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Gate type influence on thermal characteristics of injection molded biodegradable interference screws for ACL reconstruction

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Abstract: In biomedical applications high precision manufacturing is an essential requirement. With precision injection molding it is possible to manufacture implants from thermoplastic materials for both short and long term use. This paper focuses on the injection molding analysis of a biodegradable implant for tendon fixation. Finite element simulation was carried out to compare thermal characteristics of the process, with two different type of gating. All analyses, including the thermal simulations and dimensional stability analysis show, that different gating does not effect part deformation or shrinkage beyond the accepted limit, although they show some differences.

Nomenclature

B	viscosity coefficient
c_p	specific heat
D	total derivate
\vec{g}	gravity vector
k	thermal conductivity
m	flow index
n	normal direction

p	pressure
p_{in}	inlet pressure
t	time
T	temperature
T_b	reference temperature
T_m	freezing temperature
T_w	mold temperature
\bar{u}	velocity vector
x,y,z	is the Cartesian coordinate

Greek symbols

∇	Laplace operation vector
η	viscosity
ρ	density
$\dot{\gamma}$	shear rate
η_0	reference viscosity
τ^*	reference stress.

Keywords: biodegradable material, implant, injection molding, simulation, PLA

1. Introduction

Injection molding is a key polymer processing technology when part of high dimensional stability and precision are to be made from a thermoplastic material. Injections molding simulation programs such as Cadmould, Rem3D, Simuflow, Moldex3D and Autodesk Moldflow have become accepted in the industry for process and design optimisation. Some of these programs are based on models in which two-dimensional elements are used to represent the three-dimensional geometry. In these models the Hele-Shaw model is used which neglects the inertia and the gap-wise velocity component for polymer melt flow in thin cavities. For the Hele-Shaw model applications the mid-plane mesh method is necessary. In three-dimensional flow regions such as the flow around the corners, the thickness change regions or the fountain flow effect of melt fronts the Hele-Shaw model can not be used. Only 3D numerical

simulation methods based on the Navier–Stokes equation can simulate these situations. To achieve precise simulation results, it is essential to use the mathematical model of heat transfer in three dimensional flows [1-2].

König et al. [3] showed that it is possible to produce sterilized biodegradable implants with injection molding in order to avoid sterilization methods that might damage the polymer. Their results showed that the 200°C melt temperature has enough sterilising effect on the materials used if they are not heavily contaminated. It must be mentioned though that handling of medical grade polymers does not allow any bacterial contamination of the material or product, before or after processing. If contamination occurs to the granules, they can't be used for their original purpose.

There are only a small number of publications on the injection molding simulation of biomedical parts and devices. Shen et al. [4] studied the injection molding simulation of a nasal scaffold for tissue engineering. They used Taguchi method to find the optimal processing parameters for the minimum deflection of the scaffold. As the part geometry greatly affects deflection, their optimisation result can only be used for their model. Zhil'tsova et al. [5] studied the effect of injection molding processing conditions on the dimensional stability of HDPE acetabular cups. Their results showed that packing pressure and injection velocity had the most significant affect on product accuracy.

Interference screws are used for graft fixation in anterior cruciate ligament (ACL) reconstruction. They can be both manufactured from titanium alloys or biodegradable polymers such as polylactide (PLA). PLA and other biodegradable biopolymers have been used in medical implants over the last 15 years [6], and in the last 5 years biodegradable polymers are finding their way in the area of commodity plastics also [7].

Screws can be manufactured either by turning (especially metallic screws), forging [8], or injection molding which is the most productive method. Publications dealing with interference screws mainly studied the fixation strengths of specific screws on different specimens with different fixation methods [9].

2. Experimental

2.1. Mathematical model

The mass, momentum and energy conservation governing equations for the non-isothermal, generalized Newtonian fluid are given by:

Continuity Equation:

$$\frac{\partial \rho}{\partial t} + \nabla \cdot (\rho \vec{u}) = 0. \quad (1)$$

Momentum Equation:

$$\rho \left(\frac{\partial \vec{u}}{\partial t} + \vec{u} \cdot \nabla \vec{u} \right) = -\nabla p + \eta \nabla^2 \vec{u} + \rho \vec{g}. \quad (2)$$

Energy Equation:

$$\rho \left(\frac{\partial T}{\partial t} + \vec{u} \cdot \nabla T \right) = k (\nabla^2 T) + \eta \cdot \dot{\gamma}^2. \quad (3)$$

The viscosity model of fluid:

$$\eta(\dot{\gamma}, T, p) = \frac{\eta_0(T, p)}{1 + \left(\frac{\eta_0(T, p) \dot{\gamma}}{\tau^*} \right)^{1-m}}. \quad (4)$$

$$\eta(T, p) = B \exp\left(\frac{T_b}{T}\right) \exp(-p). \quad (5)$$

Then

$$\dot{\gamma} = \sqrt{\nabla^2 \vec{u}}. \quad (6)$$

Boundry and initial conditions:

$$\vec{u} = 0; \quad T = T_w; \quad \frac{\partial p}{\partial n} = 0 \quad \text{on mold wall} \quad (7)$$

$$\frac{\partial \vec{u}}{\partial z} = \frac{\partial T}{\partial z} = 0 \quad \text{on centre line} \quad (8)$$

$$p = 0 \quad \text{on flow front} \quad (9)$$

$$p = p_{in}(x, y, z, t); \quad T = T_m \quad \text{at inlet.} \quad (10)$$

This research uses control volume finite element method to solve the equations above [10].

2.2. FEM modelling

In this work 3D numerical simulation (control volume finite element method) was used for the injection molding simulation of a biodegradable interference screws, as effect of screw geometry or manufacturing method has not been studied yet. The study discusses the differences caused by different gatings of the part on the filling stage, temperature distribution, freezing time and deflection of the interference screw.

Screw design was determined after consulting with practitioner surgeons, performing ACL reconstruction. The length of tapering at the screw end was chosen to be $\sim 1/3$ of the total screw length. The screw is fully cannulated, and the screwdriver socket is hexagonal, and 17 mm deep. The pitch of the screw thread was chosen 7° . The respective dimensions of the interference screw are illustrated on Fig. 1.

AutoDesk Moldflow has been used for this work. Two type of gating system were analysed. In the first case an ideal arrangement was studied, when the polymer melt enters the part cavity evenly from the circular surface at the screw end. The total number of tetrahedral elements for the ungated model was 399793 with 73945 nodes (Fig. 2. a.)). In the second case a ring gate has been added to the surface at the bottom of the screw with a connection to the runner system of the mold. The total number of tetrahedral elements for the gated model was 427290 with 78161 nodes (Fig. 2. b.)). Sprue and runner system has not been added to either model, as they have the similar effect on both models. For the simulation NatureWorks 7000D PLA was chosen from MoldFlow material database. Processing parameters set for the injection molding simulation are listed in Table. 1.

3. Results and discussions

Flow analysis (Fig. 3.) shows that there is no significant filling time difference between the two gating types. The ring gate and it's connection to the runner system causes an asymmetrical filling pattern in the screw cavity, that can be followed through out the whole filling stage. This asymmetrical filling pattern has effect on the temperature distribution of the screws also. Fig. 4. shows the temperature distribution of the material after filling while the packing stage. The symmetrical temperature distribution throughout the packing stage can be seen on Fig. 4. a. The outer and the inner surfaces of the screw cool down during the filling caused by the significant temperature difference between melt and mold. Fig. 4. b. shows temperature distribution after filling

and during the packing stage on the ring gated screw. Results show that the temperature on the runner side of the screw is higher compared to the other. This temperature difference causes uneven cooling of the part, and can lead to the warpage of the screw. Fig. 5. shows the shear distribution in the melt on both gated and ungated models during filling. High shear level in polymer flow lead to rising of the material temperature, and can cause the overheating of the material by 10-20°C. On the ungated model (Fig. 5. a.), that presumes uniform filing of the cavity, higher shear is only present at the entry point of the melt in a circular pattern. On the gated model (Fig. 5.b.) high shear develops only on side of the runner system in the ring gate, and contributes to the asymmetrical temperature distributions in the screw. The freezing time of the material in the mold is essential for optimizing injection molding cycles. It shows the amount of time required to reach the ejection temperature, measured from the start of the cycle. With these results cycle time can be considerably shortened, and more implants can be produced during the same time period. Fig. 6. shows the calculated freezing time for the ungated (Fig. 6.a.) and ring gated (Fig. 6.b.) screws. Both models show asymmetrical freezing time in the screw head. These result are caused by the screw thread that runs into the screw head generating extra material volume in that place, which cools down slower compared to other parts of the screw head. Simulation results show that the freezing time in both occasions is under 20 sec from the beginning of the filling, which means that it is possible to reduce cycle time by 33%. The deflection of a part shows the total predicted deformation of the part during molding. Fig. 7 shows the deformation on both models. In both cases the maximal deflection of the part can be found at the screw end and in the screw head. Differences in deformation of the screws show the effect of the asymmetrical thermal history of the gated model. The screw on (Fig. 7. a.) has a uniform longitudinal and transversal shrinkage. This shrinkage can be observed on the ring gated screw also (Fig 7. b.), but the is also slight bending of the screw caused by the temperature difference on the two sides of the screw. This deformation does not reach such an extent, that it has an effect on the usability of the screw. Highest deformation (0,17 mm) can be found in the ring gate of the gated part. Since this deformation is not in the implant, it won't cause the production of defect parts, although it can harden the removal of the metallic insert from the screw after molding.

4. Conclusions

The results of our research show that injection molding cycle time can be considerably shortened from the temperature distribution, cooling time and freezing time results of injection molding simulation softwares. Gate design is essential for injection molding simulations. Optimal filling arrangement does give some essential information about the molding and freezing time, but adding a realistic gating system to our part will give more precise results about filling, temperature distribution, cooling and deflection. Simulations results can be made more accurate if inserts, mold, cooling channels are also calculated with, since these all effect melt flow and heat transfer.

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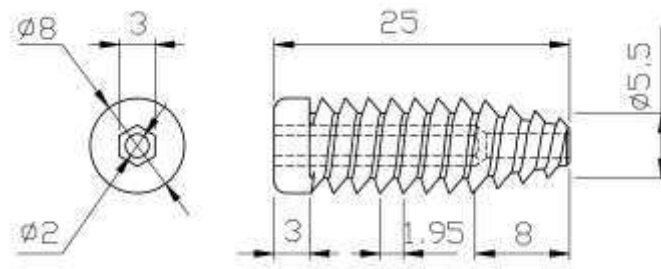


Fig. 1 Main dimensions of the interference screws in mm

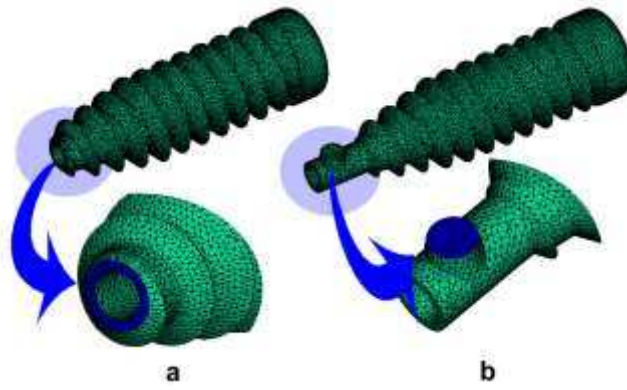


Fig. 2 Meshed models for the numerical simulation and surface of melt entry
a) ideal gate for symmetric melt distribution b) ring gate for the real case simulations

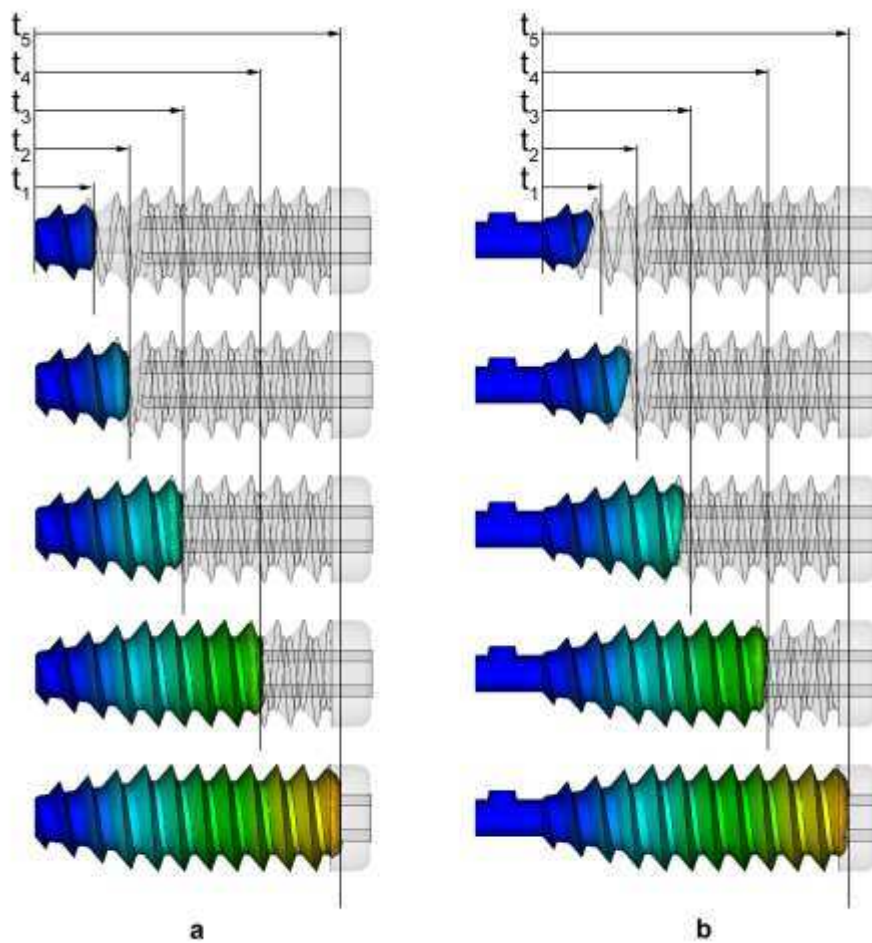


Fig. 3. Filling pattern of differently gated screws.

a) ideal gate for symmetric melt distribution b) ring gate for the real case simulations
 where t_1 is the 10%, t_2 is the 15%, t_3 is the 35%, t_4 is the 60%, t_5 is the 85% of the filling
 time

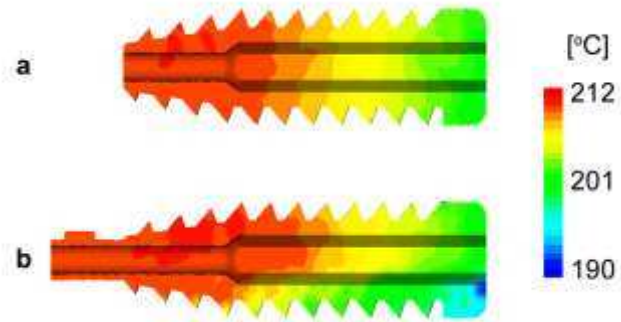


Fig. 4. Temperature distributions of the material after filling
a) ideal gate for symmetric melt distribution b) ring gate for the real case simulations

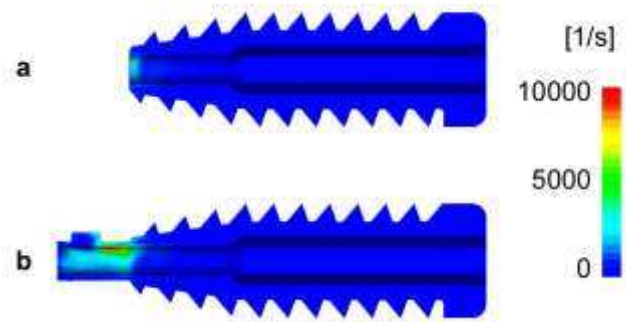


Fig. 5. Shear distribution in the mold cavity before filling

a) ideal gate for symmetric melt distribution b) ring gate for the real case simulations

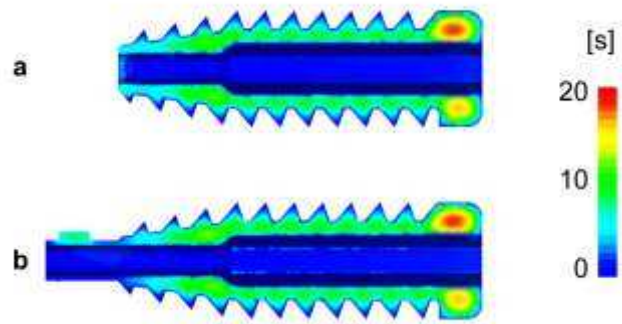


Fig. 6. Freezing time of the material in the molds.

a) ideal gate for symmetric melt distribution b) ring gate for the real case simulations

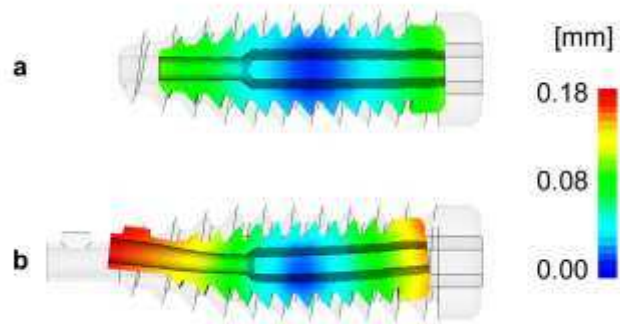


Fig. 7. Deflection of the injection molded interference screws scaled up 25 times
a) ideal gate for symmetric melt distribution b) ring gate for the real case simulations

Table 1. Processing parameters

Parameter	Value
Injection Pressure [MPa]	32.5
Mold temperature [°C]	25
Melt temperature [°C]	210
Cooling time [sec]	20
Holding Pressure [MPa]	20
Holding Time [sec]	10