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Simulation, injection, mold, medical industry

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INJECTION SIMULATION FOR THE MOLD PROCESS IN THE MEDICAL INDUSTRY

Abstract

This paper presents information on the methods of construction and selection of materials, for the manufacturing of a medical device – a syringe filter. The main scope of the research was numerical simulation made in order to optimize the injection process. This simulation comprised of two parts: the first in which the chosen optimal number and position of injection points on the surface, and a second with the chosen optimum wall thickness, using a pre-selected injection points.

1. INTRODUCTION

In medicine industry, there are plenty of products made using polymer processing methods (Kołtowska & Klepka, 2015; Canal, Sanchis & Vicent, 2011; Olędzka, Sobczak & Kołodziejski, 2007; Sikora, 2006; Sikora, 1993). An example of the product is a filter for separating solid contaminants from liquids applied with a medical syringe.

To prepared a filter, it is necessary to use methods of polymers processing in order to obtain the upper and lower housing as well as the connecting ring. For this purpose, the methods of precision injection with welding, overmolding or injection molding are recommended.

Currently known constructional solutions are made on the basis of patent application (Shick & King, 2012). An exemplary syringe filter is shown in Figure 1.

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Fig. 1. A syringe filter

2. CHARACTERISTICS OF POLYMER MATERIALS FOR MEDICAL APPLICATIONS

Polymeric materials have been used in medicine since the beginning of the 19th century. An example of one of the first applications are galital hammers for neurological tests, as well as subsequent bakelite stethoscopes, or the use of celluloid to replenish bone defects in the skull. Polymer plastics to a large extent exceed the percentage of used materials for the manufacture of pharmaceutical packaging, which in 2006 was 67% of all materials used. Due to the ease of processing and the price of both materials and processing technology, polymeric materials are increasingly used for the manufacture of medical devices, such as, for example, syringes, disposable gloves, drains and parts of diagnostic machines. The most commonly used polymeric materials in medicine are: polyvinyl chloride (PVC), polypropylene (PP), polyethylene (PE) and polyamide (PA) (fig. 2) (Garbacz & Sikora, 2012; Harper, 2006; Jachowicz & Klepka, 2012; Pielichowski & Pruszyński, 1998).

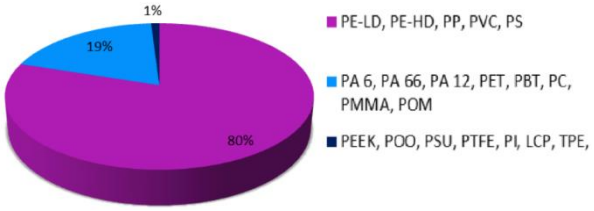

Fig. 2. Percentage of polymeric materials used in medicine

Due to the specificity of the industry, which is medicine, the materials used in it must meet a large number of properties, such as: sterility, biocompatibility or chemical resistance. One of the most important features of this type of products is sterility. The material must display good resistance to sterilizing agents, so that the shape of the product is not deformed, toxic substances are not released or the material

does not disintegrate. Table 1 shows the susceptibility of selected polymer materials to sterilization and compliance with applicable standards (Tadmor & Gogos, 2006).

Tab. 1. The susceptibility of some technical polymer materials used in medicine for sterilization and applicable standards.

Type of mat.	Sterilization methods			Compliance with standards	
	C_2H_4O	Steam	γ rad.	C_3H_7NO	Biocompatibility
POM	yes	yes	no	yes	ISO 10993-1
PBT	yes	once	yes	yes	ISO 10993-1
TPE	yes	once	yes	yes	ISO 10993-1
LCP	yes	once	yes	yes	ISO 10993-1
COC	yes	once	yes	yes	ISO 10993-1
PE-UHMW	yes	yes	yes	yes	ISO 10993-1

For the needs of medicine, many materials have been developed, dedicated to manufacturing products for various applications. The disadvantage of polypropylenes is the lack of radiation resistance required for some products for medicine. Under the influence of the fast electron beam during the sterilization, a radiolysis process takes place, i.e. radicals are formed as a result of detachment (elimination) of the electron at the weakest point of the polymer chain. In the case of polypropylene, as a result of this process, the chain breaks (degradation) and the small-molecule chemical compounds capable of migrating to water and other liquid systems form. Accordingly, modified materials are developed that have improved radiation resistance. An example of such a material is PP-Mod (Bojarski & Zimek, 1997). The basic ingredient of the PP-Mod composition is polypropylene homopolymer, Malen P J601 (so-called medical). It accounts for 80% of the content of the composition. An important addition is also poly (propylene-co-ethylene) copolymer, Malen P J330 characterized by increased resistance, which acts as an internal protective effect in this composition. Additionally, the poly (ethylene-co-vinyl acetate) copolymer, Eseorene UL00115, is resistant to radiolysis below 60 kGy, which in addition to the additional protective effect allows for even distribution of ingredients in the composition (the so-called dispersion process) (Grabowska, 2010; Kołtowska & Klepka, 2015; Olędzka, Sobczak & Kołodziejski, 2007; Rabek, 2008).

Available polymer materials can be modified depending on specific requirements. The manufactured plastic compositions can be checked for the required properties using methods such as, for example, electron paramagnetic resonance (EPR) (Ananthanarayanan, 2009; Beaumont, 2004; Beaumont, Nagel & Sherman, 2002; Kazmer, 2007; Knights, 2007).

3. NUMERICAL SIMULATION IN THE PROCESSING OF POLYMERIC MATERIALS

Nowadays, the entire manufacturing process is more and more often integrated with computer processing CAE (Computer-Aided Engineering). Thanks to such methods, there is a possibility of eliminating errors in later stages of production, already at the design level of a given product or process. One of the functions of computer-aided production is the possibility of computer simulations. The most popular software for simulating the injection process is: MOLDFLOW, CAD-MOULD, MOLDEX3D and VISI-Flow.

Due to the fact that most of the defects of molds are the result of construction errors of the injection mold in connection with the product's geometry, it is reasonable to use numerical simulations at the design stage. The use of injection molding simulation offers a multitude of benefits that are presented in table 2.11. (Fathi & Behravesh, 2004; Nabiałek & Koszkul, 2007; Sykutera, 2012; Wilczynski, 1999).

Tab. 2. Benefits of using numerical simulation.

QUALITY	ECONOMY
obtaining information about phenomena occurring during solidification of the compact inside the socket	reduction of prototyping costs and preparation of the so-called first injection
determining the kinetics of nest filling (pressure gradient, temperature)	reduction of time from the first steps related to the construction of the model to the first molding or extrudate
marking the level of stress arising inside the nest	material saving
indication of critical areas from the point of view of filling the nest	optimization of the injection process – shorter cycle time
indication of air traps together with the markings of the line connecting the streams of the material with the temperature given during the connection	reducing the amount of defective parts by indicating critical places in the volume of moldings
determination of the contraction distribution and deformation of the compact	precise cost estimation
estimation of the level of tangential stresses arising during the nest filling	reducing the costs of tool design

4. PROGRAM AND RESEARCH OBJECT

The aim of the research was to select the number and position of injection points and the appropriate wall thickness of the upper and lower housing of the syringe filter, shown in Figure 3, by performing a numerical simulation of the injection process.

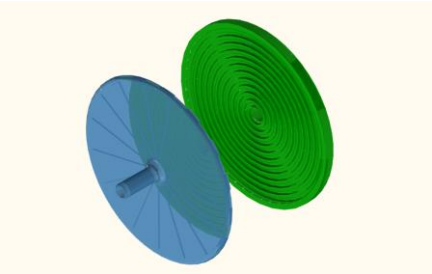

Fig. 3. The design of the syringe filter (exploded view)

The research program included the determination of injection points and the optimal wall thickness of the syringe filter. Fixed, variable and interfering factors are summarized in Table 3.

Tab. 2. Benefits of using numerical simulation.

FIXED FACTORS	
TYPE	***PARAMETER***
Geometric structure	*Construction*
Production technology	*Precision injection*
Material	*Polypropylene modified*
Injection parameters	*Suitable for selected mat.*
VARIABLE FACTORS	
TYPE	***PARAMETER***
Position and number of injection points (Figure 5)	*a) 1 point axially* *b) 2 points radially outward* *c) 2 points radially - bottom* *d) 3 axial-radial points* *e) 2 points in the middle*
Wall thickness (Figure 6)	*I: Normal; II. Bold; III. Thinned*
INTERFERING FACTORS	
All material data is missing	
Inaccuracy of mesh mesh approximation	

5. RESEARCH AND TESTS

5.1. Selection of injection simulation parameters

After checking the accuracy of the mesh geometry, the parameters for the selected material (PP-Mod), such as the plasticizing temperature, the wall temperature or the mold removal temperature, were selected. In addition, an injection pressure simulation was set in order to ensure a more accurate reproduction of the compact. The following is a p-V-T diagram for the selected PP-Mod material (Fig. 4).

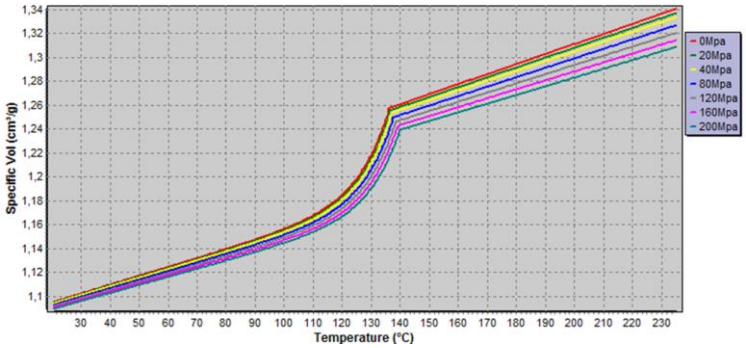

Fig. 4. Diagram p-V-T for PP-Mod plastic

Simulation parameters were used to perform the simulation, differing (by +10%) from the catalogs, recommended by the manufacturer, in order to make a better quality molding with complex and small-sized surfaces.

5.2. Selection of injection points

The selection of the best location and number of injection points was obtained as a result of five simulations. They differed in terms of the number and position of these points on the surface of the molding. The exact location of injection points is shown in Figure 5 (Nabiałek & Koszkul, 2007).

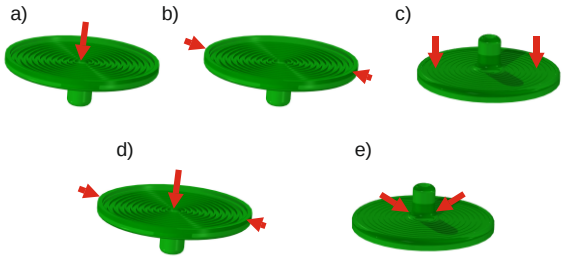

Fig. 5. Location of injection points

The first distribution of the injection point (a) is found in the center of the molding (x = 0, y = 0, z = 1.9), in order to obtain equal flow of material over the entire surface.

The second variant of the position of the injection points (b) was selected symmetrically on the diameter of the compact (I: x = 30, y = 0, z = 2, II: x = 30, y = 0, z = 2), due to the ease of bringing inlet channels with gates and symmetrical flow path of the material.

The third solution (c) is the arrangement of points symmetrically over a smaller radius, from the bottom of the molding, due to the symmetrical flow of the material (I: x = 20, y = 0, z = 0; II: x = -20, y = 0, z = 0).

The fourth option (d) is a combination of variant a and b (I: x = 30, y = 0, z = 2; II: x = -30, y = 0, z = 2; III: x = 0, y = 0, z = 1.9), designed to provide a symmetrical flow path for the material, easy to obtain supply of inlet channels with gates and faster feeding of the material to the middle parts of the compact.

The last solution (e) is to determine the injection points in place of the largest wall thickness on the compact (I: x = 0, y = 2.67, z = -0,125; II: x = 0, y = -2.67, z = -0.125) (Malloy, 1994).

5.3. Selection of wall thickness of the housing

The optimal solution of the position and number of injection points obtained was used to simulate the selection of the wall thickness. Simulation of the wall thickness selection was carried out for three structural solutions of the lower and upper part of the syringe filter.

The thickness of the wall was modified by adding or subtracting the thickness of the bottom wall of the compact (so-called addition and subtraction of the shell). The measured (modified) dimension is shown in Figure 6.

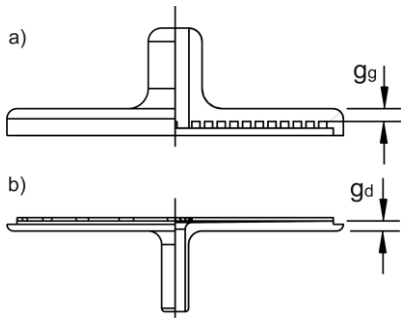

Fig. 6. Thickness of the wall at the point g: a) top cover (g_g), b) bottom cover (g_d)

The first wall thickness, called normal, was determined on the basis of the constructor's knowledge, the specification of the patented filter and general knowledge about the processing of polymer materials, and was for the upper part of g_g = 1.9 mm, and for the lower g_d = 1.5 mm.

In order to obtain the second version of the filter construction, the wall thickness was increased by 1 mm for both parts of the filter. Increasing the wall thickness, in principle, is supposed to have an impact on reducing the deformation of the compact, occurring at the thin walls. Hypothetically increasing the wall thickness, however, affects the greater value of local shrinkage.

The third structure was created by lowering the wall thickness by 1 mm for the upper part and 0.5 mm for the lower part, in relation to the "normal" thickness. The use of this treatment was to help eliminate shrinkage, reduce injection time and pressure drops. The occurrence of stagnation of the material during the flow could have negative impact on deformation of the compact in place of thin walls.

Table 4 shows the obtained wall thicknesses.

Tab. 4. Thick walls of the cover used during numerical simulation

Cover / thickness	***Normal***	***Bold***	***Thinned***
Top cover (g_g)	*1.9 mm*	*2.9 mm*	*0.9 mm*
Bottom cover (g_d)	*1.5 mm*	*2.5 mm*	*1.0 mm*

6. RESULTS AND DISCUSSION

Performing a numerical injection simulation enabled obtaining information on the flow path of the material, shrinkage strains (sags), temperature distribution of the plastic stream face, pressure distribution, time of plastic welding, sinks, problems with plastic distribution, etc.

In the case of the simulation of the selection of injection points, the following results are shown in Tables 5-9 (points a,b,c,d,e from Figure 5):

Tab. 5. Simulation calculation results for injection points a)

Filling problems	0.0 [%]
Min. FF Temp.	230.4 [°C]
Max. FF Temp.	250.4 [°C]
Max. Pressure	91.2 [bar]
Warnings	Sink marks may occur

Tab. 6. Simulation calculation results for injection points b)

Filling problems	0.0 [%]
Min. FF Temp.	233.3 [°C]
Max. FF Temp.	250.0 [°C]
Max. Pressure	94.2 [bar]
Warnings	Sink marks may occur

Tab. 7. Simulation calculation results for injection points c)

Filling problems	0.0 [%]
Min. FF Temp.	230.7 [°C]
Max. FF Temp.	250.4 [°C]
Max. Pressure	66.3 [bar]
Warnings	Sink marks may occur

Tab. 8. Simulation calculation results for injection points d)

Filling problems	0.0 [%]
Min. FF Temp.	185.7 [°C]
Max. FF Temp.	250.4 [°C]
Max. Pressure	63.8 [bar]
Warnings	Sink marks may occur May lead to surface defects

Tab. 9. Simulation calculation results for injection points e)

Filling problems	0.0 [%]
Min. FF Temp.	229.6 [°C]
Max. FF Temp.	250.1 [°C]
Max. Pressure	75.7 [bar]
Warnings	Sink marks may occur

The distribution of shrinkage strains, pressure drops, collapses, etc., was additionally depicted on the simulation, using a scale with colors, which allowed to determine the number and distribution of these parameters. Shrinkage deformations during simulation a) are shown in Figure 7.

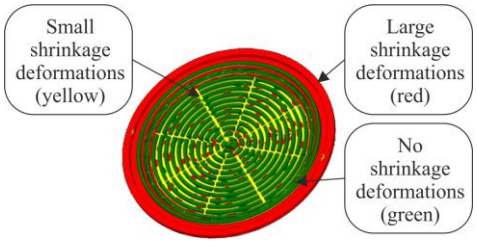

Fig. 7. Shrinkage deformations during simulation (points a))

To simulation of the wall thickness, the arrangement of injection points b) was chosen, i.e. two injection points radially outward (fig.8).

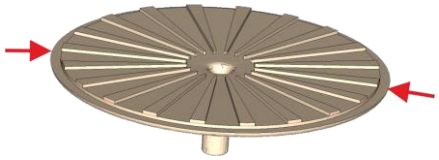

Fig. 8. Injection points for wall thickness simulation

The simulations carried out allowed to obtain the following data contained in table 10.

Tab. 10. Simulation results of wall thickness selection

	Bottom cover			**Top cover**		
	Normal	Bold	Thinned	Normal	Bold	Thinned
Filling problems [%]	10	15	0	0	0	0
Min. FF Temp. [°C]	142.7	152.3	132.4	2160	175.9	215.9
Max. FF Temp. [°C]	210.2	240.7	240.2	240.0	240.0	240.0
Max. Pressure [bar]	400.8	226.8	252.7	25.2	12.6	84.2
Sink marks [%]	120.9	364	91.3	0	0.3	9.8

Figure 9 shows a graph of the number of wall inclusions in each injection simulation, for a normal, thickened and thinned wall, an upper housing and a lower syringe filter. Figure 10 shown a graph the problem of filling the seat with plastic during the simulation of the down cover (for the up cover the value was equal to zero for all three wall thicknesses).

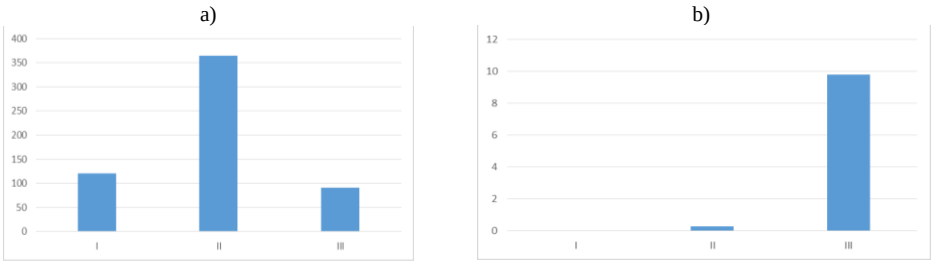

Fig. 9. Graph of wall collapse values: a) bottom cover, b) top cover, for three wall thicknesses: I – normal, II – bold, III – thinned

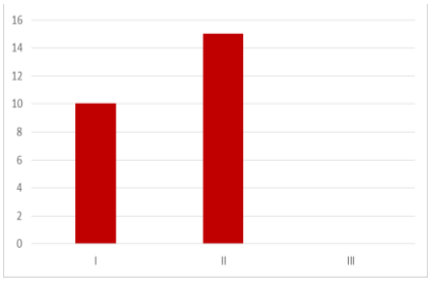

Fig. 10. Problem with filling the seat with plastic during simulation of injection of the bottom cover of the syringe filter: I – wall normal, II – bold wall, III – thinned wall

The results of the simulation also provided information about a possible problem with filling the mold cavity in the case of normal wall and bold lower housing, possible occurrence of surface collapse for all types of walls of the lower housing and walls of the thinned upper housing, possible surface deformations due to insufficient wall temperature during injection for all the walls of the lower and upper housing, and the maximum shear rate exceeding 200,000 [1/s] for the wall of the thickened lower base and the wall of the thinned upper housing. All these errors are only hypothetical and do not have to occur in physical processing conditions.

Conducting the simulation gave the opportunity to visualize individual behaviors (parameters) during the injection process. On the basis of these images, one could learn about problems that arose during numerical simulation. The image results of the injection simulation process are presented in Figures 11.

In addition, it was possible to get an image of the order of flow of the material in time, or the temperature distribution of the plastic stream during the injection. Moreover, the simulation of the injection allowed to obtain such data as the injection pressure in time, the place of stagnation of the material during injection, the flow directions of the material, the plastic flow path and others.

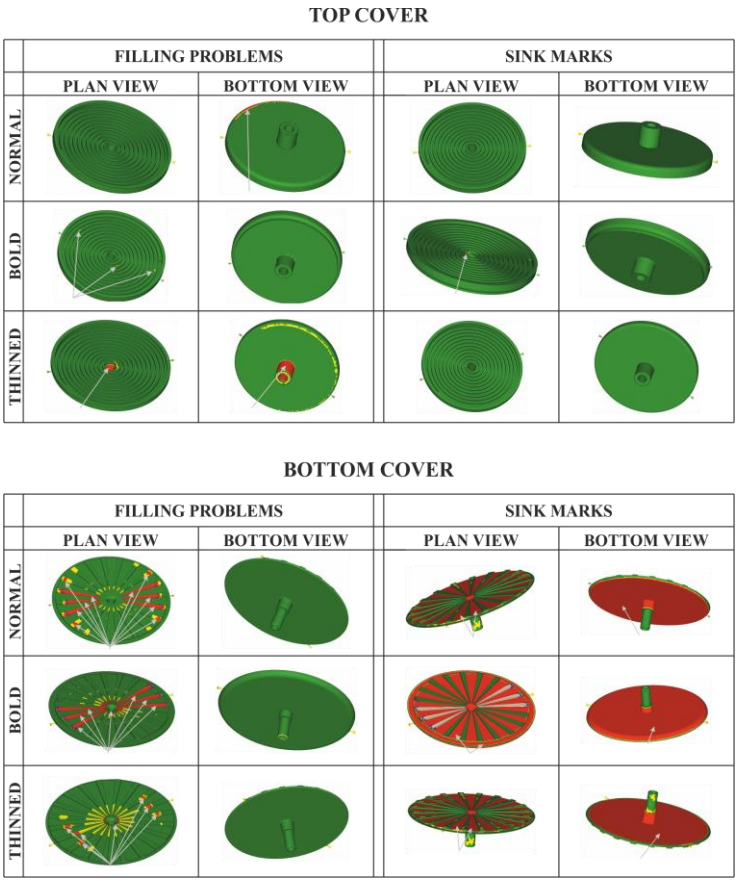

Fig. 11. Results of the injection simulation process (green = no problems, yellow = medium problems, red = big problems)

7. SUMMARY AND CONCLUSIONS

Methods for producing a syringe filter

The filter housings should be made of plastic used for medical applications, free of harmful contaminants. For the production of these parts, modified polypropylene (PP-Mod), radiation-resistant in medical quality (Zimek, Bułhak, Bojarski, Mirkowski & Stachowicz, 1992), obtained as a result of combining Malen P J601 polypropylene (80% of total content), poly (propylene-co-ethylene copolymer)) with the designation Malen P J330 and copolymer poly) ethylene-co-vinyl acetate) with the designation Escorene UL00115, with the addition of an amide lubricant, also used to manufacture syringes (in accordance with PN-EN ISO 7886-1: 2000).

The coupling ring of the housing can be made of polypropylene (e.g. Malen P J601) or high density polyethylene. Due to the processing properties, however, the use of polypropylene is recommended (in order to optimally connect to the casings).

The filter material is supplied by an external manufacturer, due wide range of variations of this element.

Selection of number and position of injection points

The numerical simulation of the injection molding process of the syringe filter showed that the shrinkage (and collapse) deformations for one injection point are the largest, and for case II and V the smallest. The other two cases (III and IV) are comparable but unsatisfactory. This is caused by a longer flow path of the material, in case of one point and incorrect placement of two injection points. It also causes higher pressure and temperature drops. This leads to differentiation of the local shrinkage and consequent increase of deformation of the entire molding. For two injection points positioned correctly and for three injection points, the deformation and collapse are of low value and can be eliminated by increasing the pressure value.

Therefore, cases I, III and IV have been eliminated for further simulation.

In the case of using three injection points (V), due to the flow of the material, there is a temperature difference greater than 20 ° C, which may result in stagnation due to the curing of the material and blocking of the further flow path.

In addition, with comparable results of injection time and molding quality, the use of three injection points is not economical.

The best solution is to choose two injection points arranged radially externally (system b)). Both the injection time, the flow temperature of the material, the pressure drop and the sealing time of the material are appropriate for the injecttion process.

The choice of wall thickness of the filter housing

The simulation of the choice of the wall thickness of the upper and lower casing made it possible to choose the right thickness from the point of injection technology.

In the case of the lower housing for a normal and thickened wall, problems with filling the seat with plastic were observed. This problem can be solved by controlling the parameters of the injection process (increasing the injection pressure, increasing the temperature). It does not appear in a thinned construction. The structure also has the smallest surface collapse that can be eliminated by modifying the injection parameters and secondary pressure.

In connection with the above, the optimal thickness of the bottom wall is a thinned construction, which additionally saves material, which translates into an economic factor.

In the case of simulation of the upper part, there were no problems with filling the socket. In the simulation of the thinned and bold construction, however, there was a problem with the surface collapse. While in the case of a thickened construction it is not significant, in the latter it would be necessary to control the injection parameters in order to eliminate it.

Based on the simulation, it was found that the optimal wall thickness for the upper housing is "normal" thickness.

All in all, there is need to remember that the simulation results are only an approximation of the actual conditions for the constitution of the compact, and the material model used in the processing process does not fully reflect the behavior of the material in real conditions. The correct interpretation of the simulation results is knowledge of the algorithms used in the description of the model (e.g. mass, motion and energy behavior equations). The accuracy of the simulation results is a derivative of the quality of preparation of the mold model in CAD programs. FEM mesh is only an approximation of the actual geometry of the molding, so the correctness of its execution depends, for example, on the relation of the thickness of the actual molding to the simulation model.

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