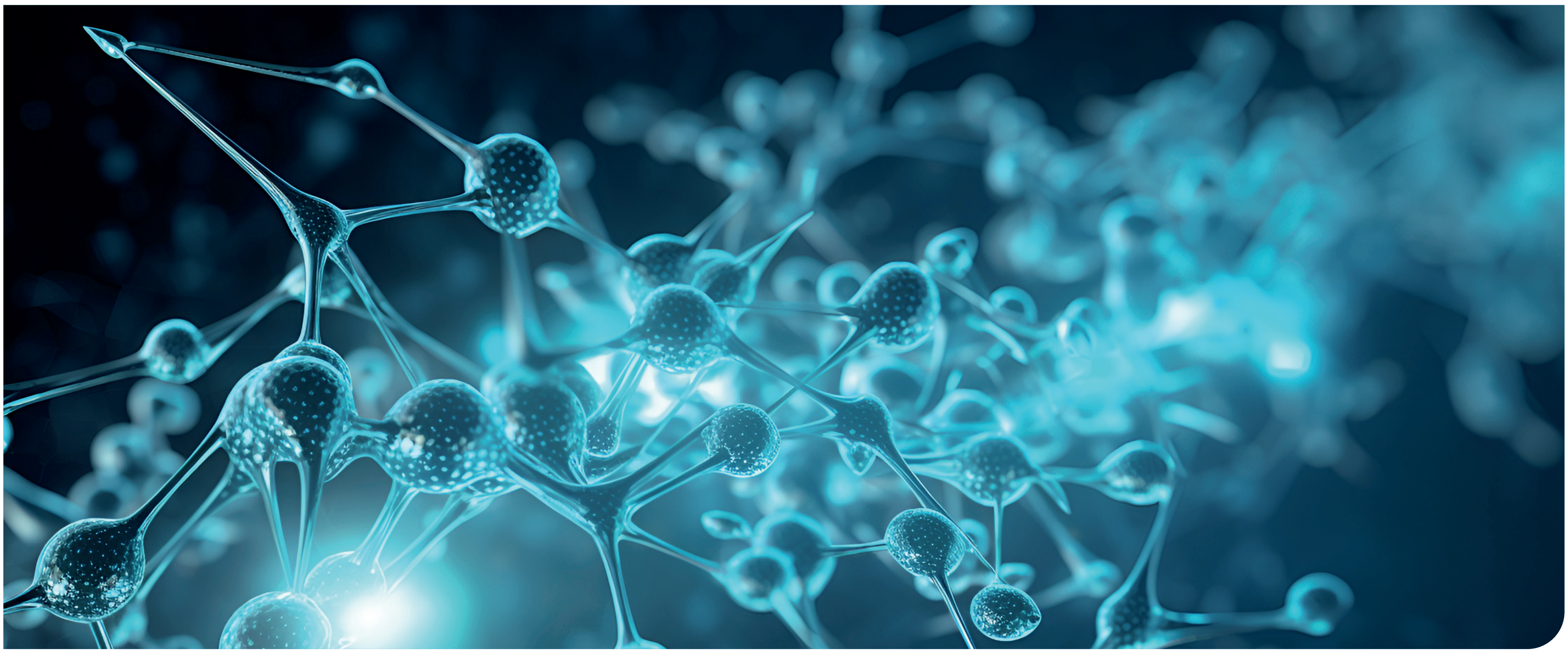
RECENT ADVANCES IN THE FIELD BIOMATERIALS



I. INTRODUCTION

Within tissue engineering and the medical field, biomaterials have played a significant role in various applications over the years. Such materials, whether they are natural or synthetically derived, provide a stimulus for biological processes to occur; the earliest versions of such materials included animal sinew for stitching. Indeed, recent advancements within tissue engineering and regenerative medicine show great promise for the future of the medical field and tissue engineering. Consider, for instance, the case of biodegradable polymers like polylactic acid (PLA) and polyglycolic acid (PGA). These biomaterials have found widespread use in tissue engineering, where they serve as scaffolds for regenerating damaged tissues and organs. They gradually degrade within the body, leaving behind regenerated tissue in their place, making them invaluable tools in the quest to repair and replace damaged body parts. Similarly, hydroxyapatite, a bioceramic derived from natural bone, has revolutionized the field of orthopedics. It is used in the production of artificial joints and dental implants due to its exceptional biocompatibility and ability to integrate seamlessly with the human body, providing patients with increased mobility and improved quality of life. By bridging the gap between the human body and biomaterials, medical treatments spanning from dentistry to stents can be revolutionized, with meaningful impact on the lives of patients.

II.1: Biomaterials & their applications (general)

Biomaterials are a class of compounds used to provide a base for biological processes to occur. Biomaterials can be natural or synthetic, combining all aspects of science and engineering for proper development [1]. Depending on the use-case, a biomaterial will need to have certain characteristics to mimic living tissue and its environment. Naturally-derived biomaterials include collagen, keratin, and cellulose; they can also be separated into three categories based on molecular structure: proteins, polysaccharides, and glycosaminoglycans [2]. Advantages for these biomaterials include abundance within nature, low production costs, and high success rates *in vitro*. Naturally-derived biomaterials have proven useful in tissue and organ remodeling. Applications include bioprinting, tissue and organ development, and drug development [2]. Emphasis on these applications remains crucial for advancements within the medical field.

Synthetic biomaterials are an alternative to natural ones and include both non-biodegradable and biodegradable polymers, metals, and ceramics [3]. Metals, such as stainless steel and titanium, are utilized in hip fractures due to corrosion resistance. Additionally, their strength against mechanical stressors indicate applications in load-bearing regions, such as the knee or hip [4]. Ceramics find uses in dentistry and orthopedics, with recent advancements focused on regenerating bone for problems such as fractures or osteoporosis. Common ceramic-based biomaterials include alumina (Al_2O_3) for arthroplastic purposes, and calcium phosphate for putties and wedges. Less commonly used is bioglass, a bioactive silicate glass network used primarily for bone reformation, though studies have shown its poor strength compared to cancellous bone [4].

II.2 Challenges

Despite the advances in biomaterials and biomaterial application, many challenges remain. For natural biomaterials,the two primary disadvantages that must be overcome are poor mechanical strength and possible immune action [5]. Mechanical strength is largely dependent on the material used, as well as structure. Natural biomaterials are generally weaker due to their structure. Furthermore, materials such as alginate and hyaluronic acid excel in cell proliferation and cross-linking for tissue regrowth, but struggle from poor mechanics and susceptibility to bacterial growth [6]. Any foreign substance introduced to a biological organism has the potential of an immune reaction that could result in death. This is a major challenge for researchers to create a natural biomaterial capable of minimal reactions. Luckily,most natural biomaterials have this advantage, although some may elicit immunological reactions depending on function [7]. Some research studies biomaterials that are "biologically safe" (i.e., inert) for tissue growth/stimulation. In their overview of past attempts at tissue engineering, engineering tissue based on inertness showed poor vascularization, excessive scarring, and lack of differentiation upon tissue regeneration [7]. Despite years of research into these areas, these challenges remain. Fortunately, recent advances in biomaterial research hold promise, though further testing is needed.

Another challenge for researchers is mounting production and testing costs. Since biomaterials are explicitly used within the medical and biomedical fields, a biomaterial must fall within strict guidelines for researchers and manufacturers. These guidelines include biocompatibility, high corrosion and wear resistance, and mechanical compatibility [8]. Failure to meet these demands for medical applications could make the affected area worse than before. Such strict guidelines followed through testing *in vitro* and *in vivo* (for both animals and eventually clinical trials with humans) accrue such prohibitive costs that researchers may be disinclined to devote time and resources. Costs have increased also due to an increasing geriatric population and their need for joint replacement and biomedical support [9]. Fortunately, the market share has increased to help address this issue, but nonetheless, costs have risen.

Indeed, the challenges for biomaterials seem insurmountable. Recent advancements, however, show promise for medical and biomedical applications. Several novel studies and examples throughout many applications show the benefits of biomaterials in many forms.

III. Advancements in synthetic biomaterials

The properties and applications of synthetic biomaterials have been extensively investigated. Recent research into synthetic biomaterials has focused on the ability to enhance their tissue regenerative characteristics. For metal biomaterials, stable metals such as titanium have applications in bone regrowth, serving as a base for joint replacement and artificial bones. Although mechanically strong and corrosion-resistant, their bio inertness and low degradability may prompt removal, accruing costs and discomfort for a patient [10]. There has been increasing interest in the use of biodegradable metals as an alternative. Specifically, biodegradable metals allow an organism to form new tissue or reshape itself while degrading overtime to eliminate surgical removal or metal toxicity. Zhang et al. reviewed different biodegradable metals for bone regrowth, including pure magnesium, magnesium alloys and zinc. Their review emphasized the need for a systematic examination of biodegradable metals before moving into clinical trials, as published studies did not provide consistent evidence for *in vivo* success [11].

Further advancements in biodegradable metals can be found in the field of neuroscience. For the cerebral region near the brain, metal choice is important for stent production for stroke recovery. Typical metals include magnesium and zinc, with zinc chosen primarily for its benefits to cognition and ability to prevent neuronal degeneration [12]. Additionally, zinc serves as an important cofactor in all six enzyme classes and protects the blood brain barrier [13]. These classes include oxidoreductases, transferases, hydrolases, lyases, isomerases, and ligases [14]. For zinc-based stents, there is sufficient biocompatibility and high ductility while used ***in vivo.*** Zhou et al. successfully demonstrated a zinc-copper alloy coronary artery stent (Zn-0.8Cu) that was implanted over two years in a pig model. Figure 1 below shows the design of these stents.

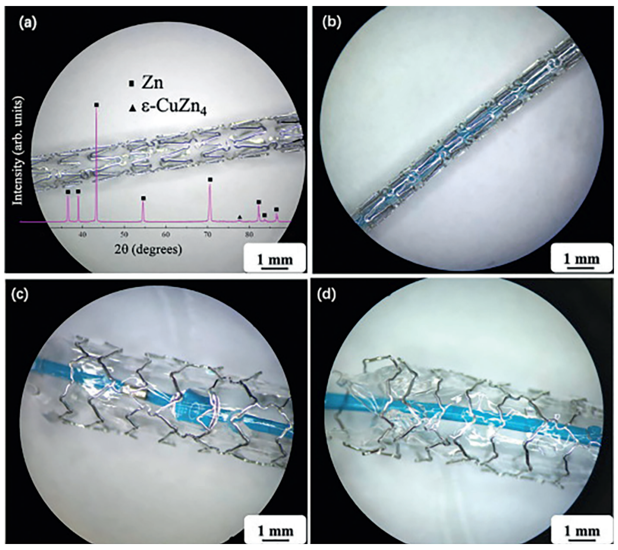


Figure 1: Surface morphology of the Zn-0.8Cu stent after balloon-burst [15]. Reproduced with permission from Zhou et. al.

Their results showed a proper stent degradation, with around 28% ± 13% volume remaining after the two years without any inflammatory response [15]. Although the study considered 16 pigs, longer *in vivo* trials among a larger sample size are still needed, and much progress is to be made within the field of biodegradable metals.

In addition to metals, ceramic biomaterials show promise for researchers. Ceramic-based biomaterials have their uses in dental and bone implants, as well as coatings for joint replacement to enhance corrosion resistance and reduce wear [16]. Two common bioceramics (ceramic-based biomaterials) are alumina (Al_2O_3) and zirconia (ZnO_2). Alumina is a bioinert ceramic primarily used in dental and orthopedic applications. Advancements focus on enhancing durability within implants through the addition of other materials. Toloue et al. examined the addition of alumina nanowires to polyhydroxybutyrate (PHB) and PHB-chitosan (PHB-CTS) scaffolds for cartilage restructuring. After randomly generating wire for PHB, PHB-CTS and PHB-CTS/3% alumina, researchers found that alumina-infused wires had a tensile strength of nearly ten times greater than that of non-infused PHB-CTS wires; the average tensile strength for PHB-CTS was 0.89 ± 0.26 MPa, whereas that for PHB-CTS/3% alumina was 11.18 ± 1.24 MPa. Importantly, cell viability increased greatly with the addition of CTS- a naturally-derived biomaterial- compared to just PHB [17]. These results prompt further research into such ceramic biomaterials for possible ***in vivo*** studies in the future.

As mentioned previously, zirconia is another ceramic biomaterial used in medical applications, including dental and orthopedic areas. Similar to alumina, zirconia can be used as an additive to enhance material properties. For orthopedic applications, researchers have noted zirconia as a "toughening" agent for other polymers. One study observed the characteristics of a silicon-nitride bioceramic toughened with zirconia (and vice-versa to note differences). The goal was to observe density changes given different silicon-nitride ratios to find an optimal density for clinical testing. Results showed a good weight-to-strength ratio for a zirconia matrix toughened with silicon-nitride. Moreover, researchers found remarkable bio-inertness for each ratio (15%, 20%, and 25% silicon nitride) [18]. Bio-inertness is crucial for medical devices because implants should not react with the body; such reactions could metabolize into the body or become lethal. These results indicate a promising future for zirconia as a matrix or toughening agent, depending on its application.

Synthetic biodegradable polymers are a promising class of synthetic biomaterials, with significant advancements in recent research. The most common group of synthetic biodegradable polymers include aliphatic polyesters, primarily used for 3D scaffolding within tissue engineering applications [19]. Common polymers in this group include polyglycolic acid (PGA) and poly(vinyl alcohol) (PVA). Numerous studies have investigated applications of these materials in the context of skin healing/wound dressing and cardiac tissue regeneration. In a study on biodegradable polymer-coated coronary artery stents, Takahashi et al. demonstrated that their custom designed biodegradable polymer-coated coronary artery stent (MiStent) reduced thrombosis better than related stents could and, more importantly, outperformed in biocompatibility [20]. This new design could promote further advances in coronary artery stents. As for wound healing, Lalhmangaihzuali et al. proposed biodegradable PLLA staples for wound closure [21]. The mechanical strength, durability, cost-effectiveness, and biodegradability of PLLA portend a promising future for wound healing with PLLA-based staples.

IV. Advancements in natural biomaterials

Research into new naturally-based biomaterials and their applications in medical devices has seen exciting progress within recent years. Much advance has been made to strengthen existing polysaccharide-based biomaterials with other natural or synthetic materials. A recent study conducted by Hassan et al. reported two novel chitosan derivatives for therapeutic use against virulent microorganisms. This research showed its highly effective antimicrobial properties, with concentrations of 250 μg/ml effective against Gram-positive bacteria. Also, these combinations could combat *Candida albicans,* a yeast commonly found in the body and could cause infection [22]. Its implications note the future for wound healing within tissue engineering. Another study reported the development of a novel hybrid hydrogel utilizing quaternized chitosan (QCS) for noninvasive wound healing and enhancing the wound healing process. QCS is preferred within biomedical applications due to its biocompatibility, increased water solubility, and enhanced antimicrobial properties [23]. Yu et al. found that poly (N-isopropylacrylamide) quaternized chitosan-graft-β-cyclodextrin (PNIPAm-AA-QCS-CD), supported with polymer nanotubes hydrogel, exhibited sufficient elasticity, antioxidative properties and resistance to *Staphylococcus aureus* (MRSA) bacteria on dummy models [24]. Figure 2 below shows how QCS-CD hydrogel works when introduced to a wound or defect in the skin.

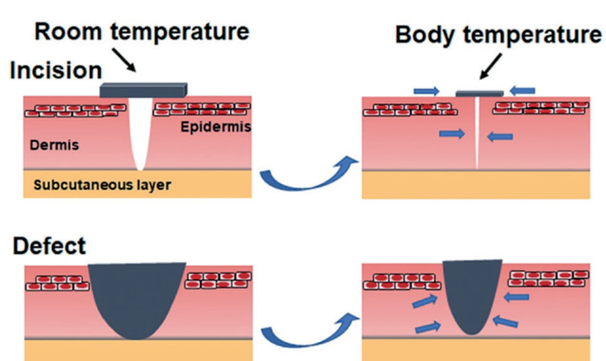


Figure 2: Visual representation of PNIPAm-AA/QCS-CD hydrogel addressing wound healing and its response to temperature [24]. Reproduced with permission from Yu et. al

As shown in Fig. 2, the QCS-CD hydrogel is reactive with temperature, contracting once exposed to body temperature and adhered to skin. These properties allow this hydrogel to act as a bioactive Band-Aid that promotes tissue regeneration almost immediately, showing considerable progress after 24 hours. Yu et al. noted the possibility of noninvasive treatments, clinical trials once tested *in vivo* on animals, and advancements in skin regeneration technologies for the near future.

Of the protein-based biomaterials, collagen shows tremendous promise in biomaterial applications. A fibrous protein-based biomaterial, collagen has applications in bone tissue engineering. Collagen is used in several forms, including gels, powders and sponges. Of these three examples, sponges are the most common type of collagen scaffold and the most studied, with recent advances in improving mechanical strength via infusion with synthetic polymers [25]. Durham et al. recently developed a novel poly-n-acetylglucosamine (pGlcNAc, "Talymed") scaffold and compared its ability to reduce negative side effects from treatment with bone morphogenetic protein 2 (BMP2) with an absorbable collagen sponge (ACS). In their results, Durham et. al. found that excessive BMP2 dosing during bone regrowth treatment may promote negative side effects, rather than the treatment itself. Whereas the Talymed scaffold exhibited healing benefits and retained BMP2 better than did the traditional ACS, slower BMP2 dosing is crucial to the healing process [26]. Indeed, collagen sponges still have great benefits within medical applications.

Lastly, glycosaminoglycans (GAGs) are the final class of natural biomaterials that will be described here. GAGs are acetylated and sulfonated sugar polysaccharides used in cell signaling pathways, including cell proliferation and wound repair. The family of GAGs comprises four categories: hyaluronic acid (HA), heparin, chondroitin and dermatan sulfate, and keratan sulfate [27]. One recent area of advancement involves the GAG profile within the human trabecular meshwork (hTM)- a region of spongy tissue surrounding the cornea used for aqueous humor outflow. In a related study, Adhikari et al. reported the role of exogenous GAGs *in vitro* on extracellular matrix gene and protein expression as they relate to glaucoma treatment. Results indicated that biomaterial scaffolds that incorporate modified GAGs can play a significant role in gene and protein regulation. For example, HA and chondroitin sulfate increased the amount of elastin and laminin produced within cell culture [28]; elastin impacts the elasticity of tissue, and laminin functions as cell receptor interactors. These results could be applied to future therapeutic treatments for glaucoma, due to increased knowledge on GAGs and their effects on the hTM.

V. Market

The market for biomaterials has increased greatly due to advances in biomaterial research. As of 2022, the global biomaterial market is valued at $155.05 billion. Economists predict a compound annual growth rate of at least 15 percent through 2023 [29]. This jump is primarily attributed to the growing demand for biomaterials, as an increasing geriatric population requires more solutions to medical problems like cardiac stents and joint replacements. The largest market for biomaterials is in North America, where the leading cause of death is cardiac disease. As a result, cardiovascular biomaterials account for a fifth of the market share for applications globally [29]. Some market analysts indicate that the next ten to twenty years will see the biomaterials market increase in value by almost $300 billion [30]. With rapid advances in biology, genetics and engineering, the demand for sustainable medical applications through biomaterials will be met by this technological boom.

VI. Conclusion

Recent advances in biomaterials, both naturally-based and synthetically-derived, have seen exciting progress in many applications. Applications range from coronary artery stents and orthopedic implants to dental implants and bone tissue engineering. In addressing mechanical weaknesses and material cost, research within the past few years has shown promising results when existing biomaterials are combined with new ones, such as the "toughening" of materials with polymers. As such, new combinations of materials are being forged to satisfy the demands of growing customers. With biomaterials having treatment applications for stents, orthopedics, and even degenerative eye diseases, the importance of continued research cannot be overstated. Due to a growing elderly population, the demand for biomaterials has skyrocketed, and market projections have predicted a growth rate of approximately 15% per year through 2030. Indeed, the future is bright for biomaterials, and with continued research and development, the field of medicine will be changed for the better.

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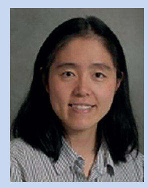

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