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生物医用锌基可降解材料的最新进展

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摘　要

锌基可生物降解合金或复合材料有潜力开发成下一代骨科植入物，作为传统植入物的替代品，以避免翻修手术并减少生物相容性问题。综述了锌基生物降解材料的研究现状。简要讨论了锌的生物功能、骨科植入物的设计标准以及可生物降解材料的腐蚀行为。从生物降解性、生物相容性和力学性能等方面对许多新型锌基生物降解材料的性能进行了评价。锌基材料在骨代谢和新细胞生长中发挥着重要作用，并在不释放过量氢气的情况下表现出介质降解。在纯Zn中添加合金元素如Mg、Zr、Mn、Ca和Li可以提高Zn合金的机械性能。应用后处理技术进行晶粒细化对于开发许多合适的锌基生物可降解材料是有效的。

关键词

生物可降解材料，生物降解性，生物相容性，锌合金

The New Progress in Biodegradable Zinc-Based Materials for Biomedical Applications

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Abstract

Zinc-based biodegradable alloys or composite materials have the potential to be developed as next-generation orthopedic implants as alternatives to traditional implants to avoid revision surgery and reduce biocompatibility issues. This article reviews the research status of Zinc-based

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biodegradable materials. A brief discussion was conducted on the biological functions of zinc, design standards for orthopedic implants, and the corrosion behavior of biodegradable materials. The performance of many new Zinc-based biodegradable materials was evaluated from the aspects of biodegradability, biocompatibility, and mechanical properties. Zinc-based materials play an important role in bone metabolism and new cell growth, and exhibit mediator degradation without releasing excessive hydrogen gas. Adding alloying elements such as Mg, Zr, Mn, Ca, and Li to pure Zn can improve the mechanical properties of Zn alloys. The application of post-processing technology for grain refinement is effective in developing many suitable Zinc-based biodegradable materials.

Keywords

Biodegradable Materials, Biodegradability, Biocompatibility, Zinc Alloy

1. 背景

矫形假体用于骨折的修复或骨折骨的置换。根据骨折的严重程度，可以使用几种类型的假体。传统上，金属装置用于固定骨折，但这些装置会导致许多不良影响，如骨坏死、骨质疏松和人体内骨愈合延迟[1] [2]。与传统固定装置相关的许多其他问题包括过敏反应、离子释放、腐蚀、疲劳失效、氢气释放、应力屏蔽和翻修手术[3] [4] [5] [6] [7]。在提供所需功能和骨愈合后，需要进行第二次手术来移除不可降解装置。为了克服与不可降解装置相关的问题，已经引入了可生物降解的假体。在愈合过程中的一段时间内，这些装置在生理环境中吸收或降解[8] [9] [10] [11] [12]。

许多基于金属和聚合物的材料是制造可生物降解假体的众所周知的选择。在这些材料中，镁基和锌基材料是最适合制造可生物降解器件的生物材料。它们的快速降解，以及镁基生物材料降解产物的过度释放，限制了它们在生物医学应用中的应用[13] [14] [15] [16] [17]。与镁基可生物降解材料相比，可生物降解的锌合金显示出中等的降解率；它们的生物降解产物是完全可生物降解的，不会释放过量的氢气。与镁合金相比，锌合金由于其较低的电极电势而表现出较低的腐蚀速率[18] [19] [20]。

为了提高可生物降解材料的性能，研究人员正专注于通过制造合金或复合材料来优化可生物降解的材料的性能。很大一部分商业部门正在进行研究，并将其资源投资用于开发骨科植入物的高效、有效的可生物降解材料。从骨科到心脏，从整形外科到肿瘤学，这些材料的应用范围是无限的。目前，许多锌基合金已通过整合生物活性物质或调整材料加工方法来利用，目的是优化其生物降解和机械性能。这些材料有可能被开发成下一代骨科植入物，作为传统植入物的替代品，以避免翻修手术并减少生物相容性问题。工业部门需要克服一些挑战，如可控的生物降解行为和可比的机械性能。

近年来，发表了许多关于锌基生物可降解材料的综述文章。袁等[21]总结了锌基生物可降解材料的表面改性方法。李等人[22]总结了锌基生物可降解材料发展的挑战和机遇。讨论了各种加工和制造方法。Kabir 等人[23]讨论了锌基生物可降解材料的生物腐蚀和生物化学前景。Shi 等人[24]讨论了第二相和合金元素对锌基生物可降解材料力学性能的影响。黄等人[25]讨论了合金元素对锌基生物可降解材料软化现象的影响。提出了尽量减少应变软化的可能策略。杨等人[26]讨论了锌和其他营养元素对伤口愈合过程的影响。Chen 等人[27]讨论了开发用于骨再生的金属基可生物降解膜的挑战。本文综述了锌基生物降解材料

的研究现状。对近年来开发的许多新型锌基生物降解材料的生物降解性、生物相容性和力学性能进行了评价。这篇综述将有助于研究人员制造合适的合金成分，以满足所需的临床需求。

2. 锌的生物学功能

锌是人体中仅次于铁的第二丰富元素。在人体中，11%的锌存在于肝脏和皮肤中，85%的锌存在于骨和肌肉中，其余存在于其他组织中[28] [29] [30] [31]。锌在不同的生物功能中起着重要作用。锌的存在在酶发挥调节或催化作用中起着重要作用[32] [33] [34] [35]。锌在骨代谢和生物体生长中发挥着重要作用。补充锌可增强骨形成，同时通过刺激成骨细胞和破骨细胞分化来增加骨强度[36] [37] [38]。锌缺乏与骨骼的虚弱和健康有关。

在可生物降解材料中添加锌可以通过促进骨髓基因如骨桥蛋白、骨钙素、胶原蛋白和碱性磷酸酶来增强成骨细胞分化[39]。与其他金属相比，锌作为破骨细胞骨吸收的强抑制剂。此外，锌在预防心肌病和心脏病方面发挥着重要作用。补充锌可以改善心脏功能，防止梗死和缺血时的损伤。锌在维持正常内皮细胞的完整性方面是重要的。此外，它还可以通过增强碱性生长因子依赖的内源性成纤维细胞增殖来刺激内皮细胞增殖。锌还参与免疫系统的完整性和发育。锌对由细胞因子、胸腺素和酶组成的某些重要免疫介质的活性有显著影响[40]。就锌而言，锌对淋巴细胞凋亡的细胞内调节至关重要。锌参与神经传递、神经元生长、突触发生和神经发生。它被选择性地储存在特定神经元的突触前小泡中，并作为神经调节剂释放。

尽管锌对许多生理功能至关重要，但过量的锌暴露或摄入除了锌摄入不足外，还会对各种器官产生不利影响。锌缺乏可导致各种病理症状，包括生长障碍、出生缺陷和低血压等。许多疾病也与锌缺乏有关，如胃肠道疾病、肾脏疾病、镰状细胞病等。另一方面，锌过量也会产生有害后果。Zn^{2+}能够抑制解偶联线粒体中的电子传输。如果锌摄入过多，它会对胚胎发生产生致畸或致命作用。据报道，Zn^{2+}对细胞活力、黏附和增殖具有双相作用。高浓度的 Zn^{2+}会导致对细胞相容性的抑制作用。

3. 矫形器械的设计标准

可生物降解装置最重要的特性是其生物降解性、生物相容性、机械性能、腐蚀行为和抗菌活性。可生物降解装置应具有低致敏性、无炎症性和无毒性，且无有害的颗粒物滞留或释放[41] [42] [43] [44]。这种可生物降解的装置必须能够促进新细胞的生长和骨的生成。这种可生物降解的装置必须能够促进新细胞的生长和骨的生成。内植物的完整性必须可以维持到植入后的 1~2 年，直到完全吸收。螺钉、克氏针和 U 形钉的器械植入后完整性必须不小于 3~6 个月[21]。另一个重要问题是可生物降解装置的腐蚀行为。体外腐蚀试验实验应显示降解/渗透速率(DR) < 0.5 mm/年，析氢量应小于 10 μL/cm^2/天。机械性能，如极限抗拉强度应大于 300 MPa，拉伸屈服强度大于 230 兆帕，伸长率大于 15%~18%，并且弹性模量应类似于骨骼(10~20 GPa) [45] [46]。

4. 体内降解性能

可生物降解材料在生理环境中通过降解过程植入时会发生腐蚀，这可能会由于 H_2 气体的形成和金属离子的释放而导致健康问题[47]。因此，周围腐蚀表面 pH 区域的移动是骨科应用的一个重要问题[48] [49] [50] [51]。通常，在金属基可生物降解装置的腐蚀机制中，金属被氧化为阳离子，H2、氢氧化物和氧化物通过电化学反应产生[52] [53] [54]。最后，在可生物降解金属的表面上形成金属氧化物层，其作为动力学屏障或被动层，防止进一步的电化学反应或离子在基底表面的释放[53] [54] [55]。然而，这种金属氧化物层可以溶解在电解质中，然后开始点蚀过程[56] [57]。点蚀是局部腐蚀，随着钝化膜的破裂而发生。这种形式的腐蚀会危害可生物降解材料，因为在侵蚀性环境中，由于腐蚀产物的存在，不容易观察到可生

物降解的材料表面的凹坑。点蚀开始后，可生物降解材料迅速腐蚀，植入物的承载能力降低。此外，由于点蚀引起的局部应力增加有可能产生裂纹，并且植入物可能由于点蚀内的应力腐蚀和疲劳裂纹而失效。因此，为了控制降解性，H_2的释放速率应该是最小的。

体外电化学和浸泡试验用于评估可生物降解植入物的腐蚀行为。在这些生理环境中，可生物降解的金属由于其电化学电势而易于腐蚀。体外和体内环境中的腐蚀受到许多因素的影响，如释放离子的类型、pH 浓度、周围组织的生物反应和植入物表面的蛋白质吸收。可以通过监测释放的离子量来评估腐蚀植入物材料的状况。在浸渍试验中监测 pH 值，以评估可生物降解材料的腐蚀速率(CR)。较低的 pH 值表示较低的腐蚀速率，并且增加的 pH 值不利于细胞黏附。快速腐蚀可能导致结构失效、不必要的降解、碱性 pH 值变化和周围腐蚀部位的析氢[54] [55] [56]。

5. 锌基生物材料

锌基可生物降解材料因其良好的生物相容性和可降解性而在骨科应用中受到关注。目前的锌基合金不具有足够的生物相容性，也不一定耐磨和机械强度[57] [58]。纯锌材料显示出较差的机械特性，并且它们不能用于大多数骨科应用。此外，锌相对较低的蠕变阻力、低疲劳强度、高磁化率和低温再结晶限制了其在植入材料开发中的应用。近年来，已经建立了许多锌基可生物降解材料的合金或复合材料，它们具有改进的生物相容性、生物腐蚀性和机械性能[59] [60] [61] [62] [63]。许多人体必需的微量元素已用于制造锌基可生物降解合金，许多类型的增强材料已用于制造 Zn 复合材料[64] [65] [66] [67]。在这些增强材料中，磷酸钙基增强材料应用最为广泛[41]。许多类型的制造方法，如铸造、粉末冶金、瞬态定向凝固、增材制造、火花等离子体烧结或其他先进加工技术，用于制造 Zn 的合金或复合材料[68]-[74]。在不同的制造方法中，铸造是大规模生产锌基合金最常见的方法。

锌基合金成分是多相系统，其机械、降解和腐蚀行为在很大程度上取决于微观结构参数和合金基体中第二相的分布。精细的微观结构和第二相在整个合金成分中的均匀分布有望改善可生物降解锌合金的性能。锌基材料的微观结构和由此产生的机械性能可以通过应用各种传统的金属成形加工技术来定制，如热挤压、轧制、选择性激光法(SLM)、火花等离子体烧结(SPS)、拉伸和锻造，以及严重的塑性变形技术，如等通道角挤压(ECAP)、高压扭转、扭曲挤压、摩擦搅拌加工、气缸盖压缩和多向锻造。在后处理技术中实现的晶粒细化提高了它们的耐腐蚀性和机械性能。由于加工后的锌基材料尺寸较小，或者由于动态再结晶导致锌基材料在高应变下软化，因此很难研究后处理技术对锌合金力学特性的影响。Capek 等人[75]研究了挤压比和温度等挤压参数对 Zn-0.8Mg-0.2Ca 合金微观结构和力学性能的影响。结果清楚地表明，挤压条件对 Zn 基体和金属间颗粒的尺寸都有显著影响。

微观结构的细化导致机械性能的提高。郭等人[76]进行了实验，以改善微观结构，从而提高机械性能和降解性能。晶粒尺寸通过多道次拉制得到细化。首先，对铸态合金样品进行预热和挤压。然后，对挤出的合金样品进行冷却，并进行变形法多道次拉伸。结果表明，塑性变形有效地影响了晶粒尺寸。通过增加变形量，实现了晶粒尺寸的显著减小。结果表明，多道次拉拔有可能改变 MnZn 相的尺寸、位置和分布。

在许多锌基材料中，锌－镁合金有望成为骨科应用的潜在候选者，具有更好的生物相容性和机械性能。向 Zn 基体中添加 Mg 导致亚共晶组织的形成。这些微观结构由 α-Zn 簇晶和 α-Zn 和 Mg_2Zn_{11} 相的共晶混合物组成[71]-[79]。由于在 Zn 中添加了 Mg，金属间颗粒(Mg_2Zn_{11})的存在显著增强了 Zn 基体的机械性能。为了改善 Zn-Mg 二元合金成分的微观结构并减小其晶粒尺寸，Pachla 等人[80]对 Zn－镁合金的热挤压样品进行了静压挤压。合金成分是在氩气气氛下通过重力铸造制备的。铸态样品通常在 250℃下挤出。然后，对样品进行静压挤压，以减小晶粒尺寸并组成两种合金相。变形和累积静水压挤压的协同作

用实现了最高的细化程度。建议三到四次静水压挤压可以有效地将塑性变形过程的最高温度降至最低。合金相的均匀分布对提高力学性能起着更重要的作用。

Guan 等人[81]通过使用搅拌铸造和超声处理在 Zn-2Fe 合金体系中添加 WC 纳米颗粒，制备了 Zn-2Fe-WC 纳米复合材料。为了改善热轧的力学性能，进行了热轧变形处理。热轧后的极限拉应力从 121.1 MPa 提高到 155.8 MPa，伸长率从 8.6%提高到 15.3%。热轧试样力学性能的提高归因于纳米颗粒的孔隙率和分散性的改善。此外，还进行了浸渍和电化学测试，以研究复合材料的生物相容性和腐蚀性。研究表明，WC 颗粒在没有浸出 W 离子的生理环境中是非反应性和惰性的。细胞毒性结果表明，WC 纳米粒子对细胞系没有毒性。

许多后处理变形方法已被用于改善锌基生物可降解材料的微观结构。其中，热挤压、热轧和 ECAP 对改善微观组织和减小晶粒尺寸最为有效。因此，很少对这些变形方法进行比较研究来找到优化的方法。Huang 等人[82]研究了挤压、轧制和 ECAP 对 Zn-Mg 合金微观结构和力学性能的影响。ECAP 最大限度地提高了塑性和强度。根据现有的对比研究，很难选择优化的变形方法。在不同的变形方法中，热挤压是改善锌基合金微观结构最广泛使用的方法。

矫形假体的机械稳定性是一个高度依赖于腐蚀行为的重要问题。Kannan 等人[83]比较了 Zn 和 Zn-5Al-4Mg 合金的降解特性和生物相容性。使用体外腐蚀，将锌合金样品浸入 SBF 溶液中 7 天。SEM 图像证实了对两种锌合金的有限腐蚀冲击。分析了降解行为随浸泡时间的变化规律。与 Zn-5Al-4Mg 合金相比，Zn 的降解率较低。

进行了体外和体内研究，以分析锌基生物可降解材料的腐蚀和降解性能。Lin 等人[58]通过铸造开发了不同成分的 Zn-1Cu-0.1Ti 合金。将轧制合金试样与铸态试样进行比较，并研究了各种参数(包括机械性能、耐腐蚀性、生物相容性和抗菌能力)。热轧试样表现出改进的机械性能。根据腐蚀电流和腐蚀密度，记录了热轧试样的最大腐蚀。锌合金表面钝化层的最小形成与溶解速率的降低有关。阻抗值越大，表示耐腐蚀性越高。

金等人[84]开发了不同的 Zn-Mg 合金成分，包括 Zn-0.08Mg、Zn-0.005Mg 和 0.002Mg。进一步挤压和拉伸铸态合金以改善微观结构。使用 Sprague-Dawley 大鼠进行体内研究。将样品放置在动脉细胞外基质中 1.5、3、4.5、6 和 11 个月。测量横截面积减少和穿透率以获得降解行为。根据渗透率评估的降解率值对于所有组合物都较高，但接近基准值(0.02 mm/y)。

Yang 等人[85]制备了 24 种不同八种元素(如 Cu、Ca、Mn、Sr、Ag、Fe、Mg 和 Li)的二元 Zn 合金成分。进行挤压以改善 Zn 的微观结构。首先，在机械和体外试验中筛选出合金的优良成分。然后，通过应用大鼠股骨对所选样品进行体内测试。Zn-Li 和 Zn-Mn 合金表现出最高的延展性和拉伸强度。与其他成分相比，Zn-Mn 合金表现出更好的腐蚀性能。在细胞活力测试中注意到新组织的生长。Yang 等人[85]还在优化的 Zn-Li 二元组分的基础上开发了九种三元 Zn 合金组分。添加不同重量分数的 Mg 和 Mn 以优化 Zn-Li 二元合金的性能。两种三元合金成分(包括 Zn-0.8Li-0.4Mg 和 Zn-0.8Li-0.8Mn)的力学性能得到了最大的提高。

锌基生物材料的摩擦学性质在文献中报道不多。目前，Lin 等人[58]对 Zn-1Cu-0.1Ti 合金进行了摩擦学研究。铸态、热轧和冷轧 Zn-1Cu-0.1Ti 合金的摩擦磨损行为表明，热轧 Zn-1Cu-0.1Ti 合金表现出最佳的摩擦学性能。其他一些研究小组也报告了锌基生物材料的摩擦学研究结果，但对锌基生物质磨损的研究有限，需要在临床试验前进行磨损研究。广泛的合金元素，例如 Mg、Mn、Fe、Ca、Cu、Li、Ag、Al、Ge、Sr、Zr 和 Ti 被用于制造 Zn 合金。Zn-Mg 合金表现出良好的力学性能，符合骨科植入物的设计标准要求。Zn-Cu 也表现出良好的机械性能，但 Cu 的存在使这些合金不适合，因为 Cu 的生物性能不合适。在不同的合金元素中，在纯 Zn 中添加 Li 提高了 Zn 基合金的机械性能，目前的锌基合金、加工手段及降

解性能总结如表 1 所示。

Table 1. Processing methods, degradation performance, and mechanical experiments of zinc based biomaterials
表 1. 锌基生物材料的加工方法、降解性能、力学实验

材料	加工方法	降解实验结果	力学实验结果	参考文献
Zn	热挤压	E_{corr}—−0.098 V I_{corr}—8.9 μA/cm^2 DR—0.133 mm/y	δ_{TYS}—55 MPa δ_{UTS}—97 MPa	[86]
Zn	热轧	E_{corr}—−1.077 V I_{corr}—20.9 μA/cm^2 DR—0.306 mm/y	δ_{TYS}—35 MPa δ_{UTS}—49 MPa	[87]
Zn-25Mg	粉末冶金	E_{corr}—−1.323 V I_{corr}—12.2 μA/cm^2 DR—0.373 mm/y	E—86 MPa δ_{cys}—403 MPa	[74]
Zn-1.3Fe	铸造	E_{corr}—−1.02 V I_{corr}—0.67 μA/cm^2 DR—0.01 mm/y	δ_{TYS}—80 MPa δ_{UTS}—134 MPa	[88]
Zn-3Cu-1Fe	挤压	I_{corr}—8.9 μA/cm^2 DR—0.13 mm/y	δ_{TYS}—272 MPa δ_{UTS}—221 MPa	[89]
Zn-0.5Al-0.5Mg-0.3Bi	挤压	E_{corr}—−1.084 V I_{corr}—16.45 μA/cm^2 DR—0.203 mm/y	δ_{UTS}—108 MPa H—44.75 HV	[90]

6. 结论

针对与衰老相关的骨病，对创新的临床骨科植入物的需求越来越大。锌基材料可以通过添加合金元素和应用后处理变形方法细化微观结构来满足所需的设计标准。锌基可生物降解材料由于其所需的机械性能和降解性能，是治疗具有挑战性的骨病的重要骨科植入物。本文综述了锌的生物功能、骨科植入材料的设计标准以及锌基生物可降解合金的性能。得出以下结论：

锌存在于人体的骨骼和肌肉中，在骨骼代谢和生物体生长中发挥着重要作用。锌基生物可降解材料可以通过促进骨髓基因来增强成骨细胞分化。

为了满足可生物降解装置的设计标准，机械性能，弹性模量(E)应与骨骼相似(10~20 GPa)。设备的使用时间必须等于执行特定功能的 1~2 年，直到设备完全吸收。体外腐蚀试验降解/渗透速率应小于 0.5 mm/年，析氢量应小于 10 μL/cm^2/天。使用体外腐蚀，锌基可生物降解材料显示出中等的降解率，并被氧化成氢氧化物和氧化物，而不会释放过多的氢气。锌基合金是多相系统，其机械性能和降解性能在很大程度上取决于晶粒尺寸和合金基体中第二相的分布。精细的微观结构和第二相在整个合金成分中的均匀分布有望提高可生物降解锌合金的性能。许多后处理方法已被用于改善锌基生物可降解材料的微观结构。其中，热挤压、热轧和 ECAP 对改善微观组织和减小晶粒尺寸最为有效。在后处理技术中实现的晶粒细化提高了它们的耐腐蚀性和机械性能。锌－镁合金具有良好的机械性能，符合骨科植入物的设计标准。在纯 Zn 中加入 Li 可以提高 Zn 基合金的力学性能。Zn-xLi-yMn (x, y = 0.1~0.8 wt.%)等三元合金系统是下一代矫形器械的最佳候选者。在进行临床试验之前，需要在各个方面测试最合适的锌基生物可降解材料。

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