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金属有机骨架材料的临床应用进展

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摘　要

金属有机骨架材料(Metal-organic frameworks, MOFs)是由金属离子或团簇与有机配体通过配位键连接形成的新型多孔杂化材料，以高孔隙率、可定制化结构、多重刺激响应性及易功能化修饰为核心特性。其兼具疾病精准诊断与靶向治疗的多重临床价值，突破了传统医用载体载药量低、药物控释效果差、靶向性不足的局限，同时可实现诊疗一体化功能的整合与生物相容性的灵活优化。本文综述了MOFs在临床医学领域的研究进展，重点分析了其核心特性、临床应用优势和局限性等，为临床疾病个体化精准诊疗方案的优化及新型医用载体的研发提供参考。

关键词

金属有机骨架材料，临床应用，临床医学，材料科学

Research Progress on Clinical Applications of Metal-Organic Frameworks

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Abstract

Metal-organic frameworks (MOFs) are a novel class of porous hybrid materials self-assembled from metal ions or clusters and organic ligands via coordination bonds, with high porosity, tailorable

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structure, multi-stimuli responsiveness, and ease of functionalization as their core characteristics. These inherent properties endow MOFs with multifaceted clinical value in both precise disease diagnosis and targeted therapy, overcoming the inherent limitations of conventional biomedical delivery vehicles, including low drug loading capacity, suboptimal controlled drug release performance, and insufficient targeting specificity. Meanwhile, MOFs enable the seamless integration of theranostic functions and flexible modulation of biocompatibility. This review summarizes the research advances of MOFs in clinical medicine, with a focus on the analysis of their core characteristics, clinical application advantages, and existing limitations, aiming to provide a reference for optimizing individualized precise diagnosis and treatment regimens for clinical diseases and the development of novel biomedical delivery carriers.

Keywords

Metal-Organic Frameworks, Clinical Application, Clinical Medicine, Material Sciences

1. 引言

MOFs 也称为多孔配位网络(porous coordination networks, PCNs)或多孔配位聚合物(porous coordination polymers, PCPs)，于 1995 年由 Yaghi 和 Li 首次提出[1]，它是一种新兴的混合多孔材料类别，由金属离子或团簇通过有机连接物连接而成[2] [3]，其形成和形态取决于反应过程中所用金属源和配体的类型，这种近乎无限组合的结构优势为其表面功能化提供了机会[4]。

MOFs 的优越性能，如可调的孔径/发达的孔隙结构、可定制的组成和结构、可调节的尺寸、多功能、高药物负载能力和改进的生物相容性，使其成为有利的药物递送宿主候选材料[5]；并且其高度有序结构、高表面积和大孔体积，使其能够吸附功能分子于外部表面或开放通道，并将这些分子锁定在框架内[6]。

其在生物医学领域，如疾病诊断[7]、药物递送[8]-[10]、肿瘤治疗[11] [12]、组织工程、抗菌防护[13]、生物传感器[14] [15]等方向取得广泛的临床应用。

2. MOFs 材料的核心特性与临床适配性

2.1. 结构与功能优势

2.1.1. 高孔隙率与载量

BET 比表面积(Brunauer-Emmett-Teller specific surface area)是表征 MOFs 多孔特性的核心实验指标，通过低温(77 K)氮气吸附等温线计算，用于定量材料单位质量的可及表面积，是判断其载药、吸附、传感性能的关键依据[16]。

目前 MOFs 单晶材料的最高 BET 比表面积可达 7000 $m^2 \cdot g^{-1}$ [17]，而生物医用纳米级 MOFs 的比表面积可根据合成需求在宽范围内精准调控，使得其具备极大孔容与丰富可利用内表面，能够高效负载高剂量小分子化疗药物[18] [19]、蛋白类生长因子[9] [20]、核酸制剂及 NO/CO 等医用气体[21] [22]，载药能力显著优于脂质体、介孔硅等传统医用载体；同时丰富的表面活性位点可强化生物传感信号响应与毒素吸附性能[14] [15]，为构建高载量智能递药系统、高灵敏诊断平台及多功能医用敷料提供结构基础。

以临床常用的化疗药物阿霉素(Doxorubicin)为例，其选用孔径约1.0~1.5 nm的ZIF-8或MIL-100 (Fe)，其孔道尺寸与阿霉素分子高度匹配，既能实现药物高效封装，又能避免药物因孔径过大而快速泄漏，保证高载药量与结构稳定性[23] [24]。MOFs的配位化学决定可控释放触发机制，在正常生理pH (7.4)下，Zn-N、Fe-O配位键保持稳定，使药物被“锁在”孔道内；进入肿瘤弱酸性微环境(pH 5.0~6.5)后，H^+竞争性结合配体导致配位键断裂，骨架逐步解聚，孔道结构被破坏，药物随之精准、可控地释放。孔径大小、配位化学共同赋予MOFs高效载药与精准递送的临床能力[25]。

2.1.2. 刺激响应性

MOFs材料可通过精准调控金属中心、有机配体的组成及表面修饰方式，设计为pH、酶、光、磁、温度、氧化还原等多重响应体系，其响应特性可精准适配肿瘤微酸、炎症高活性氧(ROS)、病灶特定酶表达等病理微环境，进而实现药物的精准控释，有效解决传统药物递送中脱靶毒性高、药物提前泄漏、控释效果不佳等问题。

其中pH响应是MOFs最具临床应用潜力的响应类型之一，依托配位键的pH依赖性实现精准释药，Wang等[26]研究构建的pH响应性仿生沸石咪唑酯骨架纳米颗粒，可协同递送西妥昔单抗与siRNA，在喉鳞状细胞癌的治疗中，该MOFs在正常生理环境(pH 7.4)下保持骨架稳定，避免药物提前泄漏，而进入肿瘤酸性微环境(pH 5.0~6.5)后，配位键发生断裂，骨架逐步降解，实现西妥昔单抗与siRNA的同步精准释放，显著提升协同治疗效果；酶响应型MOFs则借助肿瘤或炎症部位高表达的基质金属蛋白酶、脲酶、酯酶等特异性酶，通过酶对配体的特异性降解触发药物释放，进一步提升递送精准度[27] [28]；光响应型MOFs以近红外光等外部光源为触发信号，通过负载的光敏剂产热或产生ROS破坏MOFs骨架，可按需调控药物释放的时间与剂量，适配肿瘤局部治疗需求[29]；磁响应型MOFs通过复合磁性纳米颗粒，在外部磁场引导下实现病灶靶向富集，同时借助交变磁场产热触发药物释放，适用于深部肿瘤治疗[30] [31]；温度响应型MOFs依托病灶与正常组织的温度差异，通过温敏材料相转变或骨架热降解实现药物释放，适配肿瘤温热治疗场景[32]；氧化还原响应型MOFs则利用病灶部位高浓度的谷胱甘肽(GSH)或ROS，断裂配体中的氧化还原敏感基团，触发骨架降解与药物释放，这些响应体系可单独发挥作用，也可协同配合，进一步提升药物递送效率，降低脱靶毒性，为智能递药系统的构建提供重要支撑[33] [34]。

2.1.3. 多功能整合

MOFs材料凭借其超高比表面积、可调控孔道结构及良好的生物相容性，可同步搭载诊疗分子(如化疗药物、免疫调节剂、气体治疗分子等)、成像探针(如荧光探针、MRI造影剂等)与靶向配体(如叶酸、抗体、肽段等)，巧妙构建诊疗一体化平台，打破传统诊断与治疗相互独立的局限，实现肿瘤等疾病“诊断–治疗–监测”的整合[35] [36]。

2.1.4. 生物相容性可优化

MOF材料的生物相容性可通过精准调控其组成与表面修饰方式实现显著提升，有效解决其在体内应用中可能存在的金属离子释放毒性、体内稳定性不足等问题。具体而言，可优先选择生物安全性高的构建单元，包括Fe基[31]、Zn基[36]、Al基构建单元，或采用氨基酸、核苷酸等生物配体作为MOFs的有机配体，这类生物配体可增强MOFs与生物体系的相容性，减少机体免疫排斥反应。此外，通过对MOFs表面进行PEG化修饰或细胞膜包覆处理，可在其表面形成一层保护屏障，一方面显著降低MOF骨架中金属离子的泄漏速率，减少金属离子释放带来的细胞毒性和体内毒性[37]；另一方面可提升MOFs在体内的血液循环稳定性，避免其被体内免疫系统快速清除[38]，进一步优化其生物相容性，为MOFs材料的体内临床应用奠定基础。

2.2. 临床适配性

MOFs 材料在临床应用中的适配性不断提升，目前已开发出 ZIF-8、MIL-100(Fe) [39]、UiO-66、HKUST-1 等数十种生物友好型 MOFs 材料，这类 MOFs 均具备良好的生物相容性、可控的降解性能及高效的药物递送能力，适配临床诊疗的核心需求[40]。其中，部分 MOFs 材料已完成 FDA 等要求的临床前安全性评价基础研究，重点验证了其在体内的毒性、耐受性及生物相容性，为后续临床转化奠定了坚实基础。此外，MOFs 材料的降解产物具有良好的生物安全性，多为生物可代谢的金属离子(如 Fe^{3+}、Zn^{2+}，均为人体必需微量元素，可通过正常生理代谢途径排出体外)与天然配体(如氨基酸、羧酸类配体，可被机体降解吸收)，无明显长期蓄积毒性，有效避免了材料在体内残留引发的不良反应，进一步提升了其临床适配性，推动 MOFs 材料向临床实际应用转[41] [42]。

3. MOFs 在临床医学中的核心应用领域

3.1. 糖尿病诊断和治疗中的应用

在过去几十年里，糖尿病(Diabetes)的发病率和死亡率在全球范围内都在稳步上升[43]-[45]。在全球约 4.6 亿糖尿病前期成年人中，约有 20%至 50%预计将在 5 年内发展为糖尿病[46]-[48]，因此早期诊断和干预对于糖尿病病人的预后显得尤为重要。

3.1.1. 糖尿病诊断

为了实时监测患者的血糖状态，具有高灵敏度和高选择性的传感器显得尤为重要。传统的糖尿病诊断和检测依赖于血样采集，呼气检测是一种适合频繁血糖监测的非侵入性方法。丙酮(Acetone, ACE)是机体在脂肪动员显著增强、被迫以储存脂肪作为主要能量来源时所产生的内源性酮体，目前已成为糖尿病领域被广泛认可与应用的重要生物标志物[49]-[52]。一般而言，糖尿病患者呼气中的丙酮浓度高于 1.8 ppm，正常人群中低于 0.9 ppm，呼气丙酮检测为非侵入性检测方式，可便捷地反映机体酮体水平，因此其有助于我们更便捷地监测糖尿病血糖水平[53] [54]。由于人呼气中丙酮浓度较低，难以实现直接精准测定，因此研发高效的丙酮富集浓缩技术对其准确定量至关重要，因具备优异的选择性与吸附性能，成为丙酮富集与传感领域的理想载体。Yu 等[55]选择了三种 MOFs (ZIF-7、UiO-66 和 MOF-5)作为吸附剂，发现 UiO-66 富集丙酮能力最强，并成功应用于真实呼气样本。同时提升传感器对丙酮的响应性对于传感器性能的提升也至关重要，将 MOFs 与金属氧化物半导体(metal oxide semiconductor, MOS)结合，是提升气体感测性能的有效方法。Zhou 等[56]合成 ZnO@ZIF-71(Co)复合物，发现该材料对丙酮响应率极高，检测限低至 50 ppb，响应时间低至 71 秒，且恢复时间更快，是丙酮传感器的有利材料。部分经功能化修饰的 MOFs 材料具备优异的发光性能[57]，Gutiérrez 等[58]利用 Zn-BDC 中对苯二甲酸配体上的未配位氧原子，与硝酸银($AgNO_3$)溶液中的 Ag^+发生相互作用，可将 Zn-BDC 转化为 Ag-BDC；该材料对丙酮具有特异性响应，并呈现强绿色荧光，其固体粉末状态下的荧光量子产率高达 22%。在丙酮存在时，该绿色荧光会显著下降，是制备用于糖尿病诊断与监测的荧光传感器的理想候选材料。因此 MOFs 因为其优异的光致发光特性、高选择性、抗干扰能力、高灵敏度和快速响应性，作为丙酮传感器在糖尿病检测领域应用广泛[7]。

3.1.2. 糖尿病治疗

胰岛素注射是糖尿病临床主流治疗方案[59]，但存在依从性差、长期注射并发症多等问题。口服胰岛素的主要问题包括胃内强烈酸性环境以及胃蛋白酶介导的肠道降解，同时蛋白质药物穿过肠道生物膜的低通透性导致了低生物利用度[60] [61]。MOFs 材料可实现胰岛素高负载与稳定保护，其功能化递送系统

在该领域展现出良好应用潜力。Zou 等[62]设计了具有外部靶向蛋白(Tf)修饰的耐酸 nMOFs (UiO-68-NH2)，可以同时保护胰岛素免受酸性物质和酶降解，从而实现高效的口服胰岛素给药。Chen 等[63]使用基于 Zr6 的抗酸间孔间孔 MOF NU-1000 作为胰岛素载体，并在 30 分钟内实现了胰岛素 40wt%的高载药量，该酸稳定型 MOFs 胶囊可有效保护胰岛素在胃酸与胃蛋白酶环境中不被降解，且包封的胰岛素可在模拟生理条件下从 NU-1000 中缓释。

3.2. 肿瘤诊疗中的应用

MOFs 作为一类由金属离子/簇与有机配体自组装形成的有机－无机杂化多孔材料，凭借其超大比表面积、可调孔隙结构、易于合成修饰及良好的生物相容性等独特优势[64]，已成为肿瘤治疗领域的研究热点，在肿瘤诊断、药物递送及协同治疗中展现出广阔的应用前景[65] [66]。

MOFs 可通过多种方式负载抗肿瘤药物，包括孔隙包埋、表面附着、原位包封及以药物为配体直接形成生物 MOFs 等，能有效解决传统药物递送中靶向性差、载药量低、毒副作用强等难题，实现药物的精准可控释放[67] [68]。

癌症饥饿治疗(cancer starvation therapy)是指通过药物或其他方法阻断肿瘤的营养供应通路，导致肿瘤细胞凋亡，实现间接治疗的目的，已被应用于临床中[69]。近年来，纳米材料的持续发展带来了改善饥饿疗法的新思路。在癌症治疗中使用具有优良性能的纳米材料可以提高癌症治疗的准确性并减少治疗过程中的副作用[70]，与传统纳米材料相比，基于 MOFs 的纳米平台介导癌症饥饿治疗可以弥补传统癌症饥饿疗法中更易发生耐药性和突变的缺点[71]，并且其还能介导饥饿疗法与其他肿瘤治疗的结合[72] [73]。Wu 等[74]构建了包载 MOFs 材料 ZIF-8、葡萄糖转运蛋白 1 (GLUT1)、DNA 酶(GD)并修饰肿瘤靶向亲水壳体透明质酸(HA)的双门控纳米能量断路器 HZ@GD，该纳米系统可主动靶向肿瘤细胞实现高效内吞，借助肿瘤酸性微环境触发 ZIF-8 降解释放 Zn^{2+}与 GD，通过 Zn^{2+}干扰效应阻断肿瘤糖酵解、同时激活 GD 的催化剪切效应下调 GLUT1 表达以切断葡萄糖供应，抑制肿瘤细胞糖解代谢，最终实现肿瘤内的系统性能量耗竭。

在刺激响应性药物递送系统(Stimuli-responsive drug delivery systems, SRDDSs)中，MOFs 可响应肿瘤微环境(TME)的内源性刺激如弱酸性、高谷胱甘肽(GSH)、高 ATP 及特定酶过量表达等和外源性刺激如光、温度、磁场、压力等，触发框架降解或结构变化，实现药物在肿瘤部位的特异性释放，显著提升治疗效果并降低对正常组织的损伤[75]。具体而言，不同金属中心的 MOFs 在肿瘤治疗中各具优势，Fe-MOFs、Zn-MOFs、Zr-MOFs、Cu-MOFs 等已被广泛应用于构建 SRDDSs [76] [77]，其中 Cu-MOFs 表现出优异的生物相容性、其还能对 TME 中的特定刺激产生反应，Wang 等[78]开发了 Cu-MOF 辅助 PDT，利用 Cu(II)与 GSH 反应并消耗细胞内 GSH，从而增强治疗效果。目前合成的 Cu-MOFs，如 HKUST-1 和 MOF-2/3，已展示其在药物递送系统中重要作用[79]。Fe-MOFs、Zr-MOFs 等则在 pH 响应、光响应、磁场响应药物递送及协同化疗、光动力治疗(PDT)、光热治疗(PTT)等方面发挥重要作用[11] [80]-[83]。

目前 MOFs 基肿瘤治疗系统仍面临临床转化困难、长期生物安全性待验证等挑战，但随着更多的研究和临床实验 MOFs 有望成为突破传统肿瘤治疗局限、推动精准肿瘤治疗发展的新型材料[84]。

3.3. 抗感染与抗菌治疗的应用

MOFs 材料最重要的特性之一是金属离子和有机配体结合的抗菌活性，根据结构特性分为四大类：金属离子抗菌剂、有机配体抗菌剂、载体药物抗菌剂和复合抗菌剂[85]。金属离子可能损伤细菌细胞膜，穿透脂质层进入细菌体内，使重要的细胞内酶和蛋白质失活和变性，最终导致细菌死亡[86]。某些特殊金属离子在抗菌过程具有重要作用，例如 Ag^{+}可能干扰微生物细胞膜，增加膜通透性，干扰细菌呼吸过程，

并影响能量产生；Ag$^+$还能与微生物核酸结合，阻止细菌繁殖[87]。MOF 中的有机配体也可以通过配体键的断裂释放，通过自身的抗菌作用去除致病微生物[88]。MOFs 的多孔有机结构为抗菌纳米颗粒和药物的载荷提供了结构基础，在降解过程中从 MOFs 孔隙释放，并根据载荷材料的特性发挥抗菌作用[89]。复合抗菌剂可通过载药、与水凝胶等生物材料复合构建多功能体系，实现协同抗菌与促组织再生[90]，在感染性伤口愈合领域展现出重要应用价值。

4. 未来发展趋势

目前，基于 MOFs 治疗及临床转化仍处于早期阶段，仍然存在许多问题需要攻克：结构复杂性阻碍了 MOFs 的扩展性，其对重金属的依赖易引发安全隐患；现有研究大多聚焦于 MOFs 短期毒性，而长期毒性、免疫相容性和体内生物积累与代谢清除途径的研究十分缺乏；对于 MOFs 生物代谢与清除的研究也相对缺乏，全面研究 MOFs 降解、代谢和排泄途径对于防止慢性损伤和不良结局至关重要。

MOFs 未来将围绕临床刚需，向四大核心方向发展。一是智能响应与精准医疗，开发融合 pH、酶、光多重刺激响应机制与结构设计的新型 MOFs，深度匹配临床个性化治疗，突破传统给药瓶颈，实现肿瘤个体化精准可控给药[91]；二是临床转化加速，锚定 HER2、EGFR、ASGPR 等临床常用肿瘤免疫治疗靶点，推动 ZIF-8、MIL-100(Fe)等生物相容性优异的优势体系加快进入 II/III 期临床试验[92]；三是通过计算化学设计解决稳定性－可降解性矛盾。利用密度泛函理论(DFT)与分子动力学模拟，精准调控金属－配体配位键能，构建在生理环境中结构稳定、在病灶微环境中快速降解的“梯度键能”MOFs，从源头平衡结构稳定性与生物可降解性，突破体内应用的核心瓶颈[93] [94]；四是跨领域融合创新，深度整合 3D 打印、AI 前沿技术[95]，利用其高孔隙载药、刺激响应释药、高灵敏传感特性，开发 MOFs 基个性化组织工程支架、智能给药系统，持续拓展 MOFs 在临床诊疗中的应用范围[96]。

5. 总结

MOFs 凭借可调的多孔结构、可编程的刺激响应特性与生物相容性，凭借优异的多孔结构与可编程的药物递送能力在糖尿病诊疗、肿瘤精准治疗、抗菌防护等临床领域展现出巨大应用潜力，为突破传统诊疗瓶颈提供了全新思路。目前其临床转化仍面临长期生物安全性、量产可控性等核心挑战，未来需加速临床转化，推动 MOFs 从实验室走向临床落地，推动精准医疗发展。

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