



doi:10.7659/j.issn.1005-6947.260044
<http://dx.doi.org/10.7659/j.issn.1005-6947.260044>
China Journal of General Surgery, 2026, 35(4):696-702.

· 述评 ·

BIOLAP 研究对生物网片临床应用的再认识与启示

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摘 要

生物网片因具有诱导组织再生、减少永久异物残留等潜在优势, 被广泛探索应用于疝与腹壁外科。然而, 其临床价值长期缺乏高级别循证医学证据支持, 尤其在腹股沟疝和复杂腹壁疝中的应用始终存在较大争议。近年来, 多项随机对照研究及 Meta 分析显示, 生物网片在复发率、并发症及成本效益方面并未展现出较合成网片的明确优势。2025 年发表的 BIOLAP 随机临床试验采用自身对照设计, 对腹腔镜双侧腹股沟疝修补中生物网片与合成网片进行了直接比较, 结果显示生物网片不仅未降低术后慢性疼痛发生率, 反而显著增加疝复发及血清肿风险, 对其常规应用提出了重要挑战。本文结合 BIOLAP 研究结果, 系统回顾生物网片的材料学特性、临床应用现状及主要争议, 重点分析其在腹股沟疝、腹壁疝及预防性腹壁加固中的循证证据, 并探讨当前生物网片应用受限的可能机制及未来发展方向。现有证据提示, 生物网片难以作为合成网片的普遍替代方案, 其未来价值更可能体现在特定高风险场景下的精准应用, 以及新型智能化、复合化和功能化材料的研发。

关键词

疝修补术; 外科网; BIOLAP 随机临床试验

中图分类号: R656.2

Reappraisal and implications of biologic mesh use in clinical practice after the BIOLAP study

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Abstract

Biologic meshes have been increasingly explored in hernia and abdominal wall surgery because of their potential advantages in promoting tissue regeneration and reducing permanent foreign-body implantation. However, their clinical efficacy has long lacked support from high-level evidence, and their role in inguinal and ventral hernia repair remains controversial. Recent randomized controlled trials and meta-analyses have shown that biologic meshes do not demonstrate clear superiority over synthetic meshes in terms of recurrence, postoperative complications, or cost-effectiveness. The BIOLAP

收稿日期: 2026-01-21; 修订日期: 2026-04-07。

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randomized clinical trial published in 2025, which adopted a unique self-controlled design in patients with bilateral inguinal hernias, directly compared biologic and synthetic meshes in laparoscopic inguinal hernia repair. The study demonstrated that biologic meshes not only failed to reduce chronic postoperative pain, but were also associated with significantly higher rates of hernia recurrence and seroma formation, thereby challenging their routine clinical use. Based on the findings of the BIOLAP study, this article systematically reviews the material characteristics, clinical applications, and major controversies surrounding biologic meshes, with particular emphasis on current evidence in inguinal hernia repair, ventral hernia repair, and prophylactic abdominal wall reinforcement. In addition, the possible mechanisms underlying the limitations of biologic meshes and future directions for material innovation are discussed. Current evidence suggests that biologic meshes are unlikely to serve as a universal substitute for synthetic meshes, and their future value may lie in precision application in selected high-risk scenarios and in the development of novel intelligent, composite, and functional biomaterials.

Key words Herniorrhaphy; Surgical Mesh; BIOLAP Randomized Clinical Trial
CLC number: R656.2

疝和腹壁外科领域材料学的发展经历了从不可吸收合成网片、部分可吸收网片到完全可降解生物网片的演进,并正朝着复合型与智能功能化材料的方向不断发展。目前以合成网片为主要修复材料的无张力疝修补术和腹腔镜腹股沟疝修补术虽显著降低了疝修补术后的复发率^[1],但其作为永久性植入物,可以引起术后慢性疼痛、异物感及感染、侵蚀等远期并发症^[2]。因此,为克服这些局限,提高疗效、改善患者术后体验,以脱细胞外基质(decellularized extracellular matrix, dECM)为主要骨架的生物网片应运而生^[3],也标志着疝修补材料从“永久性机械强化”向“生物材料诱导再生”方向转变的一种探索^[4-5]。然而,关于生物网片能否在维持远期修补强度的同时减少慢性疼痛,目前仍缺乏一致结论。尤其是在腹腔镜腹股沟疝修补领域,既往研究结果存在较大差异,高级别循证医学证据相对不足。2025年发表在*JAMA Surgery*上的BIOLAP随机临床试验^[6]首次采用自身对照设计,对生物网片与合成网片进行了直接比较,其结果对生物网片的临床定位产生了重要影响。本文结合BIOLAP研究,对生物网片的应用现状、主要争议及未来发展方向进行综述与思考。

1 生物网片的概况

生物网片通过去除细胞成分,保留细胞外基

质的结构与生物活性,充当再生支架诱导宿主细胞浸润、促进新生血管与基质重塑,最终实现组织的修复与功能重建,并在完成修复后降解吸收,避免永久异物留存^[7-8]。凭借上述机制,生物网片理论上在减轻术后疼痛与并发症方面存在一定优势,来源也从人源性拓展至猪、牛等异种移植,材料来源更为丰富。其性能如降解速度、力学性能和宿主反应等受加工工艺,尤其是化学交联程度的影响。非交联生物网片最大程度保留了dECM的生物活性,通过降解过程中释放生物信号招募宿主细胞,诱导组织再生,实现无植入物残留的生理性修复^[9],因而适用于低张力的腹壁缺损。交联型生物网片通过化学交联增强胶原网络稳定性,延缓降解,提高机械强度,从而提供相对长期的结构支撑,适用于相对高张力部位的修复^[10]。但交联可能牺牲部分生物活性,过度交联甚至会阻碍细胞浸润与血管生成,引发过度炎症反应,导致网片被纤维包裹而非真正的整合与重塑^[11]。因此,生物网片通过选择不同的材料来源和加工工艺,在机械性加固与组织重塑之间寻找一种性能平衡,从而适用于不同临床场景^[12]。

2 生物网片在腹股沟疝和腹壁疝应用中存在的争议回顾

既往关于生物网片的研究结果差异较大,不

同研究之间甚至得出相反结论，这也是BIOLAP研究开展的重要背景之一。在BIOLAP研究发表前，生物网片的临床价值，尤其在与合成网片的比较中，存在诸多争议，主要原因在于腹股沟疝领域缺乏高质量的临床研究，且已有临床研究结果存在较大差异，甚至完全相反。与此同时，生物网片在临床中的应用仍呈明显增加的趋势，尤其是在年轻患者或存在污染风险的疝和腹壁外科病例中。一项系统评价^[13]指出，目前生物网片的应用往往基于低质量研究或仅凭专家意见，缺乏高质量证据支持。

在腹股沟疝修补中，生物网片应用的结论存在较大分歧。支持生物网片应用的研究主要围绕改善术后慢性疼痛的假设之上。2009年的一项随机对照试验^[14]显示，在Lichtenstein修补术中，以猪小肠黏膜下层为主要成分的生物网片能显著降低患者术后静息、咳嗽及活动时的疼痛程度，且3年复发率与聚丙烯补片相当。2013年一项随机对照试验^[15]结论也提示，以猪真皮基质为主要成分的生物网片可减轻早期疼痛，且在术后3个月时复发率与轻量合成网片无差异。2019年一项10年前瞻性单臂研究^[16]显示，使用猪小肠黏膜下层生物网片（SIS生物补片）行纯组织修补，10年随访复发率为1.9%，且并发症和慢性疼痛发生率较合成网片更低，进一步支持了生物网片的长期安全性。同年另一项回顾性研究^[17]同样证实，在开放与腹腔镜腹股沟疝修补术中均有效，开放手术后血清肿发生率更低，腹腔镜手术术后疼痛更轻。2020年一项随机对照试验^[18]显示，无论是开放还是腹腔镜术式中，牛源性生物网片较合成网片在术后3个月能更有效地减轻腹股沟区疼痛且未观察到复发。2024年一项针对SIS生物补片的多中心随机对照试验^[19]表明，在腹腔镜手术中应用该生物网片，术后复发率不劣于轻量合成补片，且术后慢性疼痛和并发症更少。2026年一项多中心单臂研究^[20]同样报告，SIS生物补片用于腹腔镜腹股沟疝修补的术后随访中，未观察到复发、感染及慢性疼痛。然而，质疑生物网片常规应用价值的证据同样存在。2015年一项回顾性研究^[21]结果显示，在腹腔镜腹股沟疝修补术中使用SIS生物补片的术后复发风险高，再次腹腔镜探查发现网片已被完全吸收。

2024年一项1 240例腹腔镜经腹腹膜前（TAPP）腹股沟疝修补术的大型回顾性队列研究^[22]显示，在平均超过7年的长期随访中，所有5例复发事件均发生于SIS生物补片组。2025年的Meta分析^[23]认为，在腹腔镜腹股沟疝修补术中，生物网片与合成网片在复发率、并发症及不良事件方面无显著差异。总之，生物网片在腹股沟疝修补领域的疗效目前仍存在较多争议。

在腹壁疝修补方面，生物网片的质疑声则更多。早期的观察性研究显示脱细胞真皮基质网片在腹壁重建中能够提供较持久的力学支持与较低的并发症^[24]。也有研究^[25-26]表明生物网片用于复杂腹壁疝可改善患者生活质量。然而，更多的研究并不支持其应用。一项3年随访的回顾性队列研究^[27]发现，在伴有并发症或污染风险的腹壁疝患者中，生物补片的复发率较合成补片显著增高（56.4% vs. 28.8%），手术部位感染率也更高（20.3% vs. 6.6%）。更值得关注的是，近年来多项高质量RCT研究较一致地对生物网片在腹壁疝中的应用提出了质疑。2021年的一项RCT研究^[28]发现，在缺损>10 cm、存在污染或广泛粘连的复杂开放腹壁疝修补术中，生物网片组的1年复发率是对照组的2倍多（30.3% vs. 13.5%）。同年发表的LAPSYS研究^[29]显示，无论是开放腹壁疝修补术还是腹腔镜手术，生物网片组的复发率均显著高于合成网片组，该试验甚至因此被提前终止。PRICE研究^[30]则表明，在清洁或污染的腹壁疝队列中，生物网片组的总体复发率较合成网片组显著更高（39.7% vs. 21.9%），且在污染腹壁疝亚组中差异更为显著（50.0% vs. 5.9%）。2022年一项针对污染腹壁疝的多中心RCT研究^[31]表明，合成网片术后2年复发率显著优于生物网片（5.6% vs. 20.5%），且成本优势更大。2023年一项纳入上述4项RCT的Meta分析^[32]进一步证实，生物网片在开放腹壁疝修补中的复发率和手术部位感染率均显著高于合成网片，而血清肿、血肿及补片取出率无显著差异。多项系统评价一致认为，生物网片在污染术野中的应用缺乏充分的高级别证据支持，除了在复发率和成本方面的劣势外，生物网片在术后并发症方面也并无优势^[33-35]。总之，生物网片在腹壁疝的应用较腹股沟疝受到更多质疑。

3 生物网片在预防疝发生中的作用

尽管在常规腹股沟疝与腹壁疝治疗中,生物网片的临床应用存在较多争议,但在预防疝发生中的作用获得了较为一致的、不同等级的证据支持^[36-38]。

2020年发表于 *Lancet* 的 ROCSS 研究^[39]是一项多中心随机对照临床研究,评估了在造口还纳术中使用生物网片(猪真皮基质生物网片)进行预防性腹壁加固的效果,证实生物网片可以有效降低术后切口疝发生率,且后续长期随访研究进一步证实了这一结论^[40]。在腹会阴联合切除术后预防会阴疝的随机对照研究(BIOPEX)^[41]中,5年随访结果表明,与直接缝合相比,使用生物网片可显著且持久地降低会阴疝的发生率,且不会增加远期并发症风险。这些高质量的临床研究表明,在高危发生切口疝(含会阴疝)的患者中,预防性应用生物网片可有效降低切口疝(含会阴疝)的风险,这是目前临床应用生物网片的主要指征之一。

4 BIOLAP研究对生物网片临床定位的重新定义

长期以来,生物网片在腹腔镜腹股沟疝修补术中的价值缺乏确定性证据,其核心争议在于,生物网片能否在减轻慢性疼痛的同时维持可靠的远期疗效。BIOLAP研究以其严谨的方法学为这一核心争议提供了高级别的临床证据,其真正价值在于首次直接检验了“生物诱导再生是否能够替代永久机械强化”这一核心命题。

BIOLAP研究采用自身对照设计,其纳入了491例双侧腹股沟疝患者。双侧疝患者一侧随机接受生物网片,对侧接受合成网片,这最大限度地控制了个体差异对结局评估的干扰。BIOLAP研究在21家中心开展,实施严格双盲评估,患者和评估者对使用的网片均不知情,仅手术医生知晓,主要终点由非手术医生团队评估,保证了结果评估的客观性。

该研究结果清晰而明确:在主要终点上,术后2年生物网片侧的疝复发率高达11.2%,显著高于合成网片侧的2.5%。而在术后6个月的疼痛评分上,两者未显示出统计学差异。此外,生物网

片还伴随着更高的血清肿发生率(33.4% vs. 21.6%),并且在术后早期表现出更明显的疼痛、异物感和更低的患者满意度。基于这些数据,研究者指出,在当前技术下,生物网片并未实现减轻术后疼痛的理论预期,反而在复发率和血清肿风险上显著劣于合成网片,因此不支持其在腹腔镜腹股沟疝修补中的常规应用。

当然,该研究也具有局限性。比如,该研究所使用的生物网片均为多孔、非交联的脱细胞胶原基质,因此结论不能推广至其他类型生物网片。此外,研究人群限定为双侧腹股沟疝患者,其人群特征可能不同于更广泛的单侧疝群体,其结论外推时也需保持谨慎。

5 生物网片从普遍应用走向精准应用

BIOLAP研究以其自身对照设计,为腹腔镜下双侧腹股沟疝修补中的网片选择提供了关键证据。其结论明确显示,在该场景中生物网片未能将“诱导组织再生”的理论优势转化为现实的临床价值。造成这一结果的关键原因可能在于生物材料降解与诱导再生的进程不可预知和不可调控^[42]。在宿主自身胶原尚未充分完成重塑并提供足够支撑之前,生物网片的主体结构已被吸收,导致在愈合过程中出现力学支撑的薄弱期,从而导致修复失败^[43-44]。因此,我们应重新审视生物网片的价值。生物网片的价值可能不在于作为合成材料的普遍替代,而是作为解决特定临床场景时的优选项。当前,支持生物网片应用的高级别证据包括预防性使用生物网片来降低特定高风险部位术后切口疝的发生率,例如造口还纳手术时(ROCSS试验)或腹会阴切除术中会阴重建时(BIOPEX试验)。未来,在其他特定临床场景中探索生物网片的价值,仍需高质量随机对照研究予以验证,尤其是上市后临床研究。

当然,突破现有局限的另一个关键在于材料学的进展。主要的方向可能包括可调控的降解与诱导再生进程的新型生物材料、兼具生物活性与持久支撑的智能复合材料、结合可吸收与永久性材料优势的混合型网片以及能主动调控愈合微环境的功能化支架材料等^[45-50]。

总之,BIOLAP研究为生物网片的临床价值划定了清晰边界:在治疗性腹股沟疝修补中不宜常

规使用,而预防性应用和材料学创新仍是未来的主要方向。

作者贡献声明:陈志杰负责论文撰写;黄耿文负责论文构思、修改。

利益冲突:所有作者均声明不存在利益冲突。

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(本文编辑 宋涛)

本文引用格式:陈志杰, 黄耿文. BIOLAP研究对生物网片临床应用的再认识与启示[J]. 中国普通外科杂志, 2026, 35(4):696–702. doi: 10.7659/j.issn.1005-6947.260044

Cite this article as: Chen ZJ, Huang GW. Reappraisal and implications of biologic mesh use in clinical practice after the BIOLAP study[J]. *Chin J Gen Surg*, 2026, 35(4): 696–702. doi: 10.7659/j. issn. 1005-6947.260044