磁外科器械结构规划原则及相关思考

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摘要 自20世纪70年代第一个磁外科器械出现以来,在随后的近50年里,磁外科器械取得了巨大的发展,解决了一系列复杂的临床问题,进一步优化了传统手术方式. Levita和LINX等具有代表性的磁外科器械相关成果发表于行业顶尖期刊,在外科学界及理工科学界产生了深远的影响. 经各行业专家总结相关理论和应用体系,逐渐形成了一门学科——磁外科学,这是外科学的一个重要分支. 近年来,在磁外科(磁外科)理论体系的指导下,磁外科更是取得了蓬勃的发展,各种极具创新性的磁外科器械层出不穷. 但不容忽视的是,磁外科发展将会不断遇到重重阻碍. 由于磁外科是一门交叉学科,需要外科学与理工科学进行深度融合. 在此过程中,难免因为双方信息不匹配而延误磁外科的发展,最为代表性的问题便是如何对磁性器械进行合理、有效的结构规划这一磁外科最基本的问题. 因此,本文将对磁外科器械结构规划的原则展开讨论,总结过去磁外科器械结构规划中所遇到的问题,并提出解决相应问题的潜在方法.

关键词 磁外科, 永磁, 软磁, 电磁, 电控永磁

近年来,磁外科(磁外科学)取得了迅猛的发展,各种极具创新性的磁外科器械相继问世. 但其中,不少磁外科器械在结构设计过程中存在不合理之处,导致器械未能完全体现出磁的优势,这严重阻碍了磁外科的发展. 本文旨在讨论磁外科器械结构规划的原则,对过去磁外科器械结构规划中所遇到的问题进行总结,并提出解决相应问题的方式方法.

1 磁外科器械结构规划原则

综合外科和理工科对器械结构规划过程的需求,

提出磁外科器械结构规划必须遵循磁力满足功能、安全不损伤、体积最小化、形状最优化4点设计原则.

1.1 磁力满足功能需要

磁外科器械具备相应功能是磁外科器械结构设计时应该考虑的首要问题. 根据不同应用场景,对磁器械的功能需求不同. 目前,根据之前磁器械的临床应用情况,已归纳总结出磁器械的压榨、锚定、导航、定位、悬浮、限流、定滞等功能. 其中,磁压榨、磁锚定、磁导航、磁定位、磁限流、磁定滞利用的是磁异

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性相吸的作用力,磁悬浮利用的是磁同极相斥的作用力^[1].设计时,必须确保磁力能有效实现上述功能.例如,在磁压榨吻合器设计过程中,首先要保证的就是磁吻合器能压迫穿透组织,形成有效的吻合口;同时也要保证吻合后吻合器不因管内压力而解离造成吻合失败.Wall等人^[2]在结肠的侧-侧、端-侧、端-端3种不同吻合方式的实验中,提出成功吻合分别需要4.35(3.78~4.93)、2.41(2.10~2.73)和1.48(1.11~1.86) N的压榨力,以及需要对抗至少96 mm汞柱的爆破压.为了满足以上要求,他们设计了一对外径23 mm、内径12 mm、高度5 mm的N35钕铁硼磁环,由聚碳酸酯外壳封装,最终实现了可靠有效的磁压榨结肠吻合(图1).此外,Rosenbluth等人^[3]设计了用于治疗睡眠呼吸暂停的磁牵拉装置,通过磁力将舌骨牵拉起起到畅通作用,该牵拉力经过测量确定为2 N.因此,在设计磁牵拉装置时,必须将牵拉力控制在2 N,否则可能会导致气道不能完全打开,或者导致舌骨损伤.本文总结了磁吻合器的结构设计和相关参数,见表1.同样地,在磁锚定器械的结构设计中,也应当考虑到体内、外磁体之间磁力随着两者之间距离变化的问题.Best等人^[33]在研究磁锚定手术视频导航系统的过程中,探究了不同设计的体内、外磁体组之间的磁锚定力与腹壁厚度的关系,在已知磁锚定手术视频导航系统质量的基础上,判断该磁体组是否能有效地将手术视频导航系统锚定在腹壁上而不发生脱落.

1.2 磁力在安全范围内

在磁体磁力满足临床功能需要的基础上,也要考

虑到过大的磁力可能对患者造成的安全隐患.因此,针对磁体设计,需要明确特定情况下磁力的安全范围,不能让磁外科器械解决了老问题,又带来了新问题.如在磁锚定减戳卡技术和磁锚定手术视频导航系统中,体内、外磁体之间磁力在满足有效锚定抓钳和手术视频系统的同时,不能为了锚定效果而无限增大磁力.一方面是为了防止锚定力过大导致体内工作单元移动灵敏度降低,削弱磁锚定技术灵活可控的应用效果;另一方面,过大的磁锚定力长时间作用于体内、外磁体之间的组织,会造成组织缺血坏死,导致不必要的医源性损伤^[34].磁定滞技术和磁限流技术的应用更应该严格遵循此原则.Nachev等人^[35]利用磁定滞技术为眼球震颤患者进行了眼球震颤解除手术.通过在眼下直肌下方植入一枚直径3 mm、厚度1 mm的柱形钕钴磁体,与眶底上方的直径3.73 mm、厚度2 mm的柱形钕铁硼磁体相吸引.通过两个磁体相互吸引,增强了下直肌肌力,以对抗眼球向上不自主震颤力.在下直肌下方植入的钕钴磁体磁能积远小于钕铁硼磁体,就是为了防止过大的磁力虽然达到了解除震颤的目的,但又造成了患者动眼困难.LINX的设计思路也是如此,不仅要让磁串珠有足够的收缩力来对抗胃食管反流,也要避免磁力过大导致的吞咽困难^[36,37].

1.3 磁体体积最小化

同时,磁体体积也力求最小化,使磁能达到最大效率的利用.这一点是工科专家和外科专家在磁体结构设计时共同的需求.在明确临床试用过程中所需磁力

图1 (网络版彩色)结肠磁吻合^[2]. (a) 3种结肠磁吻合方式. (b) 结肠磁吻合步骤: (b1) 定位结肠近端磁环的位置; (b2) 放置近端磁环; (b3) 经肛门控制近端磁环; (b4) 经肛门放置远端磁环; (b5) 近端磁环与远端磁环相吸; (b6) 检查吻合通畅性

Figure 1 (Color online) Magnetic compression anastomosis for colorectal^[2]. (a) Three magnetic colorectal anastomosis methods. (b) Colorectal magnetic anastomosis steps: (b1) Localize the position of the proximal magnetic ring; (b2) delivery of the proximal magnetic ring; (b3) transanal control of the proximal magnetic ring; (b4) transanal delivery of the distal magnetic ring; (b5) attract the proximal magnetic ring with the distal magnetic ring; (b6) check for anastomosis patency

表1 磁吻合器结构和排出时间^{a)}

Table 1 Magnetic stapler structure and ejection time

作者	发表年份	磁体类型	磁体形状尺寸	吻合方式	磁力	磁体排出时间
Kanshin等人 ^[4]	1978	钐钴和钕铁硼	N/A	胃-十二指肠吻合	N/A	N/A
Jansen等人 ^[5]	1981	钴	圆环直径: 25, 28, 30 mm	直肠吻合	11.8 N	7~12 d
Stepanov等人 ^[6]	1992	永磁	N/A	旁路吻合	N/A	N/A
Saveliev等人 ^[7]	1993	N/A	N/A	胆囊-胃吻合	N/A	N/A
Cope ^[8]	1995	钕铁硼或钴	圆形直径: 6.4~12.7 mm	胃-空肠吻合	N/A	7~13 d
Chopita等人 ^[9]	2005	N/A	圆形直径: 12 mm	胃-十二指肠吻合	N/A	N/A
Akita等人 ^[10]	2008	永磁	圆柱状母磁体: 直径5 mm, 高度5 mm; 子磁体: 直径4 mm, 高度9 mm	胆管吻合	N/A	N/A
吕毅研究团队 ^[11]	2008	钕铁硼	圆形外径: 7 mm; 内径: 3.8, 4.4 mm	胆管-空肠吻合	6.4 N	N/A
Jamidar等人 ^[12]	2009	钕铁硼	N/A	肠-肠吻合	N/A	7~14 d
Jang等人 ^[13]	2010	永磁	圆柱形直径: 5, 4 mm	肝移植术后胆道狭窄	N/A	14~181 d
Itoi等人 ^[14]	2010	钐钴	圆柱形直径: 4~5 mm	肝移植术后胆道狭窄	N/A	N/A
Diana等人 ^[15]	2011	钕铁硼	梯形外径: 21 mm; 内径: 12 mm	胃-空肠吻合, 空肠吻合	N/A	3~10 d
吕毅研究团队 ^[16]	2011	钕铁硼	环形外径: 16, 18 mm; 内径: 13, 15 mm	空肠吻合	N/A	6~7 d
Ryou等人 ^[17]	2011	N/A	正方形边长: 2.25 cm×2.25 cm	胃-空肠吻合	N/A	12 d
Gonzales等人 ^[18]	2012	钕铁硼	环形外径: 23 mm; 内径: 12 mm	十二指肠-结肠吻合	N/A	N/A
Wall等人 ^[2]	2013	钕铁硼	环形直径: 23 mm	结直肠吻合	4 N	N/A
吕毅研究团队 ^[19]	2013	钕铁硼	环形外径: 18~22 mm; 内径: 15~19 mm	血管吻合	N/A	N/A
Diana等人 ^[20]	2014	N/A	圆柱直径: 4 mm, 展开直径: 2.5 cm	结直肠吻合, 空肠吻合	结直肠吻合: (6.1±0.98) N; 空肠吻合: (12.88±1.34) N	5 d
吕毅研究团队 ^[21]	2014	钕铁硼	环形外径: 7 mm; 内径: 3.8, 4.4 mm	胆-肠吻合	N/A	N/A
吕毅研究团队 ^[22]	2015	钕铁硼	环形外径: 21 mm; 内径: 11 mm	血管吻合	N/A	N/A
Xu等人 ^[23]	2015	钕铁硼	球形外径: 29, 26, 24 mm; 内径: 25, 22, 20 mm	结肠-直肠吻合	N/A	6~9 d
吕毅研究团队 ^[24]	2015	钕铁硼	环形外径: 30~32 mm; 内径: 28~30 mm	黏膜切除术	N/A	(8.20±2.73) d
Ryou等人 ^[25]	2016	IAS磁体	八边形近似于小肠腔的直径	空肠-结肠吻合	N/A	12 d
Ersoz等人 ^[26]	2016	钕铁硼	圆柱形直径: 2.4 mm	肝移植术后胆管狭窄	N/A	N/A
Graves等人 ^[27]	2017	钕铁硼	梯形外径: 23 mm; 内径: 9.6 mm	小肠吻合	N/A	18 d
Parlak等人 ^[28]	2017	钕铁硼	圆柱形直径: 2.4 mm	胆囊管-胆管吻合术	N/A	N/A
吕毅研究团队 ^[29]	2017	钕铁硼	环形外径: 8 mm; 内径: 4 mm	结肠吻合	N/A	(14.5±2.08) d
吕毅研究团队 ^[30]	2017	钕铁硼	弓形长度: 51 mm; 宽度: 10 mm	直肠-阴道瘘	N/A	N/A
吕毅研究团队 ^[31]	2018	钕铁硼	环形外径: 6 mm; 内径: 4 mm	胆-肠吻合	N/A	6~10 d
吕毅研究团队 ^[32]	2018	钕铁硼	环形外径: 8~15 mm; 内径: 4 mm	小肠吻合	N/A	28~43 d

a) N/A: 无法获得该信息

后, 选取合适材料的磁体, 通过设计磁体尺寸, 改变磁体工作点(P)。对于临床上常用的钕铁硼永磁等强各向异性稀土磁体, 其退磁曲线近似为一条直线(图2(a)),

因此通过设计磁体尺寸使磁体工作点位于最大磁能积($BH_{\max}$)处, 既可利用小体积磁体, 又能获得最大磁力, 使磁性材料得到充分利用, 经济最大化^[38]。另外, 小体

积磁体对于解决临床问题也至关重要。例如,在血管、消化道吻合时,在需要相同的磁压榨力的条件下,选用磁能积高的钕铁硼磁体,便可利用小体积磁性吻合器,如若选用钐钴磁体、铝镍钴磁体等磁能积较低的磁体,就需要体积更大的磁吻合器^[39]。针对相同的管道吻合,管道直径是相对固定的,即磁吻合器直径也基本一定,体积更大意味着需要增大磁体厚度。一方面,增加厚度降低了磁吻合器吻合不稳定性;另一方面,更大的磁体带来了更多对机体感染、机械损伤以及机体对其排斥的风险。在磁锚定技术减戳卡应用中更应该强调磁体体积最小化的原则。由于人体腹腔内空间有限,即便气腹可使腹腔空间增大,为了避免气腹对人体的不良影响,气腹所提供的额外空间是有限的^[40]。如利用磁锚定减戳卡技术切除胆囊、阑尾等离腹壁较远的小体积器官,腹腔空间基本够用,但磁锚定减戳卡技术切除肝脏等贴近腹壁的大体积器官,仍未见报道。笔者认为,肝脏体积大,贴近腹壁,大量占用了腹部空间,如若使用传统的体内磁锚定抓钳,由于其本身长度较长,在小空间内不能对肝脏实现有效牵拉,因此磁锚定减戳卡技术在该领域发展受阻。

1.4 磁体形状最优化

磁体形状直接影响磁场分布。在同一空间内,不同的磁场分布所产生的磁场作用是不同的。根据临床实际需求,设计最佳的磁体形状是十分必要的。例如,虽然磁锚定手术器械可以减少戳卡,从而达到更加微创的目的,但体内工作单元的运动安全性一直备受争议。磁锚定方式的定位可靠性引起了相关从业者的广泛关注,即如何减少文献中常常提及的“解离”现象的发生——这种情况下开腹取出磁锚定手术器械不可避免,是磁锚定方式引发的最严重不良事件^[41]。Kanshin等人^[4]和Dong等人^[42]考虑通过明确体内、外磁体磁力与腹壁厚度的关系,从而得到能锚定体内工作单元的最小锚定力来保证锚定过程中不发生“解离”。但该方法假定研究对象是静态的,不能保证体内工作单元在移动过程中不发生“解离”。在移动过程中,磁锚定器械在磁力的水平分力与垂直分力共同作用下实现移动并吸附于腹壁,运动过程中如果垂直分力小于体内工作单元重力,则会发生“解离”。外磁体形状直接影响磁场分布。例如对于椭圆柱形外磁体,当内磁沿着长轴移动时,磁场变化较慢,使得垂直分力衰减幅度更小,从而更不易“解离”;当内磁沿着短轴移动时,磁场变化较快,使

得垂直分力衰减幅度更大,从而更容易发生“解离”。如果需要磁体在横向移动而纵向移动较少,同等体积的条件下,体外磁体可设计为底面为椭圆形或长方形的柱体。因此,根据实际情况设计最合适的磁体形状,可以更合理地利用磁外科器械。

2 目前磁外科器械结构中存在的问题

磁外科器械结构设计过程应当以外科医生为主体,外科专家提出对磁外科器械的功能需要,理工科专家通过合理设计实现功能。但此过程中,由于不可避免的沟通障碍,或技术难度过大,导致在过去50余年的磁外科发展历史过程中,磁外科器械结构设计出现了一些问题。笔者将这些问题总结为4点:磁体磁力不可控、磁体磁力不可退、磁体磁力不可知和磁体形状不可变。

2.1 磁体磁力不可控

过去用于压榨吻合、锚定牵引、悬浮定位等领域的磁外科器械的材料绝大多数是稀土永磁,如钕铁硼、铁钐钴、铝镍钴等。永磁具有不可比拟的优势,如永磁相比于电磁不存在励磁系统损耗,提高了效率;永磁无励磁绕组和励磁电源,结构简单,运行可靠;永磁体积小,重量轻;永磁尺寸和形状灵活多样^[43]。但永磁也存在一些问题,如一旦充磁完成,其磁场方向和磁场分布均无法改变,因此只能针对特定临床问题设计特定磁外科器械,这严重阻碍了磁外科的推广。在磁吻合应用中,由于不同患者的血管、消化道、泌尿管道存在个体差异,尤其是儿童和成年人管道直径明显不同,所需的磁吻合器的磁力也相应不同,因此在临床应用过程中需要针对特定个体、特定吻合管道制作特定磁吻合器,这不仅给外科医生选择使用磁吻合带来了不便,还增加了磁吻合器的成本,使磁吻合的推广受阻。在磁锚定技术推广过程中,该问题尤其突出,手术过程中所需的磁锚定力大小由体内、外磁体之间距离,即胸、腹壁的厚度,以及锚定对象的质量决定。个体间的胸、腹壁厚度差异极大,且锚定对象的质量也大小不一,因此所需的磁锚定力也千差万别。在现有磁锚定报道中,患者腹壁厚度多在2 cm以内^[44,45],但临床中肥胖患者的腹壁厚度可达4 cm^[5],现有的磁锚定设备无法增大磁力,导致磁锚定手术不能在该人群中施行。同样地,过大的磁锚定力导致体内工作单元移动灵敏度降低,削弱了磁锚定技术灵活可控的应用效果,也会造成腹壁组织缺血坏死,导致医源性损伤。因此,设计一款适

图2 退磁曲线。(a) 永磁退磁曲线^[38]；(b) 软磁退磁曲线^[47]

Figure 2 Demagnetization curve. (a) Demagnetization curve of the permanent magnet^[38]; (b) demagnetization curve of the soft magnet^[47]

用于大多数人的磁力可调节的磁锚定设备是十分必要的。

2.2 磁体磁力不可退

目前,常用的磁外科器械绝大多数是由永磁材料制成的,一般条件下该器械在充磁后较长时间内不会退磁。尤其是矫顽力大的钕铁硼、钕钴磁材料,此类磁性材料经过外加磁场磁化后能长期保留强磁性,其特征是具有很大的矫顽力。矫顽力是磁性材料经过磁化后再经过退磁使剩余磁性(剩余磁通密度或剩余磁化强度)降低到零的磁场强度(图2(b))^[46,47]。高矫顽力保证了磁材料对外加干扰磁场和震动等环境因素变化的高稳定性,增强了临床应用过程中磁外科器械的可靠性,但同时也给临床应用带来了一些潜在的风险。例如,磁外科器械容易误吸其他铁磁性手术器械,不仅干扰了手术操作,而且有导致组织器官损伤的风险。在磁锚定手术过程中,体外磁体常常体积很大,磁性很强,应当小心谨慎地使用,避免铁磁性手术器械与其近距离接触,一旦接触误吸,强大的磁力会使两者难以分离^[48]。另外,在腔镜下的磁性手术器械,如磁锚定摄像系统、磁锚定抓钳,也容易与其他器械误吸^[5,49-52]。虽然体内磁手术器械磁性较弱,但误吸后在腔镜下进行拆解动作的难度加大,会严重地干扰手术进程。如果体内磁外科器械能轻易退磁,误吸后只需要撤掉外加磁源,误吸即可自动解除,将会极大地便利磁锚定手术进程,也会降低磁锚定手术发生副损伤的风险。

2.3 磁体磁力不可知

当前磁外科器械在体外可通过实际测量得知磁力大小,但在实际手术过程中,由于磁体进入体内后,无

法直接测量,因此外科大夫一般只能根据既往经验判断磁外科器械磁力大小,或者通过间接手段观察磁力。然而,精准的磁力测量可以为临床带来诸多有用的信息。例如,在磁消化道吻合过程中,磁吻合器从体内排出一一般需要数天到数周时间,排出时间在个体间差异极大,因此患者不得不多次接受X射线检查,判断磁吻合器是否已经排出体外。但是,一方面,X射线检查只能判断磁吻合器是否排出,而无法预测排出时间^[53,54];另一方面,接受多次的X射线检查对患者不利,且造成了一定的经济负担。如果某种方法能精准地测量体内磁体间磁力,也就能得知磁体间距离,反映磁吻合器距离完全压穿组织还需多久,从而能有效地预测磁体排出时间。例如,在之前的磁锚定手术中,体内、外磁体磁力是未知的,只能通过直观感受磁力大小来判断当前磁锚定力能否有效锚定体内磁性器械,但直观感受往往是不可靠的,因此造成了磁锚定手术过程中易发生“解离”的严重不良事件^[55]。如果能精准地实时反映体内、外磁体的磁力或者距离大小,则可预警体内、外磁体磁力过小而发生“解离”,也可避免体内、外磁体磁力过大而造成胸、腹壁组织损伤。

2.4 磁体形状不可变

过去磁外科研究中应用的磁性手术器械多为刚性的、结构不能改变的磁体,如磁环、磁柱、磁片等。虽然此类磁体已经解决了诸多临床问题,实现了诸多功能,如压榨吻合、锚定牵引、导航定位等,但临床患者的病情是复杂多变的,之前的磁体结构已经不能满足临床需求。例如,治疗食管狭窄时,有报道在狭窄近端和远端同时开胸放置一枚磁环,最终实现压榨吻合,这种慢性的吻合方式可以在有张力的情况下完成吻合,

相比传统手术针线吻合有巨大的优势^[56-58]。但是开胸手术对患者的创伤较大,若能采用胃镜下在狭窄近端和远端放置磁环,则可以减小手术创伤,利于术后恢复。但问题是,对于轻微狭窄,磁环尚且能通过狭窄处到达远端,而对于严重狭窄,则难以通过此方式实现吻合。如果磁环是软体结构的,则能通过狭窄解决此问题。此外,在腔镜磁锚定手术过程中,目前多个研究中用到的体内磁体均是直径1 cm、高度2 cm左右的圆柱形钕铁硼磁体,成功地实现了胆囊抓钳、阑尾抓钳等的锚定^[59-63]。但是,对于牵拉暴露较大的器官,则需要更大的磁力。考虑到手术室安全性,当前已经足够大的体外磁体不能再继续增大,而受限于戳卡直径,体内磁体的直径不可能无限增大,其高度因腹腔内空间的限制也不能无限增大,因此目前磁锚定减戳卡技术的应用受到了严重限制。

3 解决上述问题的潜在方法

针对以上问题,外科学家联合理工科学家不断尝试采用新的磁体设计来解决。本文总结了一些已经过初步验证的有效技术,同时也提出了一些具有发展前景的初步构想。

3.1 电磁、电控永磁控制磁力

上文提到目前磁外科器械多由永磁材料制成,永磁存在磁力不可控的缺陷,而电磁可以彻底解决此问题。电磁由磁芯和励磁线圈构成,当励磁线圈中有电流流过时能产生磁场。其产生磁场的原理决定了电磁具有以下永磁没有的优势:它可以通过通电/断电来控制

磁性的有无,而且电磁的磁性强弱可以由电流大小决定,通过增大激励电流即可增大磁性。此外,电磁的磁极可以通过改变激励电流的方向进行变换^[64]。以上特点决定了电磁用于制作磁外科器械不仅可以调节磁力大小,而且可以更改磁力方向。

电控永磁是继永磁和电磁后出现的新的磁技术。它利用两种或多种永磁材料的组合(通常是矫顽力相差较大的永磁材料,例如钕铁硼和铝镍钴),通过调节激励电流的大小和方向,使永磁所处的外加磁场发生变化,改变永磁工作点,最终表现为永磁组合具有多种不同的磁感应强度(图3(a))。相较于永磁,电控永磁的磁力具有可控性^[65,66]。相较于电磁,它只需要极短时间(500 ms左右)的激励即可完成磁性改变,因而更节能,且不会发生“断电失磁”现象。Tugwell等人^[65]设计的手持式电控永磁为具有中心腔的圆柱形钕铁硼和铝镍钴(图3(b))。通过胃镜在胃内置入一枚钕铁硼磁环,在腹壁用电控永磁与胃内磁环相互吸引。如果未吸引成功,则说明体内、外磁之间距离过大,存在其他组织,反之则说明胃壁与腹壁紧贴,可以安全地实施胃造瘘术。该装置已在猪模型中得到成功验证(图3(c))。

3.2 应用软磁实现快速磁化和退磁

相比于永磁(硬磁),软磁是具有低矫顽力、高磁导率、低损耗特点的磁性材料。软磁材料主要有金属软磁材料(纯铁、硅钢Fe-Si、坡莫合金Fe-Ni、铁钴合金Fe-Co等合金)及铁氧体软磁材料(如MnZn系、NiZn系和MgZn系等)^[67,68]。软磁材料的特性决定了它可以被快速地饱和磁化,而撤去磁化磁场后,即可迅速退磁。利

图3 电控永磁^[65]。(a) 电控永磁原理示意图。在退磁状态下,磁通在钕铁硼和铝镍钴内闭合,呈现为无磁性。在充磁状态下,钕铁硼和铝镍钴的磁通量相加,呈现为有磁性。(b) 体外电控永磁和体内磁环;(c) 电控永磁磁锚定胃造瘘

Figure 3 Electropermanent magnet^[65]. (a) Schematic diagram of the principle of the electropermanent magnet. In the demagnetized state, the magnetic flux is closed in NdFeB and AlNiCo, and it appears to be non-magnetic. In the magnetized state, the magnetic fluxes of NdFeB and AlNiCo are added together and it appears to be magnetic. (b) External electropermanent magnet and internal magnetic ring; (c) magnetic anchoring gastrostomy using electropermanent magnet

用这一特点,可以在磁外科手术过程中将硬磁和软磁搭配使用。比如在磁锚定手术中,将体内磁体由永磁改为软磁,由于其极高的磁导率,且可以被饱和磁化,因此其与体外永磁之间的吸引力不会弱于永磁与永磁之间的吸引力。再者,如果胸、腹腔内被磁化的软磁与铁磁性手术器械误吸,则通过撤离磁化磁场(体外永磁),体内的软磁可以瞬间退磁,失去磁性,与铁磁性手术器械的误吸即可解除。总之,体内磁体使用软磁材料既可以保证磁锚定的有效性,也可以增强磁锚定手术的安全性。在磁吻合中,软磁磁吻合器也有独特的优势。由于常用的手术器械大多数是铁磁性的,易与永磁吻合器误吸,严重干扰了吻合过程,而对于血管吻合来说,吻合时间直接影响术后器官恢复情况。如果磁吻合器采用硬磁和软磁搭配,将减少吻合器与手术器械误吸的概率,也消除了两个吻合器之间磁极装反等误操作的可能。

3.3 “智慧磁”磁吻合

如前文提及,消化道磁吻合后磁吻合器排出时间范围跨度较大,难以预测具体时间,需要不断地在X射线线下观察其排出情况。磁吻合器压榨吻合过程中,两磁环之间距离不断缩短,当两磁环距离为零时,则表示吻合器完全压穿组织,形成吻合,吻合器脱落,从消化道排出。换言之,如果能实时监测磁吻合器之间的距离,也就能预测判断磁吻合器完成吻合排出体外的时间。设想,如果能在磁吻合器两端加载微型距离传感器,并通过无线传输技术将距离转换成无线电信号,通过体外接收器解译,最终得知磁吻合器之间的距离,则可以达到预测吻合完成时间的目的^[69,70]。同样地,在磁锚定手术中,在体外磁体上加载霍尔元件,随着体内、外磁体之间距离变化,体外磁体上的霍尔元件接收到磁场信号发生相应改变。该信号的变化反映的是体内、外磁体

之间的距离变化^[71,72],因为在磁体确定的条件下,磁力由磁体距离决定,可以将监测到的距离变化转化为磁力,并最终明确体内、外磁体间磁锚定力的实时变化。

3.4 可变形的流体磁和伞形磁

笔者针对治疗食管狭窄提出了一种光固化的流体磁,治疗过程为:内镜下,将球囊导管通过狭窄处,将流体磁注入球囊,再经内镜通道伸入紫外线光缆,照射光固化流体磁使之固化;而后,通过内镜在狭窄近端放置一个带有沉孔结构的圆柱状磁环,使狭窄近、远端磁相吸引,形成压榨吻合。术后数周,两个磁体经消化道自行排出体外。治疗全程无创、无需穿刺,极大地减轻了患者的痛苦,而且实现了磁体变形能通过严重的狭窄处。

为解决前文提及的于单孔腹腔镜手术(laparo-endoscopic single site surgery, LESS)过程中,在能通过戳卡的前提下,如何通过增大体内磁体体积,达到增大磁锚定力的问题,笔者受雨伞的工作原理启发,设计了一款可合、可开的内磁。为了减小加工难度,改用软磁材料铁钴合金制作内磁。该伞形磁锚定牵拉器械具有两种状态:“收合”状态和“撑开”状态,“收合”状态下横截面小(直径10 mm),能够通过戳卡进入腹腔内,而“撑开”状态下横截面大,能够为组织牵拉暴露提供足够的牵拉力,可用于抓取牵拉较大组织,同时减少牵拉器械的脱落。此外,伞形磁锚定牵拉器械“撑开”状态高度较低(相比于传统柱形内磁的2 cm),可用于狭小空间内的组织牵拉暴露(图4)。

4 总结与展望

回顾磁外科发展历史,出现了众多的新型磁性手术器械,对传统手术方式进行了革新,一方面解决了过去想解决而未能解决的手术难题,另一方面也让传统

图4 (网络版彩色)伞形磁锚定内磁设计图。(a)收合状态;(b)撑开状态

Figure 4 (Color online) The design diagram of internal umbrella magnet. (a) Closed state; (b) opened state

手术难度降低,更容易学习,让年轻外科医生快速成长。但在磁外科发展初期,由于欠缺经验和理论指导,磁外科手术器械设计不合理的现象十分普遍,未能遵循以下4点磁外科手术器械结构设计原则:磁力满足功能、安全不损伤、体积最小化、形状最优化,导致一些磁外科器械未能完全发挥其独特的优势,甚至对患者造成医源性损害,在很大程度上限制了磁外科的推广。本文总结过去的磁外科机械结构设计主要存在以下4点问题:磁体磁力不可控、磁体磁力不可退、磁体磁力

不可知和磁体形状不可变。针对以上问题,全球外科、理工科专家也在积极应对,目前已经提出了初步解决方案,并在实验验证中取得了成功。然而,有些问题仍缺少有效办法,为此,本文提出一些解决思路,供同行参考、验证。磁外科器械结构设计是磁外科的根基,其设计水平决定磁外科今后的发展水平。总体而言,近年来的磁外科器械设计越来越合理,磁外科发展呈良性趋势,随着外科与理工科的交叉程度愈发加深,相信今后的磁外科会取得更大的成就。

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Summary for “磁外科器械结构规划原则及相关思考”

Principles and thoughts of magnetic surgical instrument structure planning

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Since the first magnetic surgical instrument appeared in the 1970s, magnetic surgical instruments have made great progress in the following 50 years. They solved a series of complex clinical problems, and optimized traditional surgical methods. The master works of magnetic surgical instruments, such as Levita and LINX, were published in the top journals, and made a profound impact on the surgical and scientific communities. After the magnetic surgery theories and its application systems raised by experts in surgical and engineering fields, magnetic surgery gradually becomes an important branch of surgery. In recent years, under the guidance of the magnetic surgery theory system, magnetic surgery has achieved vigorous development. A variety of highly innovative magnetic surgical instruments have emerged endlessly. However, it cannot be ignored that with the development of magnetic surgery, there will still be many obstacles in the future. Because magnetic surgery is an interdisciplinary discipline, it requires a deep integration of surgery and engineering. The most representative problem is how to make reasonable and effective structural planning of magnetic instruments. This is the most basic problem of magnetic surgery. Therefore, this article will discuss the principles of magnetic surgical instrument structure planning, summarize the problems encountered in the past, and propose potential solutions to the corresponding problems. In the early stage of the development of magnetic surgery, due to lack of experience and theoretical guidance, the irrational design of magnetic surgical instruments was common. The following four principles of structural design of magnetic surgical instruments could not be followed: Magnetic force to meet the function, safety without damage, minimum volume, and optimized shape. As a result, some magnetic surgical instruments failed to fully utilize their unique advantages, and even caused damage to patients, which greatly limits the promotion of magnetic surgery. The author concluded that there were four problems in the design of the magnetic surgical mechanical structure in the past: The magnetic force of the magnet was uncontrollable, the magnetic force of the magnet was irreversible, the magnetic force of the magnet was unknown, and the shape of the magnet was immutable. In response to the above problems, global surgical and scientific experts are also actively responding. At present, preliminary solutions have been proposed for this purpose, and success in experimental verification has been achieved. The authors put forward some solutions for peer reference and verification. Magnetic surgical instruments are mostly made of permanent magnet materials. The permanent magnet has the defect of uncontrollable magnetic force, and electromagnetic and electronically controlled permanent magnets can completely solve this problem. The characteristics of a soft magnetic material determine that it can be rapidly saturated and magnetized, and it can be quickly demagnetized after the magnetic field is removed. With this feature, hard magnet and soft magnet can be used together during magnetic surgery. In addition, if a miniature distance sensor can be loaded on both ends of the magnetic rings, and the distance is converted into a signal through wireless transmission technology, and interpreted by an external receiver, the distance between the magnetic staplers can be finally obtained, so as to achieve an intelligent magnetic anastomosis. In addition, the magnetic structure can be deformed through fluid magnetism or self-assembly magnetism to meet clinical needs.

magnetic surgery, permanent magnet, soft magnetism, electromagnet, electropermanent magnet

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