THERAPEUTHICAL APPLICATIONS OF SEMI-FINISHED ENGINEERING PLASTICS

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Abstract: As the industry of plastics materials has explosively developed there have occurred on the market new, highly performant special materials responding to specific, strictly medicinal requirements such as bio-functionality, bio-compatibility, sterilization possibilities.

Here we are making a short presentation of today world-wide used polymers with medical applicability, especially those used for medical tools, equipments (medical grade) and those for human and veterinarian implants (implant grade).

Key words: medical and implant grade polymers

1. INTRODUCTION

Beside meeting general engineering needs, on the market of technological semi-finished plastics an ever greater role is played by some specific usage forms such as human or animal medicine.

It's understood that the use of polymers for medicinal purposes is not something new because some medicinal tools have been made since decades from plastic and this activity is still evolving today, too. Many quality books and works have been written lately about this subject offering a wide view about the importance of plastics in medicine. First, we are trying modestly to reach the subject of characteristic applications of polymers made by non semi-finished items, than we'll tackle widely the topics of applications based on cutting (dissipation) and stiching/fixing semi-finished technological plastics.

In the end of our work we present some semi-finished items used abroad for helping medicinal companies and producers to choose the proper materials and make production planning.

2. MEDICINAL POLYMERS

When talking about medicinal tools or therapeutic materials made by polymers is important to emphasize not just their mechanical characteristics but also their proper bio-compatibility and bio-functionality. In many cases are equally important their sterilization and disinfection capabilities. Practically, it means that they are required to have an increased resistance to chemicals, heat and radiation, parameters which are not requested in case of a normal, mechanical piece of engineering.

Special requirements are different for the polymers depending on specific area of usage, so we can talk about 4 categories of medicinally used plastics:

- implant materials which are implanted into the human body (implant-grade);
- materials and tools used in general medicine practice (medical-grade);
- highly pure polymers;
- mass production plastics for general use.

Before a polymer can be used for medicinal purposes it is rigorously tested. Depending on the usage area, the plastics are going through many tests.

As we hinted in our introduction, manufacturing medicinal tools and implants require a specific, characteristic technological process. That means that an item or a product can be economically worth to manufacture paying attention not just to the production numbers but also - beside functionality – to some special requirements.

3. PRACTICAL USE OF PLASTICS IN MEDICAL SCIENCE, CLASSIFICATION

Putting together the already existing information in technical literature, items originating in technological semi-refined plastics can be found in the following areas of activities:

1. mass manufactured polymers and general technological plastics as functional engineering parts in certain medical fields where are not even required to meet sterilization requirements such as enclosed engineering elements/parts of medicinal equipments.
2. different types of generally used technological plastics classified according to their usage fields as implant material, medicinal plastic or occasionally as high purity polymers (by ex.: chirurgical tools, parts of chirurgical equipments). This group is characterized by exigent requirements – many times repeted sterilization;
3. high capability/performance plastics used as critical parts of medical aiding tools. It is expected to meet special requirements, repeated sterilization and extreme handling conditions.

Application example: hip articulation (joint) endoprothezis

This endoprothezis is an outstanding example for highly resistant orthopedic prothezises which are characterized by there transmitting resistance of highly static or dynamic loads (tensions). Most of load resistance implants are put under cyclical tensions which counts at their design enginnering and testing. It's paramount to notice that their quality parameters are completely to be found only after investigating the full functional ensemble.

There's a need not only for implants which resist to tearing apart and abrasion but also for those which can keep for long time their bio-functionality.

Many types of hip articulation prothezises are in use today and it's not our goal to tackle all of them but to describe their most important features. Two basic types of implants have emerged:

- cement stiched (fixed);
- stiched (fixed) without cement (mechanical).

The first one works by pooring between the bone and the implant and there is a fast hardening polymetilmetacryl (cement) which keeps together the artificial gorge and the implant's extension fitted into the hip joint. In the second case – procedure used especially at early ages – into the bone gorge is fixed without screws by mechanical stretching-in a metal nest placing in the gorge's prothezis and the same technique – without cement - is used for the prothezis extension.

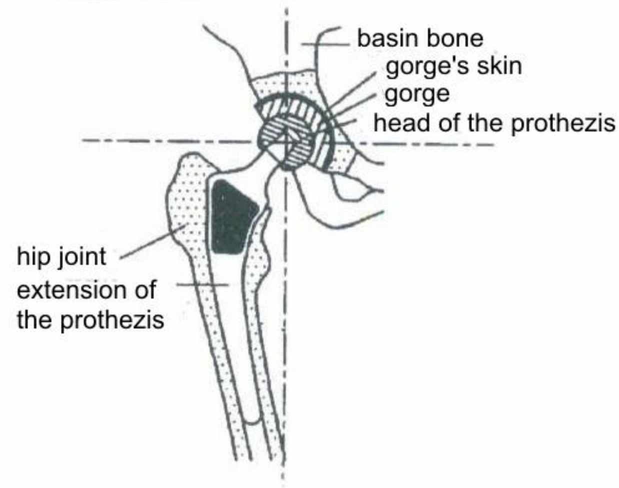

Fig. 1. *Hip joint endo-prothezis*

Initially the head and the extension parts were made of corrosion resistant steel and the gorge of teflon (PTFE). The results were not good although the friction for this pair of material is low but teflon has a great rubbing down constant. That's why they switched from PTFE to polyethylene with ultra-big molecules (UHMWPE). Nowadays developments are fueled by the short life expectancy of the hip joint prothezises: 10-15 years. Also, in 10% of the cases, even below 10 years, they have to be removed due to enlargement (dislocation). Many researchers find the reason for that in the rubbing down of the polymer-component.

Some tests shows for a ten year period a 0,7 mm rubbing down in case of good functioning UHMWPE, meanwhile the ones needing revisions are 2 mm robbed down. The mechanics of abrasion – speaking from a tribologic point of view – can be adhezic, double-body abrasive, three-body abrasive, tireing or bio-corrosive. On the course of so called revision operation the removed UHMWPE gorges' complete medium abrasion value is closed to 600 mm^3 which can mean a 1-2 mm dislocation movement at the spheric head (bull head). Only this amount of abrasion is not enough to faultier the prothezis. The long term failure's motive is the osteolyzis or the so called sterile dislocation of the gorge working paralelly with the abrasion.

4. SEMI-FINISHED TECHNOLOGICAL PLASTIC ITEMS FOR MEDICAL TECHNIQUES

Mass plastics

In the category of mass used plastics are specifically included not the dissipated but the injection moulded or extruded products but – of course – there are some techniques using dissipated elements.

We can positively conclude according to system requirements and the name of this category that these materials are used in easy, undemanding places without any special care speaking from a biological point of view.

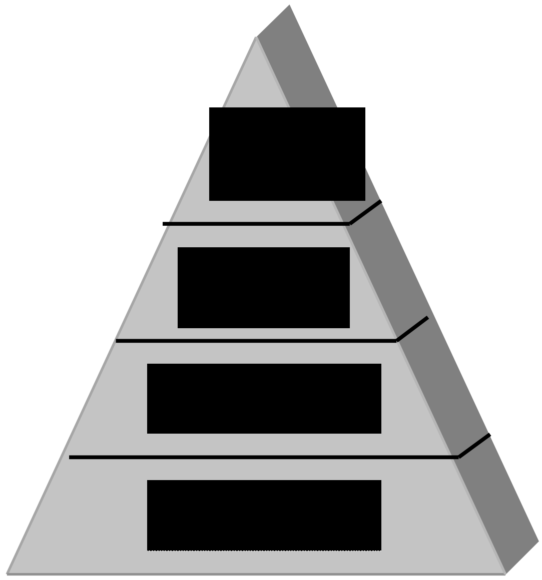

Fig. 2. *Technological level of polymers*

Medicinal plastics and pure polymers

In this category we can found the following plastic types:

DOCAPEEK Med

It's a special, excellent product from the HPM category. Besides it's high heat resistance we have to underline the hydrolytic resistance, and the fact thatt it's autoclaveable, easily dissipateable and has the "medical plastic – medical grade" qualification.

DOCATRON PPS Med

It's a member of the PPS material's family from the high capability (HPM) category. Besides the excellent heat resistance we have to underline its hydrolytic and oxidation resistance. On long term use the factory heat can reach 230 ^{0}C, on short terms 260 ^{0}C.

DOCAPEI Med

It's the medical verson of PEI. It has good heat resistance and can be sterilized it also has noticeable good mechanical and insulation characteristics. The material can be ordered in many colours, too.

DOCASON PPSU Med

It's a special autoclaveable PPSU material with the proper checking for medicinal use. It's characterized by good heat resistance, heat stability, mechanical and electric features.

DOCACETAL Med

It's a POM-C product which maintains the excellent mechanical and electric characteristics of generally used DOCAETAL C but it has a high resistance to traditional cleaning and sterilizing chemicals. The material can be ordered in many colours, too.

DOCAPREN PP Med

It's a polypropylene product sterilized in dry conditions having good a size keeping and dissipation characteristics.

DOCACOC Med

It's a clean, transparent, partially crystallized special material: Cyclo-olefin-copolymer: bio-compatible, autoclaveable, can be sterilized even with gamma-ray. It has great size keeping and it's a relatively rigid polymer. It's the new alternative material for medical tools and equipment manufacturing.

In table 1 we computed together the characteristics of above presented materials.

Table 1. Medical characteristics of polymers

Material	FDA correspondence	Bio-compatibility	Sterilization	
			Hot steam, 137^0C	Gamma-ray
DOCAPEEK Med (PEEK)	X	X	+	+
DOCATRON PPS Med (PPS)		X	+	+
DOCAPEI Med (PEI)	X	X	+	+
DOCASON PPSU Med (PPSU)	X	X	+	+
DOCACETAL Med (POM-C)	X	X	O	-
DOCAPREN PP Med (PP)	X		-	-
DOCACOC Med (C.O.C.)	X	X	+	+

X: Conform with FDA requires / biocompatibility requirements
+: resistant O: partial resistant -: unresistant
FDA: Food and Drug Administration (USA standard).

The harmonization of ISO, EN and the American FDA requires continuous efforts in the field of bio-compatibility tests and sterilization procedures. In Europe there is a standard practice for national administrations to accept when using a certain material the FDA, ISO or EN specifications.

Implant materials

On the ground of cutting-edge medical implant applications using semi-finished technological, dissipation-made plastic elements, we can observe a continuous development.

UHMW-PE materials

As a result of the continouos orthopedic developments in the last 30 years the most used implant material base is UHMW-PE. This is due to all those characteristics which are enabling it for use inside the body both mechanically and biologically.

The two UHMW-PE materials's characteristics in use today are presented in table 2.

Table 2. Main material characteristics of RAM extruded UHMW-PE

Characteristic	Measurement	**UHMW-PE 1050**	**UHMW-PE 1020**
Flowing tension	MPa	22,5	22
Ripping hardness	MPa	54	51
Tearing length	%	450	405
Charpy hitting hardness: double incision probe body	kJ/m^2	200	105
Izod hitting hardness: double incision probe body	kJ/m^2	155	95
Density	g/dm^3	935	931

These values are medium ones defeating minimal values given by ISO 5834/ASTM F648 specifications.

Other implantable materials

In a previous stage of this work it has been hinted that under continuous developmens appeared other implantable materials, too. There's a possibility to further inhance our knowledge about implants taking in consideration personal needs, public consultation asking about material characteristics, quality qualification, experiences, typical areas of usage etc. for PEEK (as functional surface: biofunctionality) and PMMA (only as a subsidiary, complementory element for cement fixing) plastics.

5. CONCLUSION

Special plastic materials have high purety (medical-grade and implant-grade) offering the possibility of projecting and engineering orthopedic implants or other necessary devices for medical science.

The world-wide used new materials presented in this work are highly bio-compatible, super-elastic, resistant to rubbing down, constant under stress, physiologically compatible, resistant to fatigue etc. which determines improved adhesion to surrounding live tissues, fast cellular regeneration and reduced healing times.

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