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A Numerical Study on the Effect of Gate Position to the Structural Integrity of Plastic Injection-Molded Biomedical Implants †

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Abstract: Optimizing the injection molding process for making biomedical implants is essential to avoid defects that impact patient safety and implant performance. This study examines how different gate positions affect defect rates in injection-molded polyether ether ketone (PEEK) pedicle screws, using numerical modeling to analyze melt flow, cavity pressure, sink mark depth, warpage, and Von Mises stress across four gate configurations. The findings show that gate position significantly influences structural integrity, with strategically placed gates reducing defects by promoting uniform flow. Gate configuration 2 was optimal, yielding minimal sink depth, low warpage, and low stress, while configuration 4 was the least effective as it was associated with higher values of defect rates. Carefully selecting gate positions can enhance the quality and reliability of biomedical implants.

Keywords: injection molding; biomedical implant; pedicle screw; melt flow pattern; warpage

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1. Introduction

Polymers have emerged as very desirable biomaterials because of their versatility, adaptability, and ability to form successful bone alternatives [1]. Some of the commonly used biomedical polymers include polyethylene, polyether ether ketone, and polylactic acid among others. Of these, polyether ether ketone is the most commonly used material owing to its high strength-to-weight ratio, high glass transition temperature, chemical stability, thermal stability, and biocompatibility [2]. Plastic injection-molded biomedical implants play a crucial role in modern healthcare, offering solutions for a variety of medical conditions [3]. However, ensuring the quality and structural integrity of these implants is crucial to guarantee patient safety and implant performance [4]. Even minor defects in these products can have significant implications, emphasizing the need for rigorous process optimization during their production. One such important aspect of this optimization is the selection of gate positions during the injection molding process, as it can greatly influence the occurrence of defects in structural components intended for biomedical implants. Gate location is one of the most important design variables that contribute to injection-molded product quality [5]. Depending on part geometry, the location of gates directly determines

how the polymer melt fills the cavity and hence the molded part quality. Proper gate location requires uniform and simultaneous flow and front cavity filling.

Although significant strides have been made in the literature in terms of the plastic injection molding of biomedical implants, the effects of variation in gate location on the structural integrity of the molded implants have not been extensively explored. Variations in gate position can create substantial influence over the quality and structural integrity of injection-molded structural components more so in the context of biomedical implants. A comprehensive understanding of this impact is thus indispensable for refining manufacturing processes and enhancing product quality. Through variations in gate positions, insights can be obtained, thereby offering pathways to optimize the production of biomedical implants for enhanced product quality. This research therefore delves into the investigation of the effects of varying gate positions, aiming to shed light on parameters crucial for enhancing the structural integrity of biomedical implants. By studying different gate configurations, manufacturers stand to obtain valuable insights that would help empower them to navigate toward optimal biomedical implant production practices.

2. Materials and Methods

This study was carried out numerically through computational modeling of the plastic injection molding process. A single cavity injection mold used for making a standard pedicle screw implant was developed as a finite element model. The selected polymer material for this study was a commercially available grade of polyether ether ketone (PEEK) produced by Lehman & Voss & Co. (Hamburg, Germany) under the trade name LUVOCOM 1105-7106 with major properties listed in Table 1. This material is commonly used in most plastic injection-molded biomedical implants. To enhance result accuracy, this study adopted a 5-layer boundary layer mesh configuration [6]. Figure 1 shows the resulting mesh configuration of the part's finite element model. Upon a series of mesh refinements, a mesh size of 0.1 mm was chosen for the part yielding a total part element number of 1318971.

Table 1. Polymer material properties.

Family Name	PEEK
Grade Name	LUVOCOM 1105-7106
Producer	Lehman & Voss & Co.
Processing Temperatures	360–400 °C
Solid Density	1.36 g/cm^3
Flexural Strength	145 MPa
Flexural Modulus	9.0 GPa
Tensile Strength	100 MPa

The numerical modeling of the injection molding process was based on the polymer melt flow governed by the principles of conservation of mass, energy, and momentum, represented by Equations (1)–(3), and the viscosity of the polymer melt was modeled using the modified cross exponential viscosity model as given by Equation (4) [7]:

$$\frac{D\rho}{Dt} = -\rho\nabla\cdot u \tag{1}$$

$$\rho\frac{\partial v}{\partial t} = \rho g - \nabla p + \nabla\cdot\eta D - \rho v\cdot\nabla v \tag{2}$$

$$\rho C_p\left(\frac{\partial T}{\partial t}+v\cdot\nabla T\right)=\beta T\left(\frac{\partial P}{\partial t}+v\cdot\nabla P\right)+\eta\dot{\gamma}^2+k\nabla^2 T \quad (3)$$

$$\eta\left(\dot{\gamma},T,P\right)=\frac{B\exp\left(\frac{T_b}{T}+DP\right)(T,P)}{1+\left(\frac{B\exp\left(\frac{T_b}{T}+DP\right)\dot{\gamma}}{\tau^*}\right)^{1-n}} \quad (4)$$

where ρ is the density, t is the time, u is the speed vector, v is the specific volume, g is the gravitational acceleration, P is the hydrostatic pressure, Cp is the specific heat, T is the temperature, β is the heat expansion coefficient, k is the thermal conductivity, $\dot{\gamma}$ is the shear rate, η_0 is the zero shear viscosity, $\dot{\gamma}$ is the effective shear rate, τ^* is the reference shear stress, n is the power law index, P is the pressure, T is the temperature, and the other material constants are represented by B, D, and T_b. The boundary conditions applied included melt temperature specification at the inlet, zero pressure at the melt front, uniform temperature at the injection point, and zero pressure gradients across mold edges and walls [8].

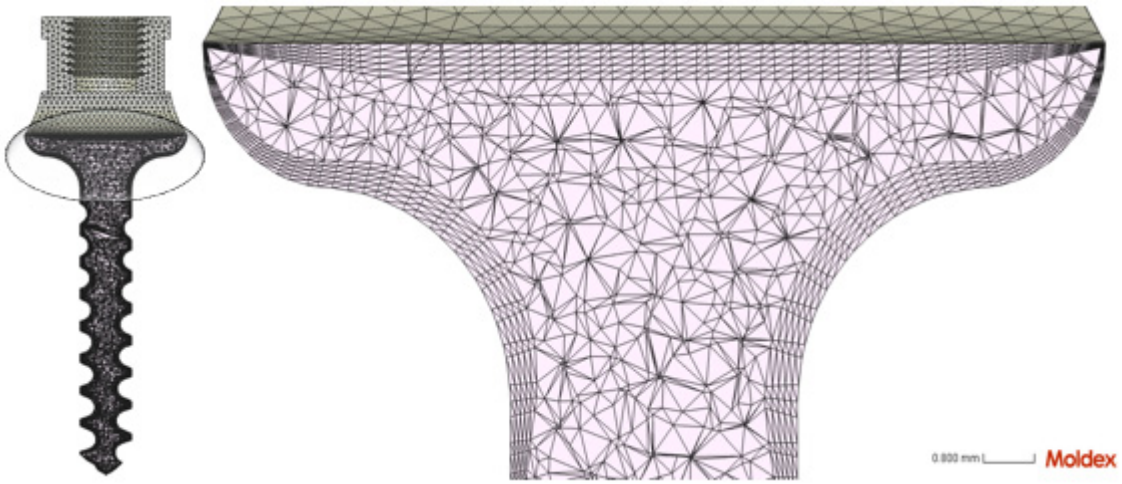


Figure 1. Finite element model of the pedicle screw.

Pressure–volume–temperature relationship characterization was used in the finite element model verification. Probing points were placed at various locations of the part and used to track the variations in pressure, temperature, and densities of the polymer melt at given periods. Using the values of pressure and temperature determined from each probe at the end of the fill, equivalent analytical densities were computed based on the modified Tait Equation, and the results were compared to the numerically obtained densities. A match in the densities was satisfactory and hence the model was used for successive simulations.

A gating suitability test was carried out to determine various suitable positions to place the gates. This was carried out computationally and was based on percentage flow length ratios, with all the regions above the threaded end of the component yielding lower flow length ratios, which indicated suitability for gate placement. Four regions were randomly selected within the suitable gate location region of the component and used as the gate position. In the first configuration, a single gate was placed vertically at the top surface of the component head whereas in the second configuration, two gates were placed vertically at the top surface of the component head. In the third configuration, a single gate was placed vertically at the screw-head bed and in the last configuration, a single gate was placed horizontally at the neck of the component. Numerical simulations were carried out for each gate position and the defect rates resulting from each gate configuration were obtained.

3. Results and Discussions

3.1. Effect of Gate Position on the Filling Patterns

Figure 2 illustrates the filling patterns associated with each of the four gate configurations. The profiles indicate the various time periods at which the melt front would fill a particular section of the mold cavity from the beginning of the fill to the end of the fill. Regions bearing a red color are the first to be filled at the beginning of the fill whereas regions with a blue color are the last to be filled at the end of the fill. Gate locations 1, 3, and 4 are associated with non-uniform filling patterns of the screw where the lower portions and some upper portions of the screw are filled last. On the other hand, the second gate location configuration has a completely uniform filling pattern where the top part of the screw is filled first, and the lower section of the screw is filled last. Non-uniform filling patterns result in flow stresses that significantly contribute to molded part defects [9]. Therefore, the second gate location configuration would be associated with fewer molded product defects.

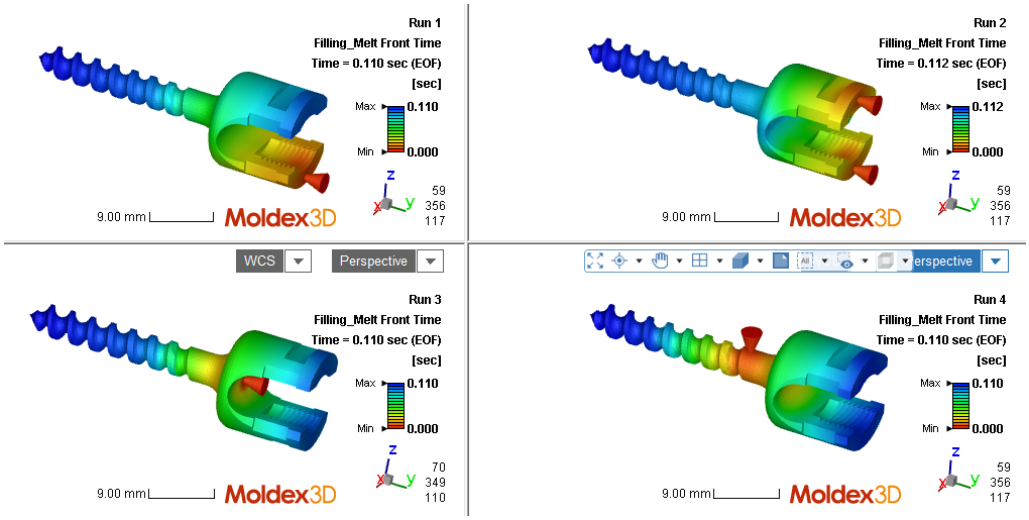


Figure 2. Resulting filling patterns.

3.2. Effect of Gate Position on the Cavity Filling Pressure

Figure 3 illustrates the variations in filling pressure with changing gate locations. The first gate position recorded the highest filling pressure whereas the second gate position recorded the lowest filling pressure. With the first gate position, the molten material had to travel a longer distance to reach the furthest points of the mold cavity. This longer flow distance increased the viscosity, hence the resistance encountered by the material, thereby resulting in higher pressure requirements to force the material through the mold [10]. The second gate position, which used two gates, had a relatively reduced flow distance, hence a lower resistance to flow.

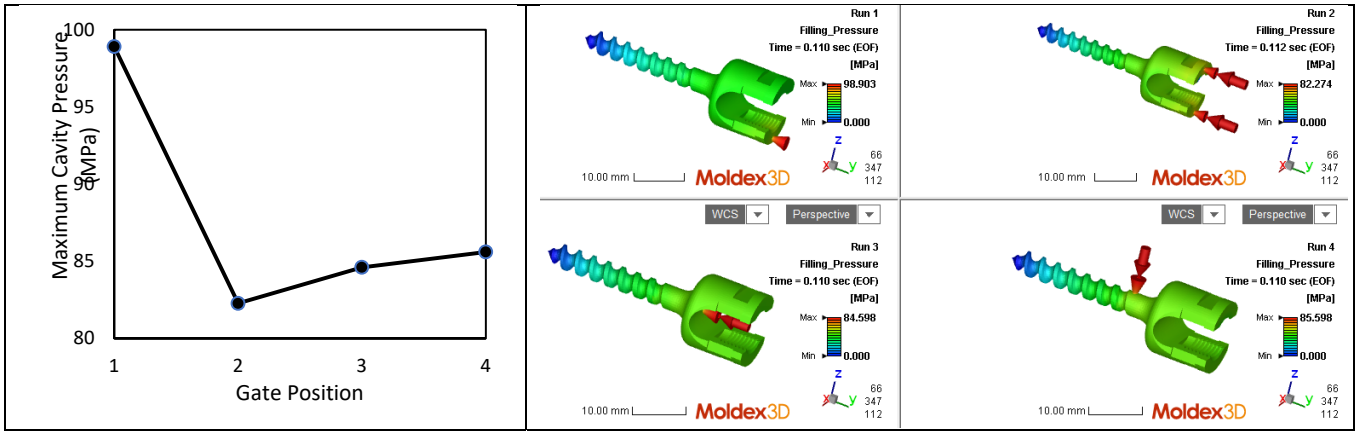


Figure 3. Variations in cavity filling pressure.

3.3. Effect of Gate Position on Structural Defects

Major structurally oriented defects such as the maximum sink mark depth and the maximum total displacement including Von Mises stress were considered in the packing and warpage stages, respectively. Figure 4 shows variations in part warpage across the four gate positions. Considering the material flow patterns, maximum part deflection occurs on the sections of the molded screw that are filled last in all four configurations. This is due to the fact that sections of the part that are filled last are subjected to higher internal stresses due to reduced melt temperature hence resulting in higher values of warpage [11]. Gate position 1 is associated with the largest maximum part warpage of 0.134 mm whereas gate position 3 is associated with the lowest maximum part warpage of 0.115 mm.

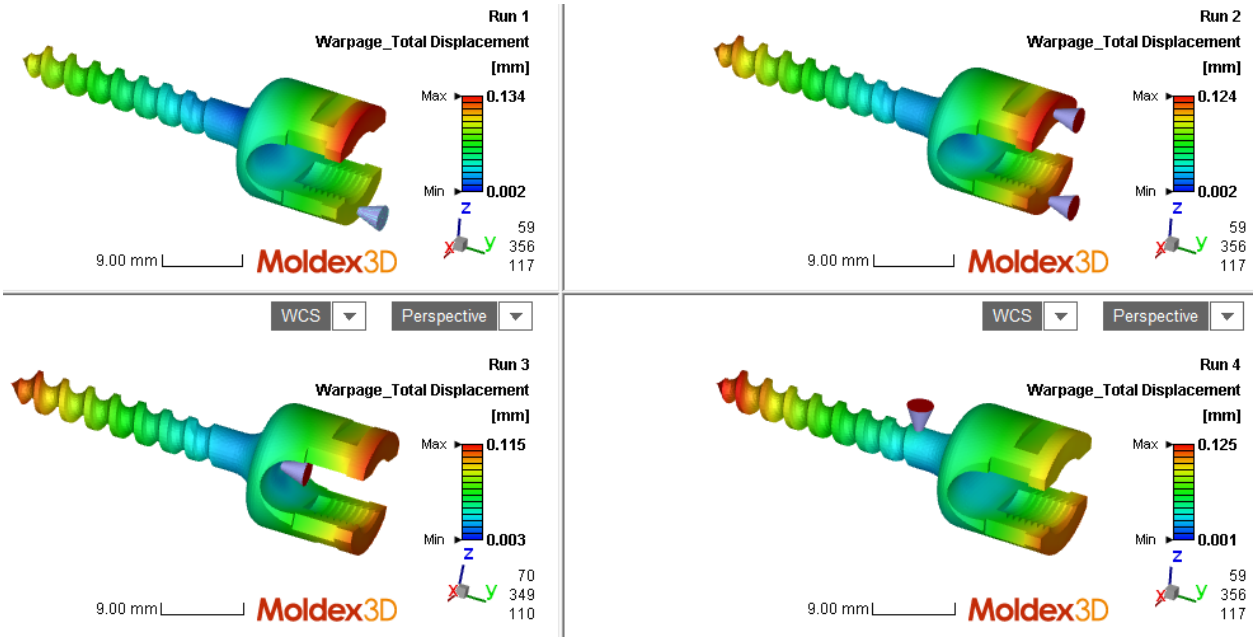


Figure 4. Variations in part warpage.

Figure 5 is a plot of variations in defects considered major with respect to gate positions. Gate position 1 is associated with the lowest sink mark depth, lowest Von Mises stress value, and highest warpage whereas gate position 3 is associated with the highest sink mark depth and lowest warpage. The highest sink mark depth indicates areas of higher localized cooling rates that could lead to non-uniform stress distribution and potentially lower warpage.

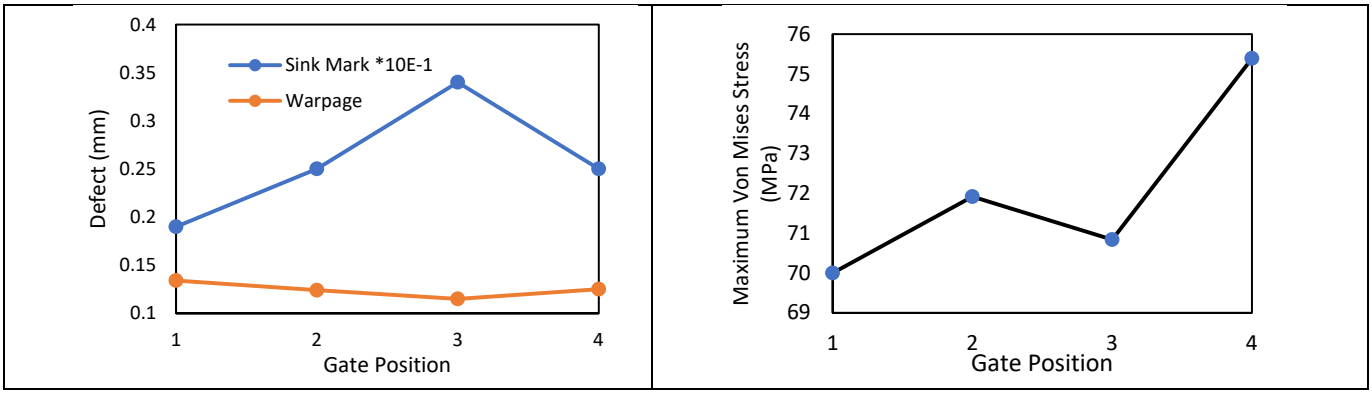


Figure 5. Variations in warpage and shrinkage defects.

Therefore, when considering the areas of application for injection-molded pedicle screws, such as in biomedical structural support, an appropriate gate location that minimizes most structural defects should be selected. For effective functionality, an injection-molded pedicle screw meant for biomedical implants should be structurally sound. Gate position 1 is associated with the lowest sink mark depth and Von Mises stress, but this would come at the cost of the highest warpage, highest cavity pressure, and non-uniform flow patterns which could result in higher internal stresses. These would significantly reduce the structural integrity of the molded screw. Therefore, for enhanced molded screw structural integrity, gate position 2 is the most appropriate as it is associated with low sink mark depth, low warpage, lowest cavity pressure, low Von Mises stress, and uniform flow pattern with the lowest possibility of internal stresses.

4. Conclusions

The main aim of this study was to investigate the effects of varying gate positions on the structural integrity of injection-molded pedicle screws intended for biomedical implant application. The following conclusions were made from this study:

1. Non-uniform filling patterns observed in configurations with gate positions 1, 3, and 4 were found to contribute to flow stresses, which in turn led to increased occurrence of molded part defects.
2. Configuration 2 with gate positions promoting more uniform filling patterns demonstrated reduced defect occurrence thereby highlighting the critical role of gate location in defect mitigation.
3. Gate position 1 exhibited the lowest sink mark depth and Von Mises stress but was associated with the highest warpage and non-uniform flow patterns, compromising the structural integrity of the molded screw.
4. Gate position 2 emerged as the most suitable choice, demonstrating low sink mark depth, low warpage, and uniform flow patterns, thereby ensuring the enhanced structural integrity of the pedicle screw. This selection was made through intuition with the filling pattern taken to have the highest severity, Von Mises to have a high severity, warpage to have moderate severity, and sink mark depth to have a low severity on the structural integrity of the molded implant.

Therefore, these findings underscore the importance of selecting an appropriate gate location to minimize defects and optimize the structural performance of injection-molded pedicle screws for biomedical applications. Further research efforts should be devoted towards the continuous exploration of additional factors influencing defect formation and advance techniques for optimizing the manufacturing process to meet the evolving demands of biomedical implant manufacturing.

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