New Application of Powder Injection Molded Product in Medical Field

Jakub Huba[1,2,a], , Daniel Sanetrnik [1,2,b], Eva Hnatkova [1,2,c] Berenika Hausnerova [1,2,d], Zdenek Dvorak [1,2,e]
[1]Department of Production Engineering, Faculty of Technology, Tomas Bata University in Zlin, Vavreckova 275, 760 01 Zlin, Czech Republic.
[2]Centre of Polymer Systems, Tomas Bata University in Zlin, Trida T. Bati 5678, 760 01 Zlin, Czech Republic
E-mail: [a)]jhuba@ft.utb.cz, [b)]dsanetrnik@ft.utb.cz, [c)] ehnatkova@ft.utb.cz, [d)]hausnerova@ft.utb.cz, [e)]zdvorak@ft.utb.cz

Nowadays, majority part of powder injection molding (PIM) market in Europe consists in automotive (43 %). In contrast, to medical applications only 13 % of market is devoted. This paper is focused on a new design and production technology of the adenoid cutting curette used in otorhinolaryngology. In the theoretical part, the present design issues of the cutting curette are shown, and time consumption and wear problems of sterilisation are described. Experimental part consists in selection of suitable metal powder for medical application, computer-aided engineering (CAE) Moldflow analysis of proper gating system followed by construction of injection mold and production of real samples. The new design of replaceable cutting edge is easily customized according to various shapes of patient oral cavity and for doctor's need.

Keywords: PIM, Adenoid, Otorhinolaryngology, Medical Device, Curette.

1 Introduction

Powder injection molding (PIM) is a modern technological process combining the shape advantage of plastic injection molding with final properties of metals or ceramics [1-3]. In comparison to machining and investment casting PIM offers an economical saving for mass production of small components having a complex net-shape. Most of PIM items find application in automotive, military, information technologies as well as in medical field [4]. The selection of an appropriate material is the first issue for given application, because the selected material affects the final structures and properties of the products. Namely, powder size, particle size distribution, and particle shape as well as binder composition have a key role in the whole process.

PIM process consists of four basic steps: mixing, injection molding, debinding and sintering as can be seen in Fig. 1. In the first step, powder particles are mixed in high concentrations with a suitable polymeric binder system into homogenous PIM feedstock. Polymer binder is mostly composed of three types of components: backbone ensuring strength, low molecular weight polymers providing good flow properties for injection molding and surfactants improving the adhesion between the binder and the powder. The feedstock usually contains around 60 vol. % of powder particles and is processed into pellets [5]. There is also possibility to purchase commercial feedstocks which are ready-to-use.

In the second step, the feedstock is melted in the injection, and then under high pressure injected into mold cavity, which has to be oversized to balance the final shrinkage. The obtained injected component containing powder and binder is called "green part". In the third step, the binder system has to be removed from the green part by heating, dissolving (in heptane, hexane, water etc.) by chemical reaction or their combination. After debinding, the porous structure from powder particles is called "brown part". The final step is sintering in which the porous sample is densified under high temperatures into the final metal or ceramic product with sintered density around 97 % of the theoretical [6-8]. After the last step, the final product can be heat-threated or put into the hot isotactic press to obtain full density components [1].

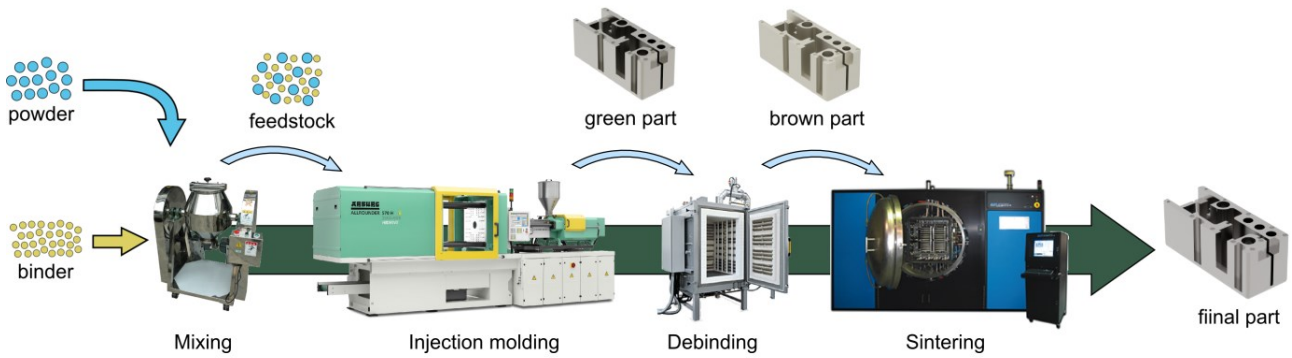

***Fig. 1** Processing steps in PIM technology*

Nowadays, according to resent research [10], only 13 % of the whole PIM production in Europe is applied in

medical industry, while PIM technology could offer a huge range of products due to its advantage to produce medical devices based on surgical steel, titanium or ceramics [9, 10]. Further, the research has highlighted excellent materials which can be produced via PIM for biomedical applications [11, 12]. Especially, in otorhinolaryngology area (ear, nose, and throat - ENT) the progress in medical device innovation has not been evidenced for a long period of time. This research paper offers a new design and manufacturing process of medical device produced via PIM technology. One of the possible cases is a cutting curette used for the removal of adenoid. Up to day, the curette is made from one piece without any possibility to replace the damaged cutting edge which is depreciated by sterilization repeated after each surgery. Thus, the cutting edge after a while should be sharpened. This additional operation leads to economical loss and time consuming.

2 Experimental

Experimental part of this work describes a manufacturing process of a new innovative cutting edge produced via PIM technology. The new proposed design illustrated in Fig. 2 contains three basic parts: holder, main body for cutting edge and cutting edge itself. Dimensions of removable cutting edge are shown in Fig. 3. As it can be seen, the holder allows to change different geometries of main body for a specific shape of a patient oral cavity and main body enables the replacement of a cutting edge for disposal use. In addition, the cutting edge can be easily replaced. The cutting edge itself is produced via PIM technology and the material selected for this application is based on stainless steel (austenitic 316 L) that is most commonly used biomaterial in medical field. Nevertheless, the cutting edge can be also produced from other metals or ceramics. The curette holder is manufactured by traditional method and can be used repeatedly.

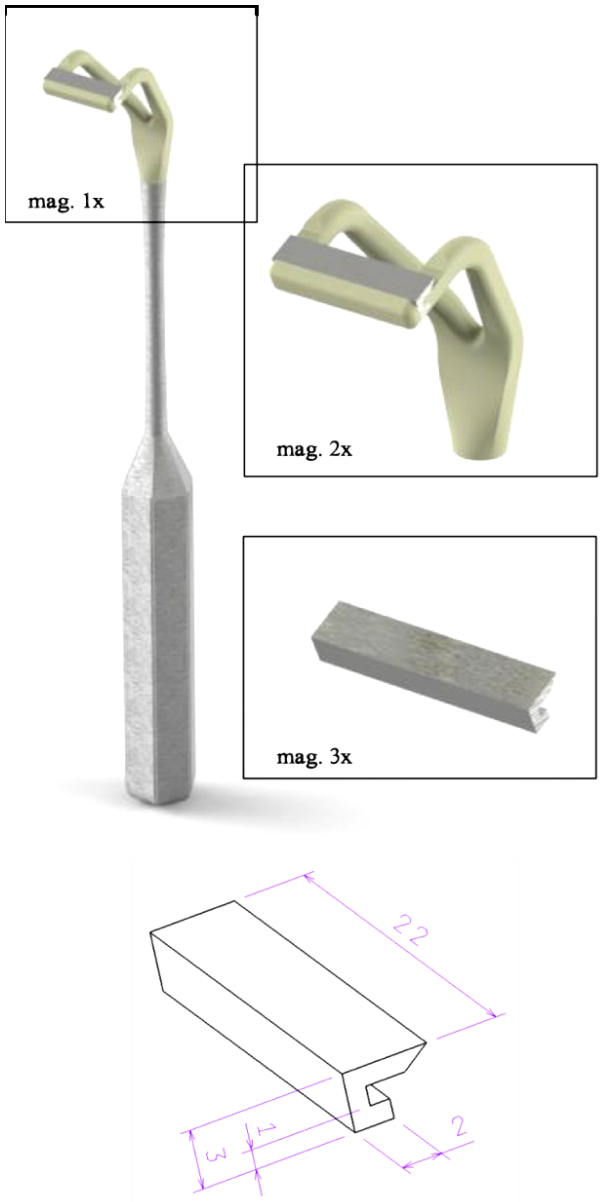

Fig. 2 *Design of curette and dimensions of cutting edge*

2.1 Material

Selected material for the final medical device was the stainless steel 316 L powder. The typical composition of sintered 316 L stainless steel is shows in the Tab. 1 and the final product has density more than 7.75 g/cm^3, yield strength 140 MPa and tensile strength 450 MPa. The selected powder was incorporated in a commercially available PIM feedstock with partially water-soluble binder based on polyolefin and polyethylene glycol. Fig. 3 demonstrates the binder thermal properties obtained from different scanning calorimeter (DSC) under nitrogen atmosphere (30 ml/min) and heating rate 10 °C/min.

Tab. 1 *Typical composition of sintered 316 L*

Element	Fe	C	Ni	Cr	Mo	Mn	Si
wt %	balance	<0.03	10 - 14	16 - 18.5	2 - 3	<2	<1

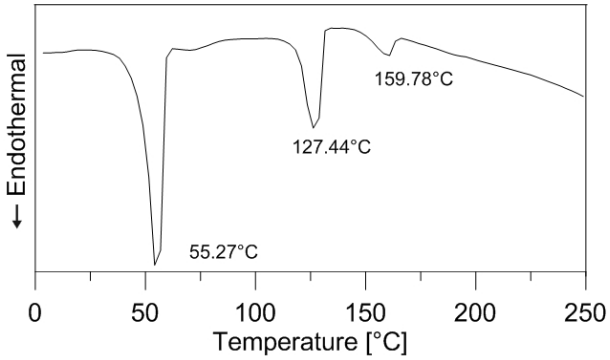

Fig. 3 *Second DSC heating scan of binder system*

2.2 Simulation of mold filling

Simulation of mold filling was done using Moldflow analysis in order to select an appropriate injection gate. For the filling analysis, there were proposed 2 types of runner systems with point gate and film gate. In both cases, the mesh was created from 3D tetrahedron elements with 0.5 mm edge length and injection time was set to 1 s. Distribution of melt inside the cavity is shown in Fig. 4. In case of point gate design, the filling of the cavity started in the centre and afterwards melt was spread out to fulfil the whole cavity. In contrast to this option film gate design ensures more uniform cavity filling.

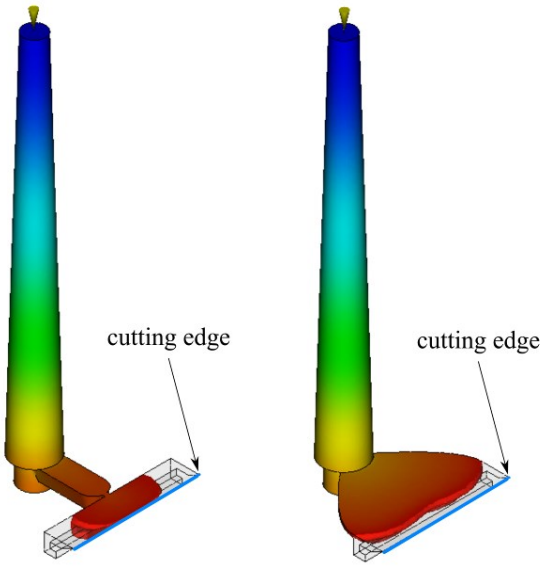

Fig. 4 *Different filling pattern*

Design of two evaluated runner systems demonstrated differences in shear rate. In case of the point gate runner system (Fig. 5a), the maximum shear rate was almost 19,000 1/s. On the other hand, in case of the film gate (Fig. 5b) the maximum shear rate was only 1,500 1/s.

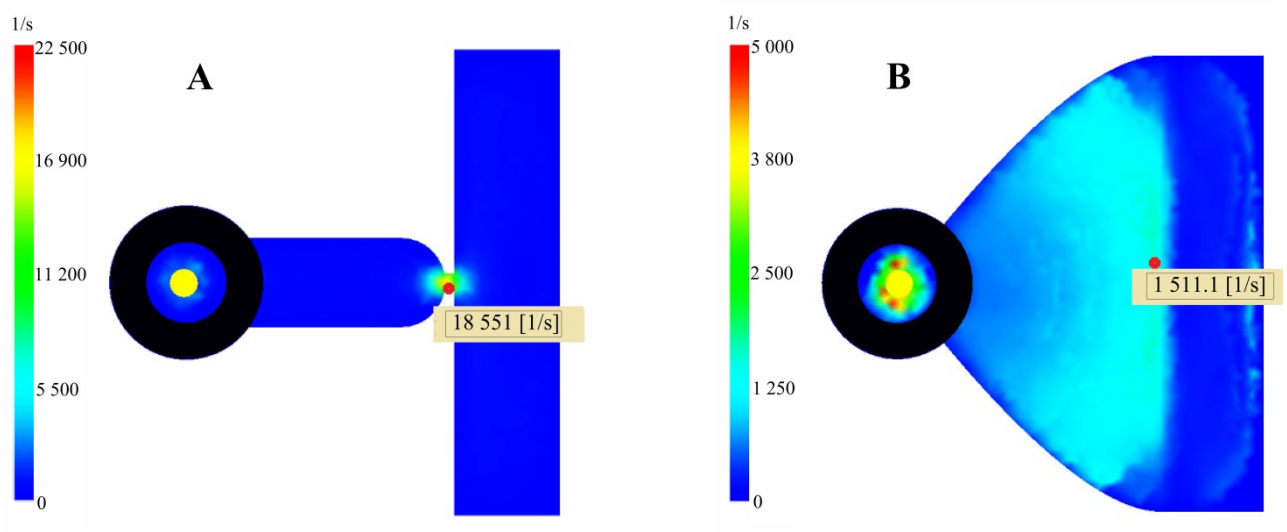

Fig. 5 *Distribution of shear rate (a) in point gate, and (b) in film gate*

2.3 Injection molding

The injection molding step was performed on an injection molding machine Arburg Allrounder 370S (EUROMAP size 700 - 100) with a special surface treatment of the screw for highly filled materials. Screw diameter was 20 mm with an effective screw length (L/D) of 16.7. Design of the mold cavity (Fig. 6) is oversized due to final shrinkage by 18 %. The red part is a core pin, while the blue color represents injected part with runner system. In the Tab. 2 the optimized processing conditions for injection molding are shown.

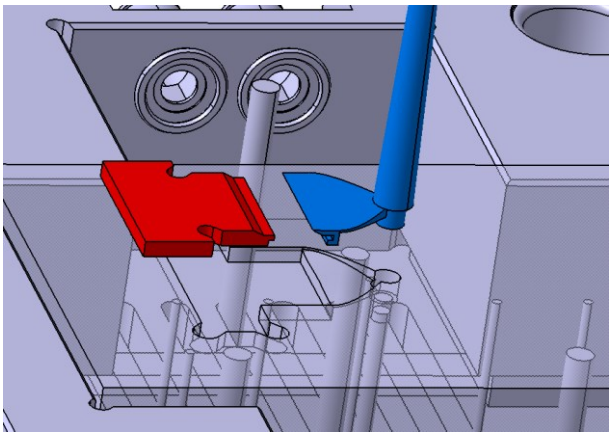

Fig. 6 *Design of mold cavity in CAD software*

Tab. 2 *Injection molding processing parameters*

Temperature		**Injection molding**	
Zone 1 (°C)	170	Injection speed (mm/s)	40
Zone 2 (°C)	175	Injection pressure (bar)	900
Zone 3 (°C)	180	Injection time (s)	0.5
Zone 4 (°C)	183	Hold pressure (bar)	800
Nozzle (°C)	185	Hold pressure time (s)	2
Mold (°C)	40	Cooling time (s)	15

2.4 Debinding

In the next step, the part of water soluble binder component (PEG) was removed in a water bath composed of distilled water and corrosion inhibitor (2 vol. %) at 60 °C. After water debinding the porous-structured components were fragile.

2.5 Thermal debinding and sintering

Sintering furnace CLASIC (Czech Republic) was used for thermal debinding of remaining binder components, which took place as an early stage of sintering process. Fig. 7 demonstrates differences between injected and sintered cutting edge component. The whole process was done under 100 % pure hydrogen atmosphere in three temperature steps:

- 25 °C – 600 °C (3 °C/min), 2 hours hold
- 600 °C – 1.360 °C (3 °C/min), 2.5 hours hold
- 1.360 °C – 80 °C (15 °C/min) cooling

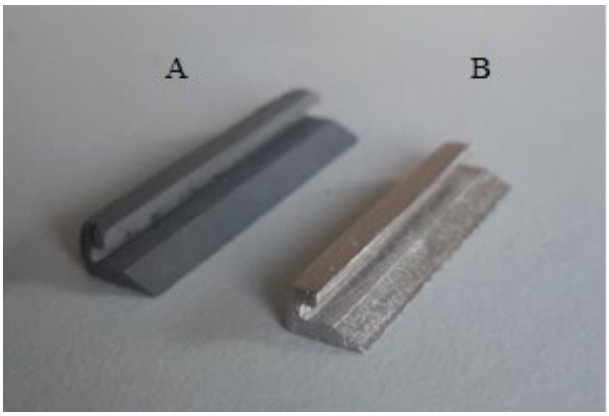

Fig. 7 *Cutting edge after, (a) injection and (b) sintering*

After sintering, the cutting edge should be grinded before use. Fig. 8 demonstrates a scanning electron microscope (SEM) view (magnification 200x) of cutting edge after sintering and after following polishing. For this purpose a diamond particles were used to polish the surface of cutting device.

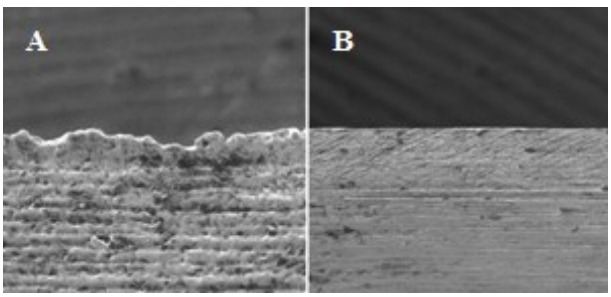

Fig. 8 *Cutting edge after (a) sintering and (b) polishing*

2.6 The real functional model

Fig. 9 shows the real cutting edge inserted in the main body. The main body was made for purpose of the study by rapid prototyping. In the case of real surgery the main body and holder could be made from any suitable material by a conventional method.

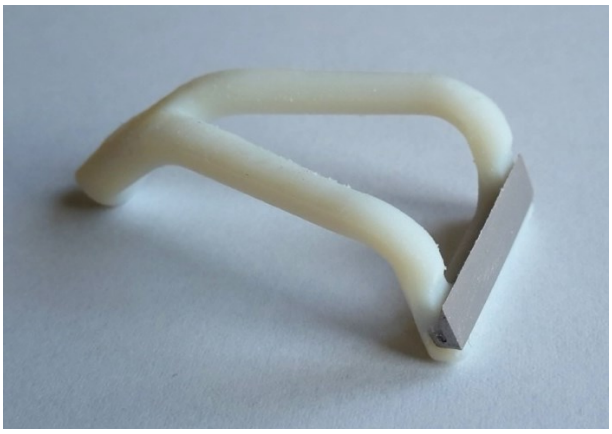

Fig. 9 *Functional model placed in a curette*

3 Conclusion

The implementation of PIM technology in a medical field could bring many new trends. In ENT, the innovative production of cutting curette does not only reduce the development time due to possibility to assembly several separate parts into one, consolidating the mechanical components and reducing the component number. PIM also allows for production of medical devices from a wide range of materials. Cutting curette consisting of several interlocking moving parts is a key to the current medical manufacturing of high volume number of components without the need for costly machining. Due to many outdated medical devices in the ENT field, this market has a high potential for growth. Therefore, the sterile and replaceable cutting edge curette is a promising candidate for a commercial success.

Acknowledgement

This work was supported by the Ministry of Education, Youth, and Sports of the Czech Republic - Program NPU I (LO1504). This study was also supported by the internal grant of TBU in Zlin IGA/FT/2016/002 funded from the re-sources of the specific university research. The authors would like also to thank MUDr. Vladimir Zlinsky who works for Otolaryngology Clinics, Trida T. Bati 3929, 76001 Zlin, Czech Republic for his collaboration, consultations and professional medical advices.

References

[1] GERMAN, R. M, BOSE, A. (1997). *Injection Molding of Metals and Ceramics*. Priceton, New Jersey.

[2] HEANEY, D. F. (2012). *Handbook of metal injection molding*. Woodhead Publishing Limited, Cambridge.

[3] GERMAN, R. M. (2011) *Metal injection molding, A comprehensive MIM design guide*. Princeton, NY.

[4] RAK, Z. S. (1999). New trends in powder injection moulding. *Powder metallurgy and metal ceramics*, vol. 38(4), pp.126-132.

[5] HAUSNEROVA, B. (2011). Powder Injection Molding – An Alternative Processing Method for Automotive Items, *New Trends and Developments in Automotive Systems Engineering*, pp. 130-146.

[6] HAUSNEROVA, B., SANETRNIK, D., PONIZIL, P. (2013). Surface structure analysis of injection molded highly filled polymer melts, *Polymer Composites*, Vol. 34, pp. 1553–1558.

[7] GASBARRE, T.G., JANDESCA, W.F. (1989). *Advances in Powder Metallurgy*, Metal Powder Industries Federation, Princeton, NJ.

[8] HAUSNEROVA, B., MARCANIKOVA, L., FILIP, P., SAHA P. (2011). Optimization of powder injection molding of feedstock based on aluminium oxide and multicomponent water-soluble polymer binder. *Polymer Engineering & Science*, vol. 51(7), pp. 1376-1382.

[9] RATNER, B. D. (2004). Biomaterials Science: *An Introduction to Materials in Medicine*. Academic Pres, Amsterdam.

[10] WILLIAMS, N. (2012). PM2012 World Congress: Special Interest Seminar Reveals Strong Global Growth for PIM, with Asia Leading the Way. *Powder injection moulding international*, vol. 6(4), p.47.

[11] SIDAMBE, A. T., FIGUERO, I. A., HAMILTON, H. G. C., TODD, I. (2012). Metal injection moulding of CP-Ti components for biomedical applications, *Journal of Materials Processing Technology*, vol. 212(7), pp.1591-1597.

[12] NEWELL, M. A., DAVIES, H. A., MESSER, P. F., GREENSMITH, D. J. (2005). Metal injection moulding of scissors using hardenable stainless steel powders, *Powder metallurgy*, vol. 48(3), pp.227-230.