1.3.1 The Materials Side of the Biomaterials Relationship

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When seeking to cover the "Classes of Materials Used in Medicine," as this section of the book states, a quick overview of the landscape, together with some caveats and definitions, is in order. What are these materials that will be brought to bear as biomaterials in devices? Materials employed as biomaterials will need to serve many needs: replacement of physiologic functions lost to trauma, disease, or congenital conditions (e.g., cardiac valves); sensing (e.g., ultrasound contrast agents); delivery of materials within the body (e.g., stent-delivery catheters); temporary mechanical support (e.g., sutures); or extracorporeal processes (e.g., dialyzers). It is not surprising that the array of applied biomaterials is very broad and growing.

However, this chapter will not consider specific classes of materials that are used daily in the clinic to meet some of the needs just outlined. Specifically, consider biomedical devices that seek to replace a given physiologic function and the analogous situation with an automobile. For an automobile, tires that no longer grip on wet roads or a battery that cannot start the vehicle elicit a trip to the mechanic's shop and replacement of these parts with "devices" that are fully capable of restoring those functions, or perhaps even exceeding the capabilities and duration of the original equipment manufacturer. The parts are designed to be fully compatible and are readily available for a quick and unambiguous replacement procedure. The situation in the clinic from a needs perspective is similar, but unfortunately society has not advanced to the state where off-the-shelf replacement parts of compositional and functional equivalence are available. Arguably, the best source for such materials in many cases is from the patient: autograft materials. Muscle flaps moved by plastic surgeons for reconstructive procedures, saphenous veins and arteries used for arterial bypass, and skin harvested and mechanically processed to increase its coverage area for burn treatment all represent current gold-standard materials used to meet clinical needs for replacement tissues. Which of these autograft materials are best selected for specific conditions and how they are isolated and processed is the focus of surgical textbooks, but may only be peripherally mentioned here. Yet the reader should be aware that biomaterials and medical device technology falls usually well short of addressing clinical needs as effectively as autografts may. This is true despite the downsides associated with autografting, such as donor site morbidity.

Similar to autografts, allografts (from organ and tissue donation) fill critical needs for tissue replacement where autografts and other material-based approaches are not possible or fall short. For instance, the best option for patients in end-stage cardiac, kidney, liver, and pulmonary failure is currently to receive an allograft. Despite the morbidity associated with immunosuppressant therapy, and issues associated with a limited supply, the quality of life and survival for allograft recipients exceeds similar populations that would be supported by the best current medical support devices for heart, lung, or kidney. The considerations, particularly immunology, surrounding allograft materials are beyond the scope of this text, but the target populations for important classes of medical devices are similar. For both auto- and allografts used in the manner already described, these materials are utilized in a minimally processed state. Particularly for allografts and certainly for xenograft materials, the application of processing methods, from decellularization to cryopreservation and cross-linking, bring these materials into the realm of biomaterials that are considered in this text.

With the preceding discussion the need for extensive consideration of surgical principles as well as broad coverage of allografting, immunology, and immunosuppressive therapy has been taken off the table. At the same time, two critically

important classes of materials used in medicine have been noted, but largely dismissed. Having recognized this, the focus for Section 1.3 is to cover the remaining major classes of materials used in medicine. Studying biomaterials requires the study of the interface between the material and the biological, and in this section the material side of this relationship is covered. To fulfill the design requirements of diverse medical devices, diverse materials are needed that can meet mechanical, chemical, and biological requirements. For some applications it may be that very different material types are being considered due to different design considerations. For instance, in articulating joint replacement devices, some parts have been made from polymer, metal, or ceramic in different designs. In vascular stents a variety of metals have been used, but with recent consideration of degradable stents, both degradable polymeric stents from poly(lactide) and degradable metallic stents made of a magnesium alloy have been tested clinically. Understanding what different material classes and subclasses offer in terms of properties and how structure relates to function is essential knowledge for the biomaterials expert. The chapters here are generally grouped into categories of polymers, metals, ceramics, natural materials, composites, and particulates with subchapters devoted to particularly important material types.

An major trend in the biomaterials community over the past several decades has been the harnessing of advances in molecular biology to design materials with specific biological functionalities. Some of these advances will be covered in this section (Chapter 1.3.2G) and also in select chapters later in the book. More recently there has been a dramatic increase in research focused on particulate biomaterials, where biological knowledge is critically leveraged to impart targeting potential, responsiveness to conditions at a targeted site (e.g., pH), and to orchestrate specific interactions at a cellular level upon arrival. Traditional bulk materials such as polymers, ceramics, and metals may be used as part of these designs, but self-assembly of macromolecules is also often a feature. Chapters 1.3.8A and 1.3.8B seek to summarize this rapidly advancing area in the biomaterials community. Finally, the use of biologically derived materials has been of growing interest and clinical impact. These materials range from highly purified single components that may be from plant or animal sources, to engineered natural materials where functionality such as photocross-linking activity may be added, to materials derived from the extracellular matrix or tissues with processing for degradation resistance (fixation) or intended remodeling (decellularized tissues). The subsections of Chapter 1.3.6 seek to cover this space.

While the theme for this section is firmly on the materials side of the biomaterials relationship, as the field progresses the knowledge bases that inform either side of the material and biological interface are merging, and with some materials the design and control of the biological response has become the critical issue in engineering the intended effect. At the same time, the reality in today's clinics and hospitals is that when autografts and allografts are not available or when devices are needed for other purposes beyond tissue replacement, the vast majority of medical devices remain comprised of materials adopted from the broader materials community to meet the principal design objectives. There remains the need for understanding and working with the fundamentals of materials science.