用 Bassini 法、McVay 法进行修补，主要的治疗思路是将缺损部位进行周围组织分离，用丝线将缺损的筋膜组织进行强行缝合在一起，在治疗后需要注意预防伤口感染、腹内压升高等，多需要患者进行较长时间的卧床休息防止疝复发、吻合失败[1-3]。疝修补的病理基础是腹壁的薄弱和筋膜的缺损，目前临床上开始采用各种生物材料补片进行疝修补，其原理是通过材料加强腹壁的薄弱区域，最理想的状态是具有一定的强度、可以诱导疤痕形成稳固的自体结构。但长期的临床应用显示采用补片材料会出现纤维变形所致的疼痛、活动受限、补片回缩及肠管粘连等并发症。目前，为了提高补片重建腹壁的效果，生物材料补片的发展迅速，各种材料源的补片不断被研发并逐渐推入临床应用[4-6]。

目前，主要应用的补片材料有聚丙烯补片、聚酯补片和膨

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化聚四氟乙烯补片，对于生物补片进行疝修补最关注的就是其理化性质及生物相容性[7-10]。补片修补的基本要求就是可以作为腹壁结构的组成部分为腹壁提供一定的抗张力，能够经受起腹压的波动。对于补片的孔径要求主要关系到其生物相容性，其孔径的直径最佳应该大约 75 μm，这样可以诱导成纤维细胞、巨噬细胞、血管内皮细胞等多种细胞迁移、生长，并分泌细胞外基质胶原类，使得补片逐渐与生物体相嵌合。现代生物学材料制备疝修补补片都是惰性材料，需要其稳定存在、无免疫原性、无毒性，但是也必须注意所有的生物材料在植入时都会发生一定的化学反应过程[11,12]。当补片植入生物体后，启动了组织炎性反应、纤维化、钙化，后期形成肉芽组织等。这些过程与传统手术的伤口愈合机制类似，但是存在区别。对于补片大小、孔径、生物相容性的不同特点，关系到后期重建腹壁的感染率、疤痕化程度及机体的适应满意程度等[13,14]。

还有一类生物补片是采用同种异体或异种异体的组织材料，经过脱细胞学处理，去除宿主免疫排斥反应的主要物质但是保留了细胞外基质和立体支架结构，吸引宿主细胞在支架上生长、分泌新的细胞外基质成分，形成自体组织，完成组织重建与修复，目前刚开始应用和研发[15-17]。但是此类补片存在的主要问题是自身重建的时间与补片的分解时间以及补片的生物强度问题。因此，临床上目前主要还是以合成材料补片为主要应用，本研究主要探讨了聚丙烯补片材料在腹股沟疝修补中的临床应用效果。现报道如下。

1 对象与方法

1.1 研究对象

入组对象为 2013 年 9 月至 2014 年 9 月就诊于我院确诊为腹股沟疝 30 名。纳入标准：临床诊断为腹股沟疝的成年患者，年龄大约 18 岁；患者有明确的手术意向，严重影响生活质量；同意按照医院的治疗方案，随机进入不同的治疗组；具有良好的随访意愿并能实施至少半年以上随访。排除标准：高龄患者，手术风险较高患者；有基础的高血压、心脏病、糖尿病及免疫系统疾病，或者有明确诊断为肿瘤的患者；手术意愿不明确，无法按照医师的治疗方案进行治疗并完成随访患者；精神或心理疾病患者。

1.2 研究分组

入组患者 30 例，采用随机数字法进入传统的疝修补手术组或者聚丙烯补片材料修补手术组方案。其中传统疝修补手术组(观察组，control)：采用经典 Bassni 修补方案。聚丙烯补片材料修补手术组 (研究组，research)：在腹股沟做 5-6 cm 斜形切口，切开后分离皮下脂肪和腹外斜肌的肌腱膜，游离精索结构，分离疝囊至高位。对于腹股沟斜疝，较大的疝囊予以横断结扎，小疝囊直接回纳腹腔；直疝疝囊则直接回纳腹腔。连续缝合腹横筋膜缺损。根据腹股沟区实际大小对补片进行裁剪，从补片尾端卷起补片，从耻骨结节端向内方向平展开补片，头端覆盖耻骨结节要超过 1 cm。预裁式搭扣包绕精索，可吸收线予以缝合腹外斜肌腱膜和皮下脂肪、皮肤。两组患者常规术后予以抗感染治疗，并予以对症药物治疗。通过护士记录完成第三方随访，保证结果的客观性。两组患者基线资料如表 1 所示，经统计分析差异均无统计学意义(P>0.05)，具有临床可比性。

表 1 两组患者基线资料的比较(n，$\bar{x}\pm$ s)

Table 1 Comparison of the baseline data between two groups(n, $\bar{x}\pm$ s)

Groups	The number of cases	Average age(years)	Sex ratio (Male/Female)	Course of the disease (years)	Classification(Direct hernia/oblique hernia)
Control	15	55.7± 7.1	13/2	31.2± 5.6	9/6
Research	15	54.8± 8.1	14/1	28.9± 7.1	8/7

1.3 生物材料

聚丙烯补片材料：由德迈特医学技术(北京)有限公司代理进口品牌材料，美国巴德疝修补补片，药(械)准字:国食药监械(进)字 2010 第 3462371 号，有效期：60 个月。其优点有：异物反应最小、有很强的张力强度、柔软性好、耐很多化学物质、软化温度为 260° F、孔隙大植入后能被结缔组织浸润、白细胞易于通过补片空隙，有效防止感染。

1.4 观察指标

围手术期各项指标如手术时间、出血量、住院时间、术后下地活动时间、镇痛药物应用例数以及随访时两组患者的不同时间的 VAS 指数(10 分制)、主观满意度指标(100 分制)。

1.5 统计学分析

所有数据采用 SPSS17.0 进行统计分析，计量资料以均数± 标准差的方法表示，数据比较采用两样本 t 检验，计数资料的比较采用 x^2 检验，以 P<0.05 为差异有统计学意义。

2 结果

2.1 两组患者围手术期各项指标比较

表 2 所示为两组患者围手术期各项临床指标的结果，采用聚丙烯补片材料修补组(研究组)手术时间、术中失血量、住院时间、术后下地活动时间、镇痛药物应用均明显短于或低于对照组(P<0.05)。

2.2 两组患者不同时间点的 VAS 评分、主观满意度比较

两组患者术后 1 个月、3 个月、6 个月的 VAS 评分、主观满意度均较术前显著降低(P<0.05)，但两组之间相比差异无统计学意义(P>0.05)，见表 3、表 4。

2.3 两组患者不良事件发生情况的比较

在随访过程中，两组患者均有 1 例出现局部伤口感染迹象，患者主诉为疼痛不适，建议患者再次入院、卧床休息并予以抗感染治疗后均缓解出院。两组总体不良事件发生率比较差异无统计学意义(P>0.05)。

3 讨论

补片材料修补疝的方案是以腹股沟区的解剖结构为基础，采用人工材料加固腹股沟管壁的材料，修补时可以做到正常解剖层次的对合和重建，克服了传统修补手术方案对正常解剖结

表 2 两组患者围手术期临床指标的比较(n,$\bar{x}\pm$ s)

Table 2 Comparison of the Perioperative indicators between two groups(n, $\bar{x}\pm$ s)

Groups	Operating time (min)	Blood loss (ml)	Length of hospital stay (d)	Down time (d)	Analgesic drug application cases(n)
Control group	55.1± 10.2	103.4± 11.2	6.1± 1.2	5.1± 1.5	8
Research group	27.6± 5.5*	35.5± 11.7*	4.5± 1.1*	1.5± 0.4*	2*

Note: Compared with Researched group, P<0.05.

表 3 两组患者不同时间点 VAS 评分比较(分)

Table 3 Comparison of the VAS score between two groups of patients at different time points(Points)

Groups	Preoperation	At 1 month postoperation	At 3 months postoperation	At 6 months postoperation
Control group	2.5± 0.5	1.5± 0.4	0.9± 0.4	1.0± 0.5
Research group	2.4± 0.7	1.4± 0.5	0.8± 0.5	0.9± 0.4

Note: Two groups of data compared with the preoperative, P<0.05, compared two groups of different time points, P>0.05. Show two groups of treatment are effective and the effect of two groups of patients.

表 4 两组患者不同时间点主观满意度比较(分)

Table 4 Comparison of the subjective satisfaction between two groups of patients at different time points(Points)

Groups	Preoperative	Postoperative 1 month	After 3 months	After 6 months
Control group	45.4± 14.1	72.4± 11.6	73.5± 8.9	75.8± 9.2
Research group	39.8± 17.2	84.3± 12.4	87.3± 5.8	86.5± 6.7

Note: Two groups of data compared with the preoperative, P<0.05, compared two groups of different time points, P<0.05. Show two groups of treatment are effective and two groups of patients with subjective satisfaction with polypropylene patch materials has obvious advantage.

构的干扰[28-30]。且此种修补方案是无张力修补,更符合生理特点,可以减轻术后由于张力造成对患者的疼痛不适,手术时间短、出血少、下地早,患者主观满意程度高。本研究通过临床对比研究分析了采用聚丙烯补片材料修补腹股沟疝与传统修补手术方式的临床疗效的差异,结果显示采用补片材料修补可以明显的降低手术的创伤,有利于患者围手术期的康复、可以较早的下地活动、促进功能修复和降低相关并发症的发生[18-22]。虽然修补术式经过多年的发展,采用自体组织缝合的方法已经明显降低了术后疝的再发生率,但是由于其病理基础是腹壁组织的薄弱缺损,采用单纯的缺损部位丝线缝合的方法组织张力较高,在腹压升高的情况下仍有再次组织撕裂、复发的风险发生。另外术后不能早期站立及离床活动,组织水肿、局部肿胀都较补片修补严重,所以采用聚丙烯补片材料修补疝的方案显得具有明显的治疗优势[23-27]。

但补片材料修补腹股沟疝也存在并发症的风险,根据目前的国内外临床资料分析,主要的并发症为感染、粘连和复发[31-33]。补片术后感染是因为补片材料作为异物本身植入体内就是有感染的概率,特别是多次感染后需要取出补片造成手术失败乃至窦道形成。随着材料技术的发展,学者们认识到补片本身的重量和网孔的大小是控制感染的两个重要因素。经过多年的研发和技术的发展,采用单纤丝方案编织轻质补片明显降低了补片修补手术的感染率,并且即便出现感染后,也可以通过局部引流处理无需取出补片本身。对于粘连主要是补片在体内与肠管接触时由于炎性刺激造成的纤维蛋白渗出物在补片存在条件下难以吸收, 所以现在学者们致力于生物型补片的研发,主要希望较好的组织相容性,通过脱细胞材料的补片实现早期的自体组织细胞嵌入,降低局部炎性刺激反应过程。导致疝复发的因素很多,可能与补片张力不足、移位、皱褶导致疝从补片的边缘或原位再次突出,引起复发[34-37]。所以,对于手术技术的培训是疝修补手术医师需要关注的一个重点方面[38]。

综上所述,采用生物补片材料修补腹股沟疝的手术创伤较小且患者恢复期短,近期疗效及安全性与传统手术相当。随着对各种材料源性的补片研发不断深入以及临床疝修补技术的规范,无张力疝修补手术会逐渐发展为一种安全有效、明显改善患者生活质量的治疗方案。虽然本研究的患者病例数少、随访时间尚短,但是通过本研究提示聚丙烯补片材料在疝修补手术中应用的重要临床价值和意义,后期需要大样本和长期的随访研究去深入了解该材料的临床远期疗效。

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