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An Overview of the Plastic Material Selection Process for Medical Devices

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Abstract

The current market trend toward increased safety and quality at a reasonable cost has urged the medical industry to select bio-compatible, clean, and environmentally-friendly materials to meet safety, manufacturability, and functionality requirements for medical products. At the same time, these requirements pose constraints and challenges on the materials selected during product development for medical devices and instruments.

Applications in the healthcare industry and medical devices in particular, have some demanding requirements for thermoplastic materials that are unique to this arena. While polymers have been used in the healthcare industry for decades, it has only been in the recent past the designers have started to explore the benefits of using special compounds in medical applications.

Metal has been the traditional material of choice for orthopedic or any surgical instrumentation, but new plastic resins, combined with scientific process development and validation, are now making inroads into those markets.

Unique technologies related to anti-static, raidopacic, wear-resistant and elastomeric compounds that have made an impact in other industries are just now finding their way into medical devices.

This paper presents an overview of the plastic material selection process, with specific emphasis on the unique requirements of medical applications.

Abbreviations

Sl. No.	Acronyms (Polymers)	Full Form
1	ABS	Acrylobutadiene styrene
2	PP	Polypropylene
3	PS	Polystyrene
4	PC	Polycarbon
5	PSU	Polysulfone
6	PPSU	Polyphenyl sulfone
7	PMMA	Polymethyl methacrylate (Acrylic)
8	PE	Polyethylene
9	UHMWPE	Ultra high molecular weight polyethylene
10	LDPE	Lower density polyethylene
11	PA	Polyamide (Nylon)
12	LCP	Liquid cystaline polymer
13	PARA	Polyaryl amide
14	PPS	Polyphenyl sufide
11	PEEK	Polyether etherketone
12	PVC	Polyvinyl chloride
13	PET	Polyethylene terephthalate
14	PTFE	Polytetra flouroethylene (Teflon)

Market Trends/Challenges

Materials, whether metal or plastic, have always limited design since man first built shelters, made clothes and undertook human conflict. But right now, materials and the processes to shape them are developing faster than at any time in history; the challenges and opportunities are therefore greater than ever before. This paper is about strategies/guidelines for exploiting plastic materials for orthopedic instruments and medical devices design.

Medical devices and instruments are in a constant state of evolution, responding to trends within and outside the hospital environment to achieve better care at lower system costs. In today's world, as far as medical device design is concerned, safety of human life is the prime objective.

The trends toward miniaturization and portability are driving new requirements for housings and drug-coated implants. Cleanliness and sanitation continue to receive strong attention globally, requiring devices to withstand a range of chemicals and sterilization techniques. Reusability of a product was considered as a leap-ahead advantage once, but not any more in the medical industry, especially in orthopedics.

The use of single-use instrument is a solution and is the latest trend in orthopedics. This may force the industry to go for plastic materials by which the cost can be reduced to an extent.

But there are still concerns over the desired mechanical properties, biodegradability, sterilizability and radiopacity of the materials used that need to be looked at in detail.

General Guidelines for Material Selection

Material selection is often one of the most intimidating and confusing hurdles encountered by medical device designers. There seem to be hundreds of polymers to choose from, but where do we start?

The material selection process requires a preliminary understanding of polymers, additives and their properties. Of primary importance is a basic understanding of polymer morphology and the properties different morphologies bring to the picture. Thoroughly defined application requirements are needed to select appropriate candidate materials. After careful consideration, the possibilities can be narrowed down to two or three candidates, and the final selection should be determined by testing. It follows the steps below:

1) **Translation:** Express design requirements as constraints and objectives

The following list of queries or considerations should be used to define the application or requirements as much as possible. In many cases the answers to these criteria will be helpful to eliminate a particular plastic or an entire family of plastics. The more completely the application of medical device/instrument is defined, the better the chance of selecting the best materials for the application.

Environmental exposure considerations:

- Should the material be biocompatible?
- Will the component be in contact with body tissues or drugs? If so, for how long?
- Is the product a single use instrument/device?
- Will the component undergo sterilization? If so, which method of sterilization will be used? How frequently will it be sterilized?
- Will any other chemicals/solvent vapours be in contact with the product (wiped/submerged) as part of hospital cleaning?
- Will the device be painted/electroplated /glued?
- To what humidity and temperature (maximum and minimum) will the product be exposed? How long will it be exposed?
- Is dimensional stability in a wet or humid environment critical? What tolerances must be met?
- Is UV resistance needed?
- Does the device need to be visible under a fluoroscope or X-ray?
- Is flame retardability a requirement?
- Is the colour of the material is an important factor?
- Will the part be used outdoors?

Functional and Mechanical Considerations:

- What are the overall parts dimensions (diameter, length, width, thickness)? Is dimensional stability a factor to be considered?
- What load will the part have to carry? How long will the load to be applied? Will the load be continuous or intermittent?
- What is the maximum stress on the part? What kind of stress is it (tensile, flexural, etc.)?
- Is toughness or impact resistance critical during use?
- Will the material be used as a bearing? Will it need to resist wear? What wear or abrasion conditions will the material see?
- Is the product going to be used as an electrical insulator?
- What are the manufacturing processes/options available?
- If it is a molded component, does it make use of any of these techniques: micro molding, over moulding, insert molding, gas assisted molding or in-mold decoration?
- What is the target cost of the component?
- What is the projected life of the part or design?
- What other mechanical properties are required?
- Are static dissipation/conductivity/dielectric properties required?
- Which manufacturing technique is going to be used for producing the final component?

2) Screening: Analyze and follow the guidelines to shorten the selection process. The selection should be based on polymers meeting both the environmental and mechanical/physical requirements.

a) One of the first requirements to be considered for medical device polymer selection is **biocompatibility** of the polymer material which comes under environmental exposure consideration.

When components are subjected to contact with body tissue/fluids, the components must be biocompatible. Two common biocompatibility test standards are USP class VI and ISO 10993, the latter being more stringent and suited for medical devices.

ISO 10993-1 specifies that process contaminants, residues, and degradation of products should be taken in to account while doing biocompatibility tests.

The table below shows biocompatibility test requirements per ISO 10993-1 for different medical products, based on their application.

Selection of the tests per ISO 10993-1 *														
Nature of the physical contact		Duration of contact	Biological Risks											
			Cytotoxicity	Sensitization	Irritation	Acute toxicity	Sub chronic toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronical toxicity	Canceroginity	Reproduction toxicity	Biodegradation
Medical products with contact to body surfaces	Skin	A	X	X	X									
		B	X	X	X									
	Mucous membrane	C	X	X	X									
		A	X	X	X									
	Injured surface	B	X	X	X	●	●	●	●					
		C	X	X	X	●	X	X	●		●			
Medical products coming into contact with the interior of the body from outside	Blood system Directly	A	X	X	X	●								
		B	X	X	X	●	●		●					
	Tissue/Bone /Dentin	C	X	X	X	●	X	X	●		●			
		A	X	X	X	X				X				
	Circulating Blood	B	X	X	X	X	●			X				
		C	X	X	●	X	X	X	●	X	X	X		
Implantable medical products	Tissue/Bone	A	X	X	X	●								
		B	X	X	X	●	●	X	X					
	Blood	C	X	X	X	●	●	X	X		●	X		
		A	X	X	X	X		●		X				

X - Test to be included to ISO 10993-1 ● additional tests may be applicable

A=short term (=24h) B=protracted (>24h to 30d) C=continuous (>30d)

* The data shown in the table is taken from www.roechling-plastics.us

In this case, however, the major concern is how the compound affects its environment, namely internal body tissues and fluids. Recently, polymers have been introduced for hip socket replacement in orthopedic applications due to their close resemblance to the natural polymeric tissue components. However, polymers undergo degradation in the body environment due to biochemical and mechanical factors. This results in ionic attack and formation of hydroxyl ions and dissolved oxygen leading to tissue irritation, inflammation and other reactions with bodylike corrosion and wear.

There are steps to be taken at the beginning of development to identify potential raw material candidates that have a high likelihood of passing biocompatibility testing.

Only a small number of polymers are available as medical grade for medical application, and an even smaller number is used for implants. The choice of polymer depends on the extent of contact with body fluids, internal and external tissue as prescribed by the regulatory framework.

The table below shows the polymers that can select based on the application

Sl.No	Application of medical devices	Polymer selection
1	**Non-contact with human body,** e.g. syringes, blood storage bags, glucose drip bags	PVC,PA,PE,PS, Epoxy resins
2	**Short-term contact with human body, e.g.** catheters, feeding tubes, drainage tubes, surgical instruments	Silicone rubber, Natural rubber, PVC, Polyurethane, PE, PP, Polyester, PEEK, Polyphenylsulfone, Nylon, Teflon, PeBax
3	**Medium term contact with human body, e.g. c**ultures, ligatures	Nylon, PP, Polyester
4	**Long term contact with human body, e.g.** implants, drug delivery devices	PE, UHMWPE, PET, Silicone rubber, Polyurethane, PMMA, Polysulphones, Hydrogels Polyphosphazenes, Thermoplastic elastomers, Polydimethylsiloxane

If a component is subjected to body tissue or fluid contact, the next question is how long it is in contact. This can be divided into three types. If it is <1 day, it is termed as short-term or limited. If the contact is between 1 and 30 days, it is termed as medium-term or prolonged. If it is >30 days, it is termed as long-term or permanent. Plastics subjected to fluid contact for longer periods need to have low permeability, as many MIS devices have electronic circuitry enclosed.

b) Another consideration when selecting a polymer in line with the above mentioned is related to the **drug flow path,** i.e. when the material is in direct contact with the flow of drugs through a device. The concerns for this situation are similar to the tissue/fluid contact concerns mentioned earlier, except we now need to look at the effect the material has on drugs as opposed to the body.

   Again, chemical resistance is important, as the drugs should not promote the material's degradation. It is also undesirable to have the potency of the drug affected by the thermoplastic compound it is in contact with, either via extraction of additives and monomers or via the chemical reactivity between the drug and the polymer. Extraction and biocompatibility data are often reviewed in such a case, and a drug master file may be utilized to convey the confidential information to the FDA on the materials for the application.

c) Another important requirement that most medical devices should be compatible with is **sterilization compatibility**. Plastic devices that require body tissue/fluid contact must undergo sterilization. Plastics react differently to various sterilization methods. The most common sterilization methods are radiation (gamma/e-beam), chemical (ETO) and autoclave (steam).

   The majority of thermoplastic polymers can withstand exposure to toxic Ethylene oxide (ETO) without significant changes to their properties or colour during sterilization.

   However, plastics subjected to radiation sterilization will be affected, and it may change the mechanical properties of the material such as tensile strength, impact strength and elongation by chain scission or cross-linking. It is also important to note that multiple exposures to radiation are cumulative. Radiation resistant thermoplastics include styrenic thermoplastics such as ABS, PARA, PEEK, PEI, PES, PSU, PPSU and TPU. In terms of mechanical performance, PC is generally resistant to radiation, but it will discolour with radiation exposure. There are some antioxidant packages that can be used to improve the radiation stability of certain polymers, but the best course of action is to select polymers that are known to perform well.

   Autoclaving, or steam sterilization, uses a combination of heat and moisture for repeated cycles of 3-15 minutes to kill germs. Parts that are molded with high residual stress levels may begin to see some stress relaxation (annealing), and therefore can have dimensional instability or can warp when exposed to high temperatures of 121ºC to 140ºC. The amorphous grade materials are more suitable due to their tendency to warp less. Materials like PP, PA, PC and PSU can be used, but care must be taken as to how many cycles they will be exposed to. The best polymers

for resistance to autoclaving are PPSU and PEEK, with both polymers able to handle exposure to thousands of cycles. Some polyethylenes can be autoclaved, but only at lower temperatures and for limited lengths of time due to their low resistance to temperature. Families of polymers like styrenes (ABS, PS) and polyesters (PBT or PET) are poor candidates for autoclaving due to poor resistance to the heat/moisture environment.

If the product is not a single-use device, its components will be subjected to multiple sterilizations before being discarded, so plastics which possess superior toughness with a lesser tendency to discolor (PEEK, PEI, PSU, PPSU and PC) are better choices.

The table below gives an idea about sterilizable polymers with respect to the method of sterilization

Sterilization resistance		Sterilization procedure *					
Material	Polymer	Hot steam		Hot air	Ethylene oxide	Plasma	Gamma rays
		250°F	273°F	356°F	140°F	113°F	RT
Polystone P MG	PP- H	⇈	⇈	↓	⇔	↑	⇔
SUSTARIN C MG	POM-C	↑	⇔	↓	↑	↑	↓
SUSTAPEEK MG	PEEK	⇈	⇈	⇈	⇈	⇈	⇈
SUSTASON PSU MG	PSU	⇈	↑	↓	↑	↑	↑
SUSTASON PPSU MG	PPSU	⇈	⇈	⇔	⇈	⇈	⇈
SUSTAPEI MG	PEI	⇈	⇈	⇔	⇈	⇈	⇈
SUSTANAT PC MG	PC	⇔	↓	↓	↑	↑	⇔

⇈ Very good resistance ↑ Good resistance
⇔ Conditional resistance ↓ No resistance

* **The** data shown in the table above is taken from www.roechling-plastics.us

d) **Resistance to hospital cleaners (chemicals):** Routine cleaning brings many devices into repeated contact with a wide variety of disinfection chemicals. Each exposure may contribute to deterioration of the plastics, and can have detrimental effects on part performance. Cleaners such as isopropyl alcohol, bleaches and peroxides may attach to the polymer chains of some thermoplastic resins and cause crazing, stress cracking or even breakage.

Chemical resistance is a polymer property, and no additives or reinforcements will significantly change the resistance of a polymer to a given chemical. Generally, semi-crystalline polymers like PP, PE and polyamides will have better chemical resistance than amorphous polymers like ABS and PC. But there can be exceptions: exposure of polycarbonate to hydrogen peroxide yields a fairly stable result while similar Nylon 6 exposure results

in swelling and a loss of mechanical properties. So, it is always important to verify the performance with the data sheet rather than going behind general facts.

RESISTANCE TO HOSPITAL CLEANERS (CHEMICAL)	
IMIDIZED MATERIALS	**SEMICRYSTALLINE THERMOPLASTICS**
• PAI (Polyamide -imide) • Vespel Polymide shapes	• Acetal • HDPE • LDPE • Nylon • PBT • PEEK • PET • Polypropylene • PPS • PTFE • PVDF • UHMW-PE

e) **Mechanical properties (tensile and compressive strength, bending stiffness, impact strength, wear resistance, etc.):** Selecting a plastic material is based on a number of traditional material requirements such as strength, stiffness or impact resistance. Engineered thermoplastics like PC, PEEK, PPSU, POM, nylon, poly acetal, etc., show excellent mechanical properties at low and high temperatures. These properties are required for a variety of climate conditions, including during transportation, where the influence of temperature on drop impact may result in different outcomes for device integrity.

The concept of miniaturization is another factor which helps decide plastic material selection. To reduce patient trauma and improve the safety and effectiveness of surgical procedures, some surgical instruments have been significantly redesigned for use in minimally invasive surgery. Materials such as polyether amide (PEI) resins are designed to provide high strength and stiffness for the management of higher loads on components such as gears.

Material selection is also influenced by other factors like wear pairs (a combination of materials in contact with each other), wear conditions/medium (ex: wet or dry) and wear configurations (ex: rotary, sliding, oscillatory, etc). Lubricity improves wear resistance.

The tables below show the details of tensile strength, bending stiffness and toughness for different plastic materials.

* Mechanical, electrical and thermal data shown in the tables below are taken from www.curbellplastics.com

MECHANICAL PROPERTIES – TENSILE STRENGTH *	
AMORPHOUS THERMOPLASTICS	**SEMICRYSTALLINE THERMOPLASTICS**
Tensile Strength (psi)	**Tensile Strength (psi)**
• Ultem 15,200 • Polysulfone 10,200 • Radel R 10,100 • Acrylic 10,000 • Noryl 9,600 • Polycarbonate 9,500 • PETG 7,700 • PVC 7,500 • R Kydex 6,100 • ABS 4,100 • Polystyrene (HIPS) 3,500	• PEEK 14,000 • Nylon (6cast) 10,000-13,500 • PPS 12,500 • Nylon (6/6 extruded) 12,400 • PET 11,500 • Acetal(Homopolymer) 10,000 • Acetal(Copolymer) 9,800 • PBT 8,690 • PVDF 7,800 • Polypropylene (Homopolymer) 5,400 • HDPE 4,000 • Polypropylene (copolymer) 3,800 • UHMW-PE 3,100 • PTFE 1,500-3,000 • LDPE 1,400

MECHANICAL PROPERTIES – FLEXURAL MODULUS*	
AMORPHOUS THERMOPLASTICS	**SEMICRYSTALLINE THERMOPLASTICS**
Flexural Modulus - Stiffness (psi)	**Flexural Modulus - Stiffness (psi)**
• Ultem (30%glassfilled) 1,300,000 • Polycarbonate (20%glassfilled) 800,000 • PVC 481,000 • Ultem 480,000 • Acrylic 480,000 • Polysulfone 390,000 • Noryl 370,000 • Radel R 350,000 • Polycarbonate 345,000 • Kydex 335,000 • Polystyrene (HIPS) 310,000 • PETG 310,000 • ABS 304,000	• PPS 600,000 • PEEK 590,000 • Nylon (6cast) 420,000-500,000 • Acetal(Homopolymer) 420,000 • Nylon (6/6 extruded) 410,000 • PET 400,000 • Acetal(Copolymer) 370,000 • PBT 330,000 • PVDF(Kynar) 310,000 • Polypropylene (Homopolymer) 225,000 • Polypropylene (copolymer) 215,000 • HDPE 200,000 • UHMW-PE 110,000 • PTFE 72,000 • LDPE 30,000

MECHANICAL PROPERTIES – TOUGHNESS*	
AMORPHOUS THERMOPLASTICS	**SEMICRYSTALLINE THERMOPLASTICS**
Izod Impact (notched) toughness (ft-lbs/in)	**Izod Impact (notched) toughness (ft-lbs/in)**
• Kydex 18.0 • Polycarbonate 12.0-16.0 • Radel R 13.0 • ABS 7.7 • Noryl 3.5 • Polystyrene (HIPS) 2.0 • PETG 1.7 • Polysulfone 1.3 • Ultem 1.0 • PVC 1.0 • Acrylic 0.4	• LDPE no break • UHMW-PE 18.0 • Polypropylene (copolymer) 12.5 • PTFE 3.5 • PVDF (Kynar) 3.0 • PEEK 1.6 • PBT 1.5 • Acetal(Homopolymer) 1.5 • Polypropylene (Homopolymer) 1.2 • Nylon (6/6 extruded) 1.2 • Acetal(Copolymer) 1.0 • Nylon (6cast) 0.7-.9 • PET 0.7 • PPS 0.5

Electrical and Thermal Properties (dielectric strength and thermal resistance): Enclosures for medical devices may require high heat resistance, electrical properties such as dielectric strength, etc. Engineered thermoplastics like PC, PC blends, polyphenylene, polystyrene blends, etc., show excellent electrical properties at all temperatures. The tables below show the details of dielectric strength, heat resistance and its relation to costs.

ELECTRICAL PROPERTIES *			
AMORPHOUS THERMOPLASTICS		**SEMICRYSTALLINE THERMOPLASTICS**	
Dielectric Strength – Insulation (v/mil)		**Dielectric Strength – Insulation (v/mil)**	
Ultem	830	Nylon (6cast)	500-600
PVC	544	Acetal(Homopolymer)	500
Kydex	514	Acetal(Copolymer)	500
Noryl	500	PTFE	400-500
Acrylic	430	PEEK	480
Polysulfone	425	PPS	450
PETG	410	PET	400
Polycarbonate	380	PBT	400
Radel R	360	Nylon (6/6 extruded)	300-400
		PVDF	280

THERMAL PROPERTIES *			
AMORPHOUS THERMOPLASTICS		SEMICRYSTALLINE THERMOPLASTICS	
COST	TEMPERATURE RESISTANCE	COST	TEMPERATURE RESISTANCE
HIGHEST		HIGHEST	
• Ultem	Radel R	• PPS	PPS
• Radel R	Ultem	• PEEK	Nylon
• Polysulfone	Polysulfone	• PVDF	Acetal
• Noryl	Polycarbonate	• PTFE	PBT
• Polycarbonate	Noryl	• PET	PVDF
• ABS	Acrylic	• PBT	PTFE
• Polystyrene (HIPS)	Polystyrene (HIPS)	• Nylon	PET
• Kydex	ABS	• Acetal	Polypropylene
• PVC	Kydex	• UHMW-PE	HDPE
• PETG	PVC	• HDPE	LDPE
• Acrylic	PETG	• LDPE	
		• Polypropylene	
LOWEST		LOWEST	

f) **Other factors for material selection:**

Dimensional stability: Tight tolerance is often another key property for miniaturized internal components. The functionality of the device may depend on the precise interaction of its components. The section of materials for dimensional stability can be even more complex, considering the variety of operating environments which may include exposure to chemicals and high temperatures. Amorphous plastics have low, uniform shrinkage that provides good dimensional stability and low warpage to hold tight tolerances in complex components. Dimensionally stable plastics include PC, PEI, PES, PSU and PPSU. Semi-crystalline plastics have higher, less uniform shrinkage but fillers can be used to retard shrinkage. Liquid crystal polymer (LCP) has one of the lowest shrink rates and provides excellent dimensional stability.

Durability and Aesthetic: Devices designed for hospital use are often shared, and may need to be transported from one clinical area to another, so durability of the plastic enclosure is important in the selection of material. ABS, PC and PC-ABS blends are commonly used in housing components. Another important healthcare trend focuses on providing a reassuring and pleasant environment for patients. Molded-in colors and effects are available directly from resin suppliers, and can eliminate the cost

of secondary operations including painting. Color technologies like chroma shift, metallic and even glow-in-the-dark can add a perceived value that is beyond their cost. ABS is used where electroplating is required.

Radiopacity: Certain additives can be used to make a polymer radiopaque, that is, able to be seen by X-ray imaging or fluoroscope. This technique is useful in surgical implants, and catheters that need to be seen during surgery. Barium sulfate is the most common additive used to obtain radiopacity. Tungsten-Bismuth based minerals like bismuth sub-carbonate and bismuth trioxide can also be used, though they are costlier options.

Conductive: In some dry powder and aerosol drug delivery applications, static build-up on the surface of thermoplastic part can attract the drug and cause incorrect dosages. The use of permanently antistatic compounds in these applications reduces or eliminates static build-up and allows accurate dosing. Compounds based on acrylic, polypropelene, clear ABS, ABS+PC blends, etc., are commonly used in these types of devices.

Lubrication: Many devices that have any plastic-on-metal or plastic-on-plastic sliding parts need to have high wear resistance. Gears, implants, and sliding covers are all examples of this. UHMWPE shows high wear resistance, and it can be improved through a process called cross-linking, which creates stronger bonding between the molecular chains that make up the polyethylene. Additives like PTFE and silicone are commonly used to improve lubricity and wear resistance of a plastic material.

Manufacturing feasibility: This is another factor, based on which plastic materials need to be identified for a particular product, the same way thermoplastic and thermosetting plastics are produced using different manufacturing processes.

It is all very well to choose the perfect material, but somehow we have to make something out of it as well! An important part of understanding a product is to consider how it was made. In other words, what manufacturing *processes* were used, and why?

There are two important stages to selecting a suitable process:

- **Technical performance**: Can we make this product with the material, and can we make it well?
- **Economics**: If we can make it, can we make it cheaply enough?

The table below provides a brief introduction to the various manufacturing methods by which a plastic material product can be manufactured.

* Manufacturing data shown in the table below is taken from www.mikrotech.com

MATERIAL	COMPRESSION MOLDING	TRANSFER MOLDING	INJECTION MOLDING	EXTRUSION	ROTATIONAL MOLDING	BLOW MOLDING	THERMOFORMING	REACTION INJECTION MOLDING	CASTING	FORGING	FOAM MOLDING	REINFORCED PLASTIC MOLDING	VACUUM MOLDING	PULTRUSION	CALENDERING
Acetal			•	•	•	•	•				•	•			•
ABS			•	•	•	•	•			•					•
Acrylic	•		•	•		•	•		•						•
Cellulose acetate	•		•	•			•								•
Nylon			•	•	•	•		•	•	•		•			•
Polyimide			•												
Polycarbonate			•	•		•	•								•
Polyethylene			•	•	•	•	•			•	•	•			•
Polypropylene	•		•	•	•	•	•		•	•		•			•
Polystyrene			•	•	•	•	•				•	•			•
Polysulfone			•			•	•					•		•	
Polyurethane			•	•	•						•	•	•		•
PVC	•	•	•	•	•	•	•				•	•	•		•
Polyvinyl acetate	•	•	•	•	•	•	•				•				•
Tetrafluoroethylene	•	•	•	•											•

So, to summarize the table below provides basic information to initiate the selection of plastic materials for medical devices.

* The data in the table below is taken from www.mikrotech.com

Acronym	Common Name	Trade Name	Bonding	Chemical Resistance	Creep Resistance	Dielectric Strength	Dimensional Stability	Heat Resistance	Impact Strength	Implantable	Strength & Stiffness	Surface Finish	Toughness	Wear Resistance	Reinforcement	ISO 10993	USP Class VI	High Flow into Thin Walls	Lase Friendly	Micromachining Friendly	Autoclave	EtO	Radiation
Amorphous Plastics																							
PC	Polycarbonate	Lexan®	+		+		+	+	+				+		+	+	+		+	+		+	+
PC	Polycarbonate	CALIBRE™	+		+		+	+	+				+		+	+	+		+	+		+	+
PEI	Polyetherimide	Ultem®	+	+	+	+	+	+			+	+	+				+				+	+	+
PES	Polythersulfone	Radel®A			+	+	+						+							+		+	+
PPSU	Polyphenylsulfone	Radel®R		+	+	+	+	+	+				+			+	+			+	+	+	+
PPSU	Polyphenylsulfone	Veriva®		+	+	+	+			+			+			+					+	+	+
PSU	Polysulfone	Udel®	+	+	+	+	+	+			+		+			+				+	+	+	+
PSU	Polysulfone	Eviva®	+	+	+	+	+	+		+	+		+			+				+	+	+	+
SRP	Self-Reinforced Polyphenyler	PrimoSpire®		+	+		+				+	+	+			+		+		+		+	
SRP	Self-Reinforced Polyphenyler	Proniva®		+	+		+			+	+	+	+			+		+		+		+	
TPU	Thermoplastic Urethane	ChronoThane™														+			+			+	+
TPU	Thermoplastic Urethane	Pellethane™																+	+			+	
Semi-Crystalline Plastics																							
LCP	Liquid Crystal Polymer	Vectra®		+	+	+	+	+			+			+	+	+	+	+			+	+	+
PARA	Polyarylamide	Ixef®		+	+		+				+	+		+	+	+		+			+	+	+
PEBA	Polyetherblockamide	Pebax®		+					+			+		+	+		+	+	+		+	+	+
PEEK	Polyetheretherketone	Victrex®PEEK™	+	+				+	+		+		+	+	+				+	+		+	+
PEEK	Polyetheretherketone	Invibio®PEEK-Classix™	+	+				+	+	+	+		+	+	+	+	+		+	+		+	+
PEEK	Polyetheretherketone	Invibio®PEEK-Optima™	+	+				+	+	+	+		+	+	+	+	+		+	+		+	+
PEEK	Polyetheretherketone	KETRON®PEEK	+	+				+	+		+		+	+	+				+	+		+	+
PEEK	Polyetheretherketone	KETRON®PEEK LSG	+	+				+	+	+	+		+	+	+	+	+		+	+		+	+
PEEK	Polyetheretherketone	KETRON®PEEK-Classix™ LSG	+	+				+	+	+	+		+	+	+	+	+		+	+		+	+
PEEK	Polyetheretherketone	KetaSpire®PEEK	+	+				+	+	+	+		+	+	+	+			+	+		+	+
PEEK	Polyetheretherketone	Zeniva®PEEK	+	+				+	+	+	+		+	+	+	+			+	+		+	+
PMP	Polymethylpentene	TPX®		+		+		+				+		+				+				+	
PPS	Polyphenyl Sulfide	Ryton®		+		+		+						+	+	+				+	+	+	+

3) Ranking

(Find the materials that do the job best)

Still, there can be these possibilities:

- What if there are multiple material parameters for evaluation?
- What if multiple materials remain after screening?
- Which one is most suitable?

Now you have to rank on objectives, because objectives define the performance of the product, and then evaluate the remaining materials against each of the objectives, based on the plastic material index. You can plot a Pugh matrix or any other ranking matrix to perform this activity. Choose the best plastic material based on the resulting ranking.

Advanced Ranking

- Procedure :

1) Identify function, constraints, objective and free variables (as before)
2) Define the combination of material properties that maximize performance (the material index)
3) Write down an equation for the objective (the performance equation), and use the above-mentioned material data to determine the ranking.

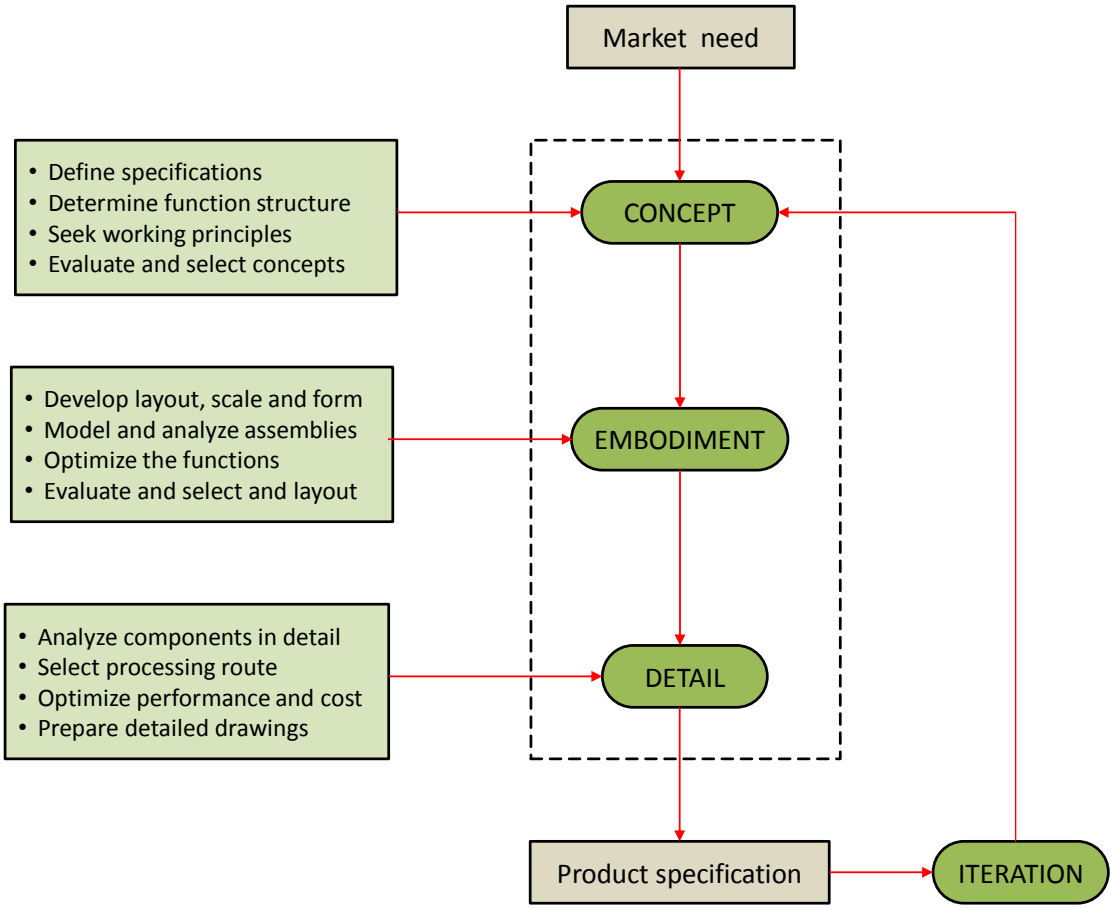
The Performance Equation

$$P = \left[\begin{pmatrix} \text{Functional} \\ \text{requirements, F} \end{pmatrix}, \begin{pmatrix} \text{Geometric} \\ \text{parameters, G} \end{pmatrix} \begin{pmatrix} \text{Material} \\ \text{properties, P} \end{pmatrix} \right]$$

Material Selection Flowchart

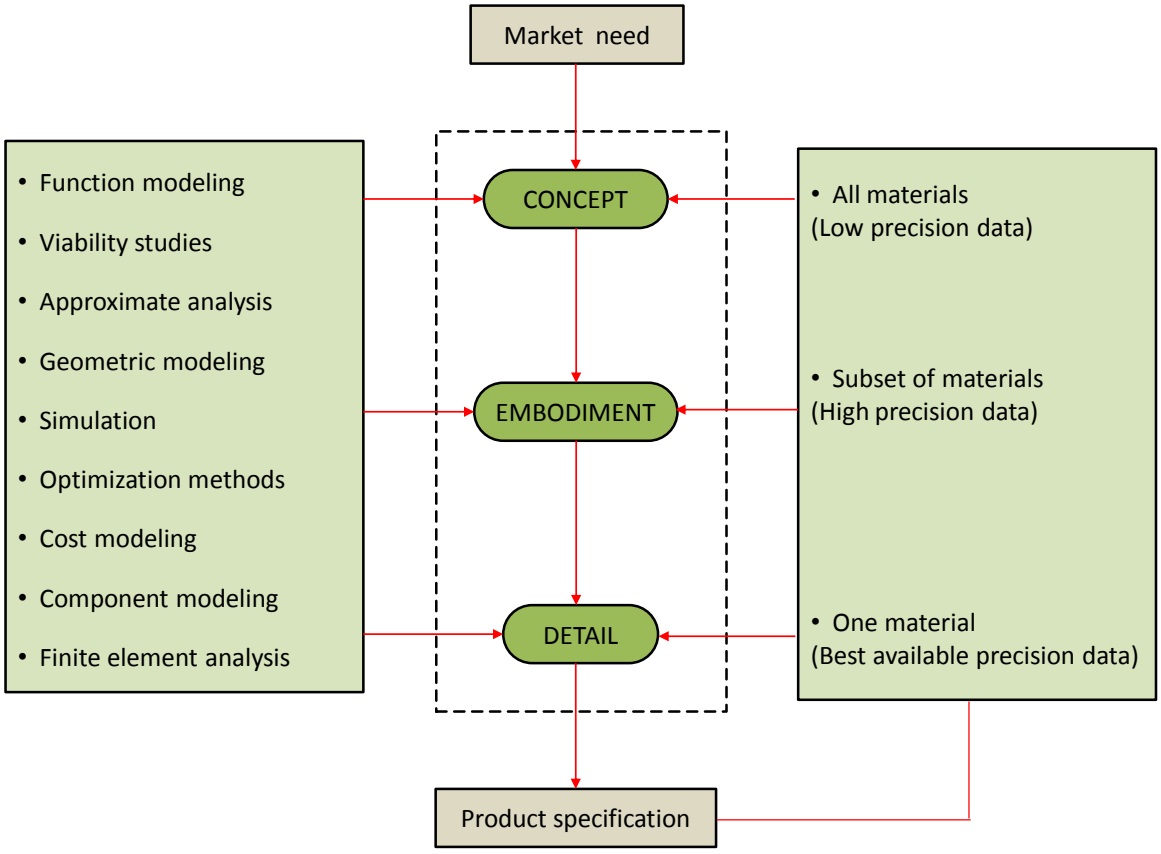
In mechanical design, we are concerned with physical principles and proper functioning and manufacture of the designed object. The following process of industrial design, dealing with pattern, color, texture, and aesthetic then follows.

Design is perhaps best understood through a number of ways. One of the ways for better representation is shown in the following figure.



The process can be thought of as a solution to a market need or a solution to some kind of problem. This process requires an iterative process that is refined in several steps.

At each stage of design, from conceptual to detailed, materials data is needed, but the type of data is different and gets more precise and less broad as the final design is approached, as shown in the next figure. Final design is often done with the manufacturer's specifications, and may require in-house testing of critical properties.



Benefits of Pre-Material Selection

Preselection is a valuable tool for helping product designers find materials that comply with safety standards. It can also greatly reduce the time and cost associated with final end product testing, thereby speeding time to market.

Preselection allows product designers to determine the function of a component in the end product application.

The preselection process involves applying specific small scale material test methods and minimum performance criteria for each critical material characteristic. Because, the process often more comprehensive than end product testing. So pre-selection can result in an increased level of safety.

Preselection can also result in more predictable design and testing costs. There are no additional costs associated with end product testing of assembled plastic parts, no contending with inconsistent test results, and no retooling costs due to unanticipated end product test failures.

Preselection also permits the evaluation and use of alternative materials without end product testing on assembled plastic parts, providing manufacturers the ability to easily substitute alternate materials without incurring additional costs. That is, rather than conducting costly and time consuming end product tests, the properties of the new material can be compared to the properties of the existing material to determine whether the new material's performance is equivalent to or better than the existing material.

Overall preselection helps manufacturers maintain a competitive advantage by reducing development and certification costs and turnaround time.

Preselection also provides several advantages to product designers:

- Reduced design costs
- Availability of material data

With the expertise HCL has in this field, we work closely with OEMs to understand product requirements and thoroughly analyze the suitability of different plastic materials for the required application. In recent years, this proactive and systematic approach to plastic material selection has made our new product design for medical devices much simpler and more cost-effective.

Conclusion

As the trends toward miniaturization, portability, improved aesthetics, and environmental responsibility drive ongoing changes in medical devices, selecting the right materials has become more critical. To achieve optimal product usability, appearance, endurance and performance, designers must carefully consider available materials.

Given the range of influence on device design, designers may opt to involve suppliers early in the design process to identify the appropriate materials that support all of these considerations.

Material selection does not have to be an intimidating process once preselection is done. But ensuring the appropriate plastic material selection always depends on the actual product testing, because as much information as you may have been able to collect, nothing replaces actual product testing.

With the expertise HCL has in this field, we work closely with OEMs to understand product requirements and thoroughly analyze the suitability of different plastic materials for the required application. In recent years, this proactive and systematic approach to plastic material selection has made our new product design for medical devices much simpler and more cost-effective.

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