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·综述·

Ecoflex在口腔医学领域的研究进展

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【摘要】 Ecoflex是基于环保与柔韧性理念开发的弹性体商品化材料统称，多个厂商提供不同类型的Ecoflex产品，具有不同成分和功能，其中，铂催化硅橡胶Ecoflex系列，凭借优异的柔韧性、生物相容性、宽温域稳定性及可调控力学性能，在口腔医学各相关领域均展现适配优势：组织工程中，其可模拟口腔黏膜力学行为，用于唇裂手术训练模型以及颞骨凹陷重建术前评估等；可穿戴设备领域，依托其封装保护与柔性特性，构建的高灵敏度传感器能实现口腔咬合力、咀嚼肌活动等信号监测，助力颞下颌关节紊乱病诊断与唇腭裂术后评估；与生物废物材料形成复合材料，可推动未来口腔可穿戴设备的“功能化＋绿色化”发展；药物传递系统中，其柔性贴合特性与控释能力可解决口腔局部给药痛点，基于柔性微针、温度响应复合系统等设计为牙周炎、口腔溃疡治疗提供精准方案；微创手术器械方面，其柔软特性赋能软体机器人与磁控微流体阀，提升手术安全性与精准度；口腔修复领域，仿章鱼吸盘结构的Ecoflex软衬材料可增强义齿固位，低模量特性减少黏膜刺激，兼顾舒适性与耐久性。尽管Ecoflex在生物医学领域展现了巨大的应用潜力，但仍面临一些挑战，尤其是在长期植入后的稳定性、机械疲劳性能以及微生物定植等方面需要深入研究。未来，随着3D打印技术的发展，Ecoflex有望在多个领域实现更精准的临床转化，并推动智能生物材料的创新发展。

【关键词】 Ecoflex；　有机硅弹性体；　功能化改性；　组织工程；　可穿戴设备；　药物传递系统；　微创手术器械；　口腔医学

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Research progress on Ecoflex in the field of stomatology　BI Huimin, CHEN Jianhang, ZHANG Jingxin, YANG Maohua, DENG Shuangshan, SU Yingyue, GAO Shanshan.　State Key Laboratory of Oral Diseases Research, National Clinical Medical Research Center for Oral Diseases, Department of Prosthetics, West China Hospital of Stomatology, Sichuan University, Chengdu 610041, China
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【Abstract】 Ecoflex is a commercial designation for elastomers developed based on the principles of environmental sustainability and flexibility. Various manufacturers offer different types of Ecoflex products with distinct compositions and functions. Among these, the platinum-catalyzed silicone rubber Ecoflex series has demonstrated considerable applicability in various fields of oral medicine due to its excellent flexibility, biocompatibility, stability across a wide temperature range, and tunable mechanical properties. In tissue engineering, it can simulate the mechanical behavior of oral mucosa, and is used in cleft lip surgical training models and preoperative evaluation for temporal bone defect reconstruction. In the field of wearable devices, leveraging its encapsulation protection and flexible characteristics, highly sensitive sensors constructed from Ecoflex can monitor signals such as oral bite force and masticatory muscle activity, thereby aiding in the diagnosis of temporomandibular joint disorders and postoperative evaluation of cleft lip and palate.

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Moreover, when combined with bio-waste materials, it promotes the functionalization and sustainability of oral wearable devices. In drug delivery systems, its conformability and controlled-release capability address challenges in localized oral drug administration. Designs such as flexible microneedles and temperature-responsive composite systems provide precise solutions for treating periodontitis and oral ulcers. In minimally invasive surgical instruments, its softness enables the development of soft robots and magnetically controlled microfluidic valves, enhancing surgical safety and precision. In the field of oral rehabilitation, Ecoflex soft liner materials, inspired by the suction cup structure of octopus tentacles, improve denture retention. Their low modulus reduces mucosal irritation, ensuring both comfort and durability. Although Ecoflex shows great potential in biomedical applications, it still faces certain challenges, particularly regarding long-term stability after implantation, mechanical fatigue resistance, and microbial colonization, which require further investigation. In the future, with advancements in 3D printing technology, Ecoflex is expected to achieve more precise clinical translation across multiple fields and drive innovation in intelligent biomaterials.

【Key words】 Ecoflex; silicone elastomer; functional modification; tissue engineering; wearable devices; drug delivery system; minimally invasive surgical instruments; stomatology

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有机硅弹性体作为新一代生物医学材料的代表，其化学稳定性、类组织力学特性及可加工性优势，为动态生物界面的构建提供了关键材料基础。"Ecoflex"是一种基于环保与柔韧性理念开发的弹性体商品化材料统称，多个厂商提供不同类型的Ecoflex产品，具有不同成分和功能，如巴斯夫的生物聚酯[1-3]，其中铂催化硅橡胶Ecoflex系列，凭借长期稳定性、极低模量和高延展性，成为生物医学工程领域的重要材料，聚焦于此的研究近年来也呈上升趋势[4-5]，本文聚焦铂催化硅橡胶Ecoflex在口腔医学相关领域的应用。传统医用材料（如钛合金、硬质塑料）难以模拟软组织力学行为，而Ecoflex的类组织力学性能填补了柔性生物界面材料的空白，在柔性传感器、仿生机器人和人工肌肉等前沿领域展现独特价值[6-7]。此外，Ecoflex支持3D打印与模具成型技术，为患者特异性医疗模型和个性化植入物开发提供技术支撑，成为多学科技术融合的纽带[8-9]。笔者对Ecoflex有机硅弹性体在口腔医学相关领域的研究进展进行综述，分析其在当前医疗实践中应用面临的挑战。

1　Ecoflex的基本特性与功能化改性策略

1.1　基础材料特性

有机硅聚合物是一种含有硅氧键（Si-O）的高分子化合物，作为基础材料，可以通过交联技术转化为弹性体[10]。硅氧烷弹性体是一类基于硅氧链结构的弹性体，包含有机硅弹性体，硅橡胶是其核心应用形式[11-12]。铂催化硅橡胶Ecoflex通过技术创新将有机硅的耐候性、柔韧性与生物安全性结合，是高性能硅橡胶的代表[13]。

有机硅弹性体系统根据其固化温度可分为室温硫化橡胶（room-temperature vulcanizate，RTV）和高温硫化橡胶（high-temperature vulcanizate，HTV）。RTV的主要特征是能够在室温下固化，加热可显著加快固化反应的速度[14]。它可以通过缩合反应或加成反应固化。RTV按组分可分为单组分（湿气固化）和双组分（催化固化），加成固化型RTV通常为双组分，按比例混合后引发固化反应。而HTV需在高温条件下（通常150~200 ℃）借助过氧化物等引发剂进行固化，具有更高的机械强度和耐热性，常用于制造轮胎、密封件等工业产品[15-16]。

Ecoflex有机硅弹性体是一类室温固化的有机硅聚合物材料，其核心成分为聚二甲基硅氧烷（polydimethylsiloxane，PDMS），通过添加增塑剂、耐热剂等功能性助剂，经双组分混合后在铂催化剂引发下发生加成反应实现固化[17-19]。PDMS是一种典型的有机硅聚合物，传统的有机硅弹性体如Sylgard 184，具有良好的热稳定性和电绝缘性，较高的化学稳定性，优异的可拉伸力学性能（杨氏模量为0.5~ 4 MPa，弹性极限为200%），是最常用的柔性器件基底材料之一[20-21]。与PDMS相比，Ecoflex具有更低的杨氏模量（0.05~0.1 MPa，接近人体皮肤）和更高的拉伸极限（≈1 000%）[21]。其邵氏硬

度（Shore hardness）覆盖范围广泛，涵盖从极软（Shore A-5）到较硬（Shore 00-50）等不同等级。这种精确的硬度调控能力使其能够精准匹配皮肤、肌肉等生物软组织的力学响应特性[22-23]。

Ecoflex 的性能与硬度紧密相关。Liao 等[23]的研究表明，其刚度、滞后、弛豫时间和平衡应力会随着 Shore 硬度的增加而上升；材料结构影响亦显著，多孔结构的 Ecoflex 拉伸性随孔径增加而提升，420 ~850 μm 孔径范围尤为明显[24]。从整体特性来看，Ecoflex 在不同温度和拉伸条件下弹性与循环耗散特性良好（如应变≤5、温度 23 ℃±80 ℃）[25]。随着温度上升，Ecoflex 材料的力学响应呈现分段特征：−20 ℃~80 ℃区间内刚度随温度升高而增加，−40 ℃~−20 ℃区间内刚度随温度升高而降低；而失效应变则随温度上升持续降低[26]。在单轴拉伸测试中，其展现出轻微可压缩性，且压缩性随拉伸而增强[27]。此外，Ecoflex 粘度低、固化时间合理（室温下几分钟至几小时），可拉伸至原始尺寸数倍而不撕裂，且能回弹至原始形状[25]。

Ecoflex 性能也存在局限性。在力学性能方面，Ecoflex 在循环载荷作用下呈现出应力软化和恢复现象[28]，这表明其应力恢复和热粘弹性行为较为复杂，而且在高应变状态下，Ecoflex 存在失效风险[29]，同时在动态载荷环境中，其机械疲劳阈值有待进一步提高，这限制了它在一些对材料力学性能要求苛刻的场景中的应用[25]。原料配比（1A∶1B）、固化条件（温度、湿度）、分散条件（温度、搅拌转速）和填料添加顺序等因素的微小波动可能会影响其最终性能（硬度、伸长率），这种敏感性导致大规模生产时批次性能一致性难保障。在生物相容性和稳定性方面，硅橡胶表面疏水性强，易吸附细菌，进而引发微生物定植问题，同时还可能导致粘接失效[30-31]。因此，若将 Ecoflex 应用于长期植入人体或处于极端环境的场景，须采取针对性措施增强其耐久性和生物稳定性，以确保其安全性和可靠性。Ecoflex 有机硅弹性体的基本特性和性能参数分别见表 1、表 2[32]。

表 1　Ecoflex 有机硅弹性体的基本特性

Table 1　Basic characteristics of Ecoflex silicone elastomers

Characteristics	Description
Biocompatibility	Complies with the ISO 10993-10 standard
Mechanical properties	High elasticity, low modulus, high tensile strength
Rheological properties	Low viscosity, high reproducibility, large deformability
Chemical stability	Chemically inert, no reaction with most chemical substances
Processing flexibility	Can be cast, injected, 3D printed; can be compounded with other materials to form composite materials
Transparency	Low transparency (light transmittance < 7%)
Thermal stability	Wide operating temperature range (− 50 °C to 250 °C)
Properties of different grades	Mechanical properties increase with the rise of Shore hardness
Surface modification function	Surface functionalization can be achieved through ionization, plasma, laser treatment and other methods

表 2　Ecoflex 系列硅橡胶的特定材料参数

Table 2　Specific material parameters for the Ecoflex series of silicone rubbers

Ecoflex Series	00-10	00-20	00-30	00-35	00-50	5
Working time	30 min	30 min	45 min	2.5 min	18 min	1 min
Curing time	4 h	4 h	4 h	5 min	3 h	5 min
Elongation at break	800%	845%	900%	900%	980%	1 000%
Mixed viscosity	14 000 cps	3 000 cps	3 000 cps	3 500 cps	8 000 cps	13 000 cps
Shore hardness	00 − 10	00 − 20	00 − 30	00 − 35	00 − 50	5A
Tensile strength	120 psi	160 psi	200 psi	200 psi	315 psi	350 psi
Shrinkage rate	< 0.001%	< 0.001%	< 0.001%	< 0.001%	< 0.001%	< 0.001%

Parameters of 00-10, 00-20, 00-30, 00-35, 00-50 were from reference[20]

1.2　Ecoflex 功能化改性策略

Ecoflex 作为一种核心成分为 PDMS 的铂催化固化有机硅弹性体，其分子结构中的 Si-O-Si 主链和甲基侧基赋予其独特的物理和机械性能，如高

弹性、低模量和优异的拉伸性能。为满足不同医学应用需求，可通过以下策略进行改性（图1）。

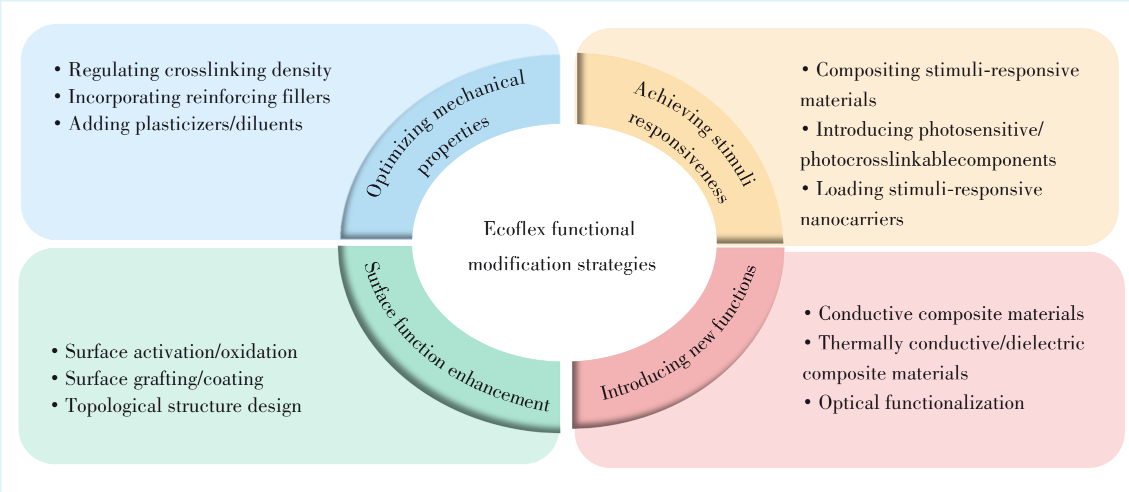

Figure 1　Ecoflex target-oriented functional modification strategies

图1　Ecoflex目标导向的功能化改性策略

1.2.1　优化机械性能　围绕力学适配性与耐久性需求，通过调控内部结构与引入功能组分实现性能定制：调控交联密度平衡硬度与柔韧性，引入增强填料提升强度及耐磨性，添加增塑剂改善材料柔顺性。

1.2.1.1　调控交联密度　在铂催化剂作用下，通过硅氢加成反应，形成交联点。增加交联剂比例或使用更高官能度的交联剂，可显著提高交联密度，提升材料模量（硬度）和拉伸强度，但断裂伸长率通常会降低[33-34]。研究表明，Ecoflex材料中PDMS含量的增加提高了粘合强度[35]。

1.2.1.2　引入增强填料　加入高比表面积的纳米或微米级填料（如气相法二氧化硅 SiO_2、钕铁硼等）可增强机械性能[7]。填料作为物理交联点和应力传递载体可显著提升拉伸强度和耐磨性[36]。填料的类型、粒径、形貌、表面性质（亲疏水性）和添加量是决定增强效果的关键。

1.2.1.3　添加增塑剂/稀释剂　加入有机硅稀释剂可降低杨氏模量3倍，显著提升材料柔顺性（伸长率 >800%），降低粘度，但会牺牲拉伸和撕裂强度[37]。

1.2.2　表面功能强化　针对生物界面交互与整合需求，突破表面惰性限制实现功能升级：经活化处理引入反应位点，通过化学接枝或物理涂覆赋予生物活性功能，设计微纳米拓扑结构调控细胞行为与润湿性，增强生物界面适配能力。

1.2.2.1　表面活化/氧化　Ecoflex表面惰性甲基使其呈现强疏水性和低表面能，不利于细胞粘附、生物分子固定或与其他材料的粘接。表面活化处理（如氧等离子体、紫外线/臭氧UV/O_3处理、激光处理、强氧化剂溶液处理）可产生亲水硅羟基（Si-OH），为后续的化学功能化（如硅烷化）提供“锚点”[38-40]。

1.2.2.2　化学接枝　硅烷偶联剂一端（烷氧基）与Si-OH发生水解缩合反应形成牢固的Si-O-Si共价键；另一端携带功能基团用于共价固定生物分子，从而赋予表面特定的生物功能（如促进细胞选择性粘附、抗凝血、抗菌）[41]。物理涂覆：涂覆功能性涂层（如抗菌涂层、水凝胶层）依赖物理吸附和范德华力结合，方法简便[42]。

1.2.2.3　拓扑结构设计　通过模板法或微加工技术在Ecoflex表面构建微纳米级拓扑结构（如仿生微柱、凹槽、褶皱）可调控细胞行为、影响蛋白质吸附、改变润湿性（超疏水/超亲水）或增强机械互锁[43-44]。

1.2.3　引入新功能　为拓展诊断、治疗及能量采集应用，通过复合功能材料赋予新特性：复合导电纳米材料制备可拉伸导体/传感器，添加导热/介电填料优化热管理与能量器件性能，结合光学功能化进一步拓宽应用场景。

1.2.3.1　导电复合材料　将导电纳米材料（如碳纳米管CNTs、石墨烯/氧化石墨烯GO/rGO、银纳米线

AgNWs、导电炭黑CB分散到Ecoflex基体中[45-49]。Ecoflex极低的模量和高弹性确保了复合材料在大变形（拉伸、弯曲、扭转）下仍能维持导电网络的连通性，从而实现可拉伸导体或传感器的功能[50-54]。

1.2.3.2　导热/介电复合材料　将六方氮化硼（h-BN）与液态金属（EGaIn）构建h-BN@EGaIn杂化填料并分散于Ecoflex中，既能使复合材料的导热性能较纯Ecoflex提升5倍，又能保持电绝缘、低模量（<1 MPa）、抗泄漏等特性[55]。加入高介电常数填料（如钛酸钡 $BaTiO_3$）可增强其介电性能[56]，是制造介电弹性体驱动器或提升摩擦纳米发电机（triboelectric nanogenerators，TENG）输出性能的关键[57]。

1.2.3.3　光学功能化　添加染料或荧光物质可赋予Ecoflex特定颜色、发光或结构生色特性。

1.2.4　实现刺激响应性　聚焦智能诊疗与按需治疗的动态响应需求，通过多元方式构建刺激响应机制：与智能材料复合驱动结构变形，引入光敏组分实现光刻图案化，负载纳米载体触发按需释药。

1.2.4.1　复合刺激响应材料　将Ecoflex与本身具有刺激响应性的智能材料复合。例如嵌入预变形形状记忆合金（shape memory alloy，SMA）丝，如镍钛诺（NiTi）线，受热收缩驱动Ecoflex变形（如从2D→3D）[58]；集成温度/光/pH敏感水凝胶，其溶胀/收缩带动Ecoflex结构变形或控制微流道，实现药物控释或执行器动作[59]。

1.2.4.2　引入光敏/可光交联组分　加入光敏剂或光可交联单体（如含丙烯酸酯基团单体、苯甲酮）。在紫外光（ultraviolet light，UV）照射下，这些组分发生光化学反应（如自由基聚合、光交联），使Ecoflex实现直接光刻图案化，用于制造复杂的可拉伸电路、传感器阵列等[60]。未曝光区域可通过溶剂洗脱，形成图案。

1.2.4.3　负载刺激响应性纳米载体　将能响应特定刺激（如pH、温度、近红外光）并释放药物的纳米载体（如介孔二氧化硅纳米粒、脂质体、多功能化氧化石墨烯GO纳米异质结）负载到Ecoflex基体中。当受到相应刺激时，纳米载体释放药物，通过Ecoflex基体扩散出来，实现智能药物递送[59, 61]。

这些多维度、多层次的改性策略不仅实现了Ecoflex性能的精细化调控，更构建了“结构设计-性能优化-功能集成”的完整技术链条，为其在生物医学工程各领域的创新应用提供了从材料基础到功能实现的关键保障。

2　Ecoflex在口腔医学领域中的应用潜力

口腔及颅面区域因运动频繁（说话、咀嚼、吞咽）、结构特殊（牙体组织、牙周组织、口腔黏膜、唾液腺、舌头）且成分复杂（唾液、细菌、酶、食物），对柔性电子产品的应用提出了较高要求[62-63]。当前柔性电子技术在口腔医学中的应用主要涵盖唾液生物标志物检测，面部活动监测、口腔气体/呼吸检测及正畸力、种植体、龋病、牙周炎相关的信号监测[64-65]。在众多生物材料中，Ecoflex凭借优异的柔韧性、生物相容性及可调控的功能特性[66]，成为应对上述挑战的理想选择（图2）。

2.1　组织工程

Ecoflex作为一种铂催化加成固化的有机硅弹性体，具备优异的柔韧性、生物相容性以及宽工作温度范围，在组织工程领域展现出极大潜力。其疏水性与亲油性的独特结合，以及在制造过程中无需复杂合成工艺的优势，使其在大规模生产中颇具经济竞争力[45]。

在组织工程应用方面，Ecoflex可用于制造人造皮肤和软组织替代物，模拟天然组织的力学环境。在口腔医学领域，这一特性具有特殊价值：口腔颌面部软组织（如牙龈、口腔黏膜）长期处于动态力学环境中，需承受咀嚼压力、温度变化及唾液侵蚀，且口腔内不同区域的软组织表现出不同的机械行为[67]，而Ecoflex具备低模量优势，其力学性能可通过配方调控精准匹配口腔内不同区域黏膜的力学需求，为口腔医学领域提供理想材料选择。在口腔颌面外科临床实践中，已有研究将Ecoflex用于颞骨凹陷重建相关的术前评估。如某21岁女性患者治疗中，研究人员选用肖氏硬度00-10的Ecoflex制作面部皮肤复制品（质地类皮肤且可调色，能高保真还原皮肤形态），与3D打印颅骨模型组装后，搭配不同羟基磷灰石（hydroxyapatite，HA）个性化植入物（patient-specific implant，PSI）变体至颞骨缺损区，直观评估植入物对皮肤轮廓的影响，助力筛选最优植入物方案，弥补计算机模拟不足[68]。

此外，Ecoflex在其他软组织替代中已有的研究成果，也为其在口腔医学领域的应用拓展提供了重要参考与技术支撑：如利用Ecoflex制造模仿发音动作的柔软机器人舌头[69]，可类比口腔运动功能重建研究或用于口腔癌、唇腭裂序列治疗等复杂口腔手术模拟训练辅助工具[70]。同时，这类基于Ecoflex的软组织替代研究，也为后续探索其

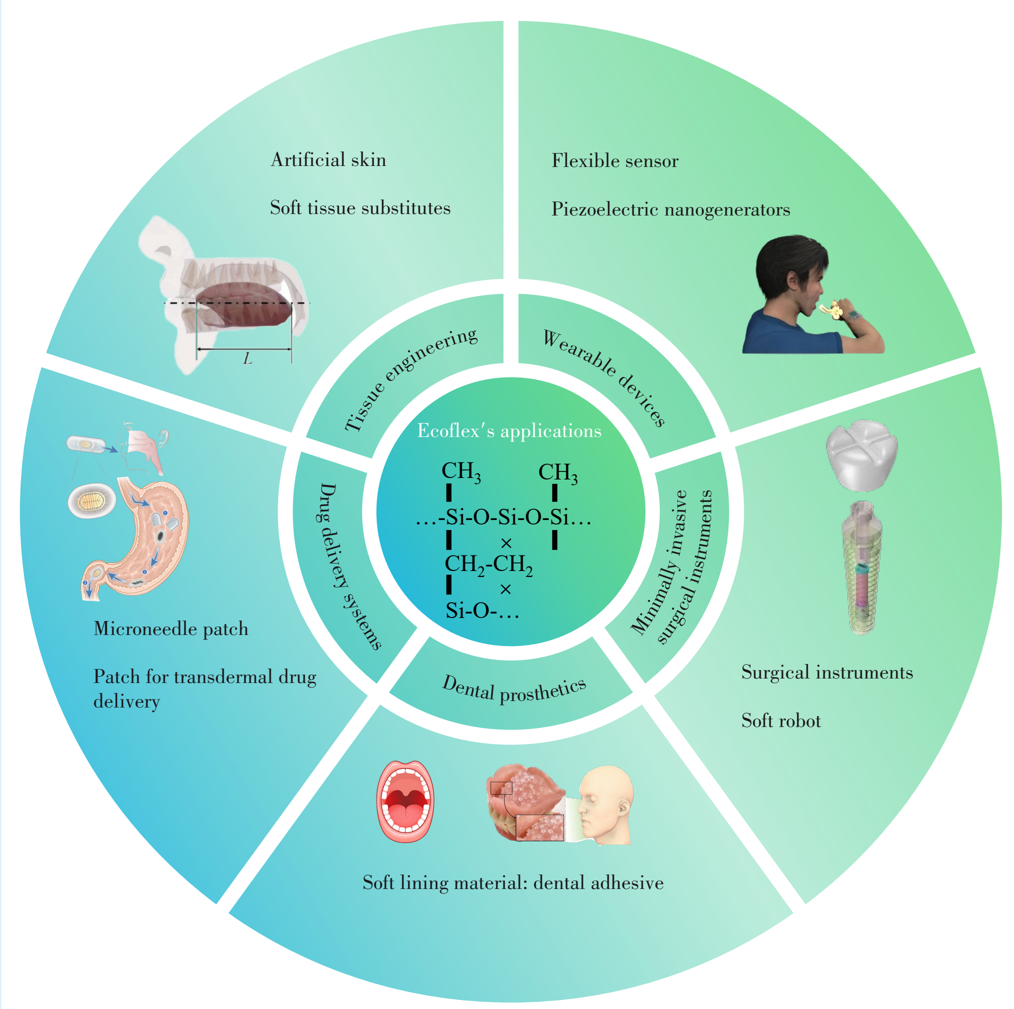

Figure 2　The application potential of Ecoflex silicone elastomers in the field of stomatology

图 2　Ecoflex 有机硅弹性体在口腔医学领域的应用潜力

在口腔黏膜替代、牙周软组织修复等细分场景的应用,奠定了材料性能验证与结构设计的基础。

2.2　可穿戴设备

当下,柔性电子产品在日常生活与医疗领域的普及程度与日俱增。医用柔性电子器件依托柔软、高拉伸性、生物相容性良好且适配湿环境的低模量材料[71-72],能紧密贴合人体皮肤,实现生物物理/生化信号的无创持续监测[73-74],同时在疾病治疗与康复环节发挥作用。

Ecoflex 因低粘度、高再现性、大变形性以及温度低敏感性等性能,成为制作柔性拉伸传感器的理想之选。在口腔医学领域,可穿戴设备的需求集中于口腔功能监测与疾病早期诊断[75]:例如正畸治疗中的牙齿移动力监测[76]、颞下颌关节紊乱病的运动轨迹分析、唾液生物标志物的实时检测等,而 Ecoflex 的特性恰好适配口腔潮湿、多运动、空间受限的复杂环境[77-78]。这一适配性在生物废物衍生摩擦纳米发电机(triboelectric nanogenerator, TENG)的口腔应用中验证:基于聚乙烯醇(polyvinyl alcohol, PVA)与螃蟹壳衍生壳聚糖等生物废物材料构建的自供电咬合传感器,经 Ecoflex 封装可缓冲 900 N 最高测试咬合力、隔绝唾液,且高柔韧性贴合牙齿[79]。

基于 Ecoflex 开发的高灵敏度柔性传感器具备口腔应用潜力:通过反向成型与喷涂技术将 CB/Gr 导电纳米复合材料集成于 Ecoflex 基板,构建 45°应变莲花形结构,实现传感器高灵敏度(GF=35)、宽应变范围(0~100%)、快速响应(200 ms)及 5 000 次循环稳定性[80],此类传感器可进一步拓展应用于贴合面部皮肤或嵌入口腔矫治器,精准监测咀嚼

肌活动、下颌运动幅度，为颞下颌关节紊乱病的诊断与康复评估提 供量化数据；基于溶液浇铸与浸涂技术制备的 MWCNT/Ecoflex 复合结构应变传感器，具备高拉伸性和高灵敏度[81]，可用于人体运动监测等场景，其性能特性为后续拓展至面部动作检测、肌肉功能评估（如口腔唇部运动恢复监测）等领域提供了潜在可能。

生物废物衍生材料（如鱼鳞明胶、木材废料纤维素、蟹壳壳聚糖）与可生物降解的PVA复合构建传感器基材，搭配 Ecoflex 作为封装层，既借助 Ecoflex 的高弹性保留了传感器的柔性与结构完整性，又通过 PVA 与生物废物衍生材料的生物降解特性解决了传统传感器的环境污染问题，为未来口腔可穿戴设备的"功能化 + 绿色化"发展提供了参考方向。

2.3　药物传递系统

Ecoflex 作为兼具灵活性、生物相容性及稳定药物负载能力的多功能材料，在透皮药物递送系统中极具潜力[82-83]，可用于开发控释系统和经皮给药贴剂。如受章鱼吸盘启发设计的带有微结构的 Ecoflex 贴片，结合 GelMA 水凝胶实现药物缓释与靶向递送，为伤口愈合提供支持[84]。在口腔医学领域，由于口腔环境特殊（存在唾液冲刷、pH 波动、咀嚼机械刺激等），常规局部给药易出现药物流失快、生物利用度低等问题，而 Ecoflex 基药物传递系统凭借优异的黏膜粘附性、可控释放性能及生物相容性，可成为口腔疾病局部治疗的理想载体。正如 Kang 等[85]研发的机械水下软黏附系统（mechanical underwater soft adhesive system，MUSAS），其以 Ecoflex 为核心柔性材料，已在猪颊部、咽部验证了 mRNA 递送效果，证实了该系统在口腔及头颈部软基材上的黏附可行性，为口腔局部药物递送研发提供思路。

在药物递送系统的设计与应用中，Ecoflex 的优势主要体现在模具制备与材料兼容性方面：Ecoflex 通过激光雕刻工艺实现超细微针模具的个性化制备，支持匹配不规则创面的图案设计，且微针系统具备"软针覆盖不刺激、硬针固定不脱落"的特性[86]。这一特性可针对性解决口腔黏膜给药的核心痛点 —— 口腔黏膜脆弱易损伤、病灶形态不规则（如牙周袋、口腔溃疡）、传统给药易被唾液冲刷流失。Ecoflex 与 PDMS 混合作为空心微针（hollow microneedles，HMNs）的阴性模具，可制备不同内径（0.2~0.5 mm）、高度（0.8~1.4 mm）的定制化 HMNs，且 HMNs 具备"低剂量高效给药"特性（0.1 倍口服剂量达同等疗效）[87]。这一特性可解决口腔"深部病灶给药"难题（如根尖周炎、智齿冠周炎），避免全身用药副作用。Ecoflex 作为商用 PDMS 参考材料，与热敏材料 EGaIn（镓铟共晶合金）复合后具备各向异性导热，可实现柔性电子设备的热管理[88]。结合口腔可穿戴设备（如正畸托槽、口腔黏膜监测设备）的"长期佩戴需热舒适 + 持续给药"需求，可衍生出"热管理 - 药物缓释"一体化系统。

总体而言，基于 Ecoflex 的硅基药物递送系统在提升患者依从性与治疗精准度方面优势显著，为口腔常见疾病的局部治疗提供了创新方案，在糖尿病、慢性疼痛等需长期给药的疾病中也展现出广阔应用前景[89]。

2.4　微创手术器械

在微创手术领域[90]，Ecoflex 弹性体凭借柔软、可变形的特性脱颖而出，为提升手术安全性与灵巧性提供了有力支持，因此被广泛应用于开发新型软体机器人和手术器械[26, 91]。

口腔微创手术（如种植手术、根管治疗、颌骨囊肿摘除术）对器械的精准性、灵活性及组织相容性要求极高。传统刚性器械易对周围软组织（如牙龈、神经）造成损伤且无实时力监测能力。而 Ecoflex 基软体器械可通过仿生设计实现自适应变形，降低手术风险：例如，基于 Ecoflex 的导管状软机器人辅助支气管内介入的技术[92]，可迁移至口腔种植手术，将搭载微型摄像头与超声探头的 Ecoflex 软体导管经口腔自然通道进入术区，精准探查颌骨骨量与神经位置，且柔软特性避免划伤黏膜。在口腔种植领域，Ecoflex 00-30 是构建口腔种植体无线控制微流体阀的关键材料，其作为柔性磁性瓣膜基体，与 NdFeB 磁性颗粒（重量比 1∶2）混合制成 140 μm 厚叶片，经 1.8 T 脉冲磁场磁化后，可在外部轴向磁场（>60.4 mT）驱动下开启流道，反向磁场（≈64.5 mT）下复位密封，解决传统刚性瓣膜磁控灵敏度低、易卡滞问题。同时，该瓣膜的高弹性可与 PDMS 密封塞紧密贴合确保液体在输送过程中无泄漏，柔性还能适配种植体植入后的角度偏差与流道形变，避免刚性瓣膜密封失效或输送受阻，确保液体能稳定、精准地被递送至植体-骨界面，满足抗生素防生物膜、干细胞促骨整合等治疗需求，且适配微创治疗场景，降低植入后干预风险[93]。

此外，Ecoflex用于制造触觉力传感器、自供电压力传感器等研究[94-96]，可直接服务于口腔微创手术：一种具有喷墨打印导电性与水凝胶生物相容性的软触觉传感器，已用于尸体手术试验的牵开器，依托Ecoflex实现高柔韧性，既能适配口腔复杂解剖形态以保障手术操作灵活度，又能提升口腔牵开器的力反馈精准度，进而降低组织损伤风险[97]。

2.5　口腔修复软衬材料

口腔修复领域中，全口义齿、局部义齿的固位与舒适性是临床面临的主要挑战，尤其对于牙槽骨严重吸收、口腔黏膜敏感的患者，传统义齿易出现松动、压痛甚至黏膜损伤等问题。Ecoflex凭借可调节的机械性能、优异的生物相容性及独特的粘附机制，成为理想的口腔修复软衬材料，为解决上述问题提供了创新方案。

Ecoflex低模量特性可模拟人类舌头的力学刚度，制备3D仿生舌头表面弹性体，用于口腔摩擦学测试中模拟真实口腔的接触环境[98]，为研究食物体系的润滑性能、口腔黏膜摩擦行为等提供可靠的仿生测试平台，该特性可拓展至口腔修复体研发阶段的"黏膜适配性预测试"，减少修复体临床应用后的黏膜刺激风险。并且Ecoflex的高弹性回复率(>90%)可确保在咀嚼循环中快速回弹[99]，利于维持义齿稳定性，提升佩戴舒适性。口腔环境复杂，存在唾液酶解、温度波动(35 ℃~40 ℃)及微生物侵蚀，对材料的耐久性提出严苛要求。Ecoflex作为有机硅聚合物，具备耐用性和抗老化性能，长期使用仍能维持力学性能与结构完整性。此外，其生物相容性已通过细胞毒性、皮肤致敏性等测试，在口腔黏膜接触应用中无明显炎症反应，适用于长期佩戴场景。

口腔湿润环境下的义齿固位是核心难题，传统软衬材料依赖机械嵌合或化学黏合剂，效果有限且易引发过敏。受章鱼吸盘启发，Lee等[66]开发的超适应性的Ecoflex硅橡胶仿生粘附剂，通过集成剪纸结构与垂直自对齐吸盘，模仿章鱼触手和拉胀背板，利用毛细作用和负压吸力增强粘附机制，可牢固可逆地粘附于不规则3D口腔空腔表面。在人类受试者评估中，该仿章鱼吸盘结构Ecoflex口腔粘附剂能显著增强全口义齿与腭黏膜间的黏附力，适用于湿润、光滑、高度弯曲和不规则的湿黏膜表面，且在持续咀嚼运动中仍保持稳定固位，无残留、无刺激、可重复使用，其佩戴舒适性优于传统义齿软衬。

3　未来展望与挑战

在生物医学工程领域，Ecoflex有机硅弹性体已取得一定成果，并凭借其独特性能展现出巨大应用潜力，但其实际应用与发展仍面临多重挑战：在性能方面，体液酶促降解、循环载荷致材料失效、表面疏水性易引发感染、批次性能波动等。针对这些挑战，未来解决方案已初步明确，包括微流控动态交联调控力学梯度、仿生鲨鱼皮结构抗菌、机器学习模型优化填料分散等[100]。在组织工程中，将来可通过将Ecoflex与胶原、透明质酸等天然生物材料复合，构建具有仿生结构的口腔黏膜替代支架，模拟天然黏膜的柔韧性与抗摩擦性能，为口腔溃疡、黏膜缺损等疾病的修复提供新方案。基于Ecoflex的口腔可穿戴设备可进一步拓展：结合微流控技术构建"传感器-微泵"集成系统，实现唾液中葡萄糖、炎症因子等标志物的实时检测与反馈，辅助糖尿病、牙周炎等疾病的管理；开发柔性无线正畸力传感器，嵌入隐形矫治器中实时监测牙齿受力状态，优化矫治方案。在口腔疾病治疗与预防场景中[101]，药物递送系统展现出明确潜力：针对复发性口腔溃疡，可设计搭载抗炎药物的Ecoflex响应性贴片，通过环境敏感机制实现溃疡部位的高效释药；针对义齿性口炎，可在Ecoflex衬垫中复合抗菌成分，利用其缓释特性抑制致病微生物定植；而可编程微针系统则可精准递送抗菌药物至牙周病灶，提升局部疗效。在微创手术领域，结合形状记忆合金与Ecoflex的复合结构，可开发具有"可控变形-精准复位"功能的口腔微创手术机器人，实现复杂颌骨区域的精准操作，进一步提升口腔微创手术的安全性与效率。

目前，基于Ecoflex的复合墨水已实现多组分3D打印技术突破：通过Ecoflex与纳米二氧化硅复合制备ESC墨水，可精准调控材料模量(低-中-高梯度)，成功打印耳状、鼻状等软硬复合仿生结构及可拉伸电子基板[102]；利用Ecoflex 00-50的高拉伸性，通过优化打印参数(流速0.3 mL/min、打印速度10 mm/s)实现复杂结构(如气动执行器、心脏模型)制造，已应用于软机器人研发与医疗解剖培训[103]。从技术发展来看，3D打印技术在仿生结构制造、功能材料集成方面的优势，为其拓展至生物医学相关领域提供了重要基础[34]。在口腔医学领域，Ecoflex因生物相容性和高延展性可用于制作

临时义齿软衬、颌面赝复体、咬合分析模型等,但由于其生物安全认证缺失限制,且硅橡胶类材料受口腔环境影响易出现硬度增加、老化变形、粘接强度不足等问题[104-105],Ecoflex尚未大规模商业化。未来通过材料改性与3D打印结合,可开发个性化修复体、微流控检测芯片等,但需突破化学稳定性、智能化开发及成本控制瓶颈。随着生物材料改性技术和数字化制造发展,Ecoflex有望在口腔软组织修复领域发挥重要作用,但成功需要跨学科协作,材料科学家需优化耐久性与功能性,临床医生要验证长期安全性,法规机构需加快相关认证流程,共同助力这一柔性材料从"实验潜力"迈向"临床实用"。

突破"性能-稳定性-制造"瓶颈后,Ecoflex有望通过动态交联、人工智能工艺优化等成为变革性工具,未来研究聚焦自修复材料[106]、3D/4D打印创新[107]、再生医学应用及口腔临床转化,推动柔性器件向智能化、个性化发展。

4 小 结

Ecoflex作为低模量、高延展性、良好生物相容性的典型柔性材料,在模拟生物组织、制造柔性电子器件、设计智能药物载体及构建软体医疗机器人等方面展现出显著优势,推动了医疗技术从传统刚性材料向生物模拟、智能适配方向的转型升级。

然而,Ecoflex的长期植入稳定性、生物环境中的机械疲劳性能、抗微生物侵蚀能力以及大规模生产的一致性仍然面临较大的挑战。未来,应围绕材料的功能化改性、智能响应机制探索及先进制造技术优化等方面展开深入研究;尤其是借助高精度多材料3D打印技术[108]和纳米复合材料改性策略,有望进一步提升Ecoflex的机械性能、生物耐受性及多功能适应能力,从而推动导电纳米材料、生物活性成分等功能材料与Ecoflex的融合应用,进一步优化其在口腔诊疗中的性能,完善口腔医用设备研发,加快该材料由实验室研究向临床实际应用的转化进程。

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