

The Material of Choice for Medical Device Manufacturing

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Commentary

The medtech sales have been improved since 2015, with around 5% annual increase in the medical devices and technology globally. There are expectations for such growth, which was \$370 billion in 2015 to reach \$530 billion in 2022 [1]. Different medical devices are designed for the treatment of different organs (e.g., lung, neurons, skin, heart and bones), drug delivery, diagnostics and in the designing of surgical devices. However, there is still a long journey for creating the materials which can achieve the optimal properties for [1] the repairing of each organ, [2] providing the optimum condition for the delivery of different therapeutic molecules, whether this is locally or systemically, [3] giving the most accurate results for diagnosis as well as [4] providing the ideal properties for using in minimally invasive surgeries.

There are different classifications of the bioactive materials: organic and inorganic, amorphous and crystalline, macromolecules and materials with simple structures, and natural and synthetic materials. These include polymers, plastics materials, metals, ceramics and glasses. Taking the latter two classes as examples; although they have proven efficiency for using as bone implants, coatings, fillers and in dentistry [2-4], their usage in soft tissue repair has started as well, but still in the primary stages of development [5,6].

Choosing the Right Material for Medical Device Designing

For the designing of a medical device, each composing material should have certain characteristics, which should be in a harmony with the final properties of the medical device as well the target application. The manufacturing companies take into consideration the following criteria as bases for choosing each material towards their targeted applications [7]:

- The first criterion is the availability of the material in sufficient quantities for the mass production of the device to meet the market needs.
- The second one is the flexibility of the material towards a targeted design, where the material can be needed in different forms (e.g., filaments, fibers, nanoparticles, etc.). For instance, the flexibility can be achieved using certain types of polymers, which can be processed as fibers, nano fibers, hydrogels, etc. towards certain application [8,9]. The usage of bioactive ceramics or glasses can be the best choice for others, especially in bone applications, which require implantation of rigid structures [10-12]. Moreover, bioactive glass-based fibers can be also designed for bone grafting [13,14], and drug delivery [15].
- The third criterion is the material cost. This includes the costs of production, transportation, and amounts required for each device. However, on deciding the best material from this point of view, a

general look at the true lifecycle costs is essential. For instance, the melting-quenching technique for bioactive glass synthesis requires higher temperatures and energy than the sol-gel method; however, the costs of chemicals used in the latter method are to somewhat higher [16].

- The fourth criterion depends on the matching between the material properties and the required specifications of the designed device. For instance, certain polymers with certain properties are suitable for wound healing applications, and soft tissue repair; while the usage of metals is efficient for bone healing. However, through the recent improvements in the bio ceramics/glasses design and modification, they have found different applications. In fact, this is the most important factor which the biomaterials researchers concentrate on. However, the other criteria should be taken into account as well, especially for the further shifting to the industrial production stage to guarantee the productivity of the final medical devices.
- The fifth criterion is the choosing of the trusted/certified materials for the medical applications. Although the stage of research for finding and optimizing the properties of the material is essential for the development of medical devices industry, this criterion may be of importance for shortening the period required for the device approval.
- The sixth criterion is the biocompatibility of the finally designed device, as well as its components. It can be considered one of the most important factors for selecting the material, where the formation of any harmful products following the usage of the device will lead to its failure [17]. Moreover, according to the type of the device and its application, the sterilization method, as well as the storage conditions, which can guarantee its optimum biocompatibility, can be decided [18,19]. The biocompatibilities of the different composing materials before and after processing are assessed under certain protocols. Although the degradation products of some biomaterials (e.g., synthetic polymers and metals) in the body may induce some immune reactions and device rejection may happen in severe cases, four main options can solve these problems. The first one is the combination of the polymer with a compatible material, so the severity of such reactions can be reduced, especially if the outcome using this polymer is desirable [20,21]. The second option involves the further purification of the polymer before using in the device manufacturing [22,23]. The third option is to replace it by another compatible polymer, or other inorganic material which can provide similar mechanical properties and outcomes. The last option is the coating of the material (e.g., metal) with a biocompatible material (e.g., bioactive ceramic/glass), so the compatibility can be improved [24,25]. Moreover, the compatibility of the device is tested, but this stage may take a long time for validation of the sterilization efficacy and confirmation of compatibility.

- The seventh criterion is accordingly the used sterilization technique, where every type of medical devices requires a certain effective sterilization method, which can preserve the structure and properties of the constituting materials as well. For instance, the plastic medical devices may crack and loss their properties following continuous autoclaving; while the metal devices don't. However, the weight of the latter devices may increase and their shapes may change.
- The eighth criterion is the usability of the device. However, this is only applied to the devices which are used without direct clinical supervision.
- The ninth criterion is the choosing of the material which can guarantee efficient manufacturing.
- The last criterion is the sustainability of the medical device, which starts from the designing stage, choosing of the material, the manufacturing method and its related economic issues, and finally the disposal of the device.

Conclusion

It's hard to find a material which can fulfill all the previously mentioned criteria, but the producing company has to evaluate and compare between the different materials and their properties, and choose the most efficient types. Moreover, the modification of some materials can give them new enhanced properties with overcoming some of their native problems. That's why we can't judge that a certain material is the best just from its properties, ease of manufacturing, cost, etc., but there should be an overall investigation taking all these criteria into consideration. However, in the future through the continuous research, we may reach the biomaterial which can fulfill most of these criteria.

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