Precision Manufacturing for Medical Implants

N. Salk, B. Tröger, P. Imgrund

Fraunhofer Institute for Manufacturing Technology and Applied Materials Research, Germany

Natalie.Salk@ifam.fraunhofer.de

Introduction

In medical technology it is of extreme importance to manufacture implants and other medical devices cost effectively in series with ultra high precision. The micro powder injection moulding process (μ-PIM), where a great variety of materials can be processed with complex geometries, can be applied for this. In this technology a ceramic or metal powder is mixed with a binder system composed of polymers and waxes. The resulting "feedstock" can thus be injected under temperature in a mould showing the negative structure of the corresponding component. In the case of polymer injection moulding the process is finished after cooling down and demoulding of the component. PIM or μ-PIM however, is followed by a debinding step were the binder is removed from the component. The following sintering step condenses the component up to full density of the respective bulk material. The complete μ-PIM process [1] is illustrated in figure 1.

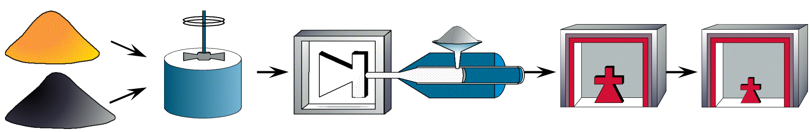

Figure 1: Schematic drawing of the micro powder injection moulding process (μ-PIM) [1]. Here the micro ceramic injection moulding (μ-CIM) process is illustrated.

As examples the series production of polymer Polymethylmethacrylat (PMMA) and ceramic (Al_2O_3) stapes (the reproduction of the smallest bone in the human ear) is presented. The length tolerances for both materials were determined. For this a series of 400 PMMA stapes and 320 ceramic stapes were manufactured. All stapes were characterised in respect to dimensional variations of 6 different positions starting from 270 µm to 2470 µm length. Tolerances of 0.14 to 5 % were obtained, depending on the length of the measured section. Considering this corresponds to absolute numbers of ± 4 – 20 µm, a cost effective series production of medical components and implants without post processing becomes possible for a wide range of applications.

1 Determination of the dimensional tolerances

For the determination of the length tolerances all manufactured polymer as well as ceramic stapes were analysed with an optical macroscope (Leica, objective: Z16APO). Pictures were taken of each part and 6 different positions were defined, L1 to L6 (see figure 2) for measuring the dimensional accuracy. In order to detect the accurate position and to minimise the systematic measurement error it was necessary to integrate ledger lines into the optical macroscope image as indicated on the right of figure 2.

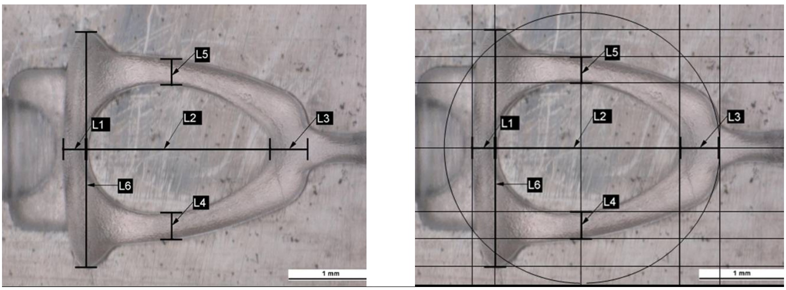

Figure 2: left: Illustration of the 6 positions for determining the length tolerance. Right: Ledger lines to reduce systematic errors.

For both materials it took approximately 40 to 50 injection cycles to reach steady state conditions of the micro injection moulding process. This corroborates with well with the results from Ti stapes analysed in our previous work [2].

1.1 Dimensional tolerances of the PMMA stapes

Table 1 illustrates the dimensional tolerances of the 360 analysed PMMA stapes at the 6 measured positions. The absolute length and standard deviation in % are depicted.

Table 1: Results of the dimensional tolerances of the PMMA stapes

Tolerances of the PMMA stapes						
	L1	L2	L3	L4	L5	L6
Length [µm]	301	2170	467	306	306	2804
Standard deviation [µm]	6	15	13	4	4	4
Standard deviation [%]	**2**	**0.7**	**2.8**	**1.3**	**1.3**	**0.14**

Tolerances of 0.14 % and 0.7 % were obtained for the lengths L6 and L2, respectively. Both length values are in the mm range with extremely good standard deviations, indicating a good reproducibility as well as dimensional control of the component. For these length scales very tight tolerances with a relative low systematic measurement error compared to the absolute length were determined. For the dimensions in the micron range the systematic measurement error has a greater influence on the tolerances, which results in tolerances of 1.3 % to 2.8 %.
Figures 3 and 4 present examples of two different lengths in the micron (L5) and mm (L6) range, respectively.

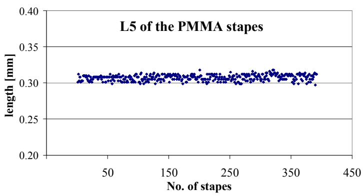

Figure 3: Measurements of the length L5.

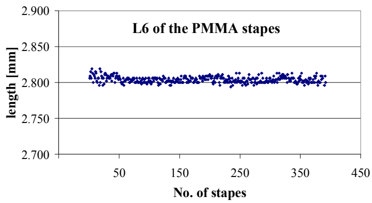

Figure 4: Measurements of the length L6.

1.2 Dimensional tolerances of the Al_2O_3 stapes

The dimensional tolerances of the Al_2O_3 stapes are illustrated in table 2. The green as well as the sintered stapes were evaluated.

Table 2: Dimensional tolerances of the Al_2O_3 stapes before and after sintering.

Tolerances of the Al_2O_3 stapes before and after sintering						
	L1	L2	L3	L4	L5	L6
Length before sintering [µm]	331	2140	440	315	320	2809
Standard deviation [µm]	9	17	14	9	8	14
Standard deviation [%]	**2.7**	**0.8**	**3.2**	**2.8**	**2.5**	**0.5**
Length after sintering [µm]	267	1882	392	273	269	2468
Standard deviation [µm]	9	18	20	7	8	13
Standard deviation [%]	**3.3**	**1.0**	**5.1**	**2.5**	**2.9**	**0.5**

The tolerances of the green stapes before sintering are slightly better than for the sintered stapes. Tolerances of 0.5 % to 5.1 % were obtained for absolute lengths of 267 µm to 2468 µm, see table 2. The length of L3 indicates the highest deviations, due to the fact that the absolute length was defined by the ledger lines, see fig. 2. The measurement error is therefore higher than for the other distances that are clearly defined by the stape edges.

2 Conclusions

A series of PMMA and Al_2O_3 stapes were manufactured and characterised with regards to the dimensional tolerances at 6 positions. The values of the PMMA stapes (0.7 % to 2.8 %) were slightly better than for the Al_2O_3 stapes (0.5 % to 5.1 %). The complex PIM process and the coarse ceramic powder with a mean particle size of 17 µm are responsible for this. Nevertheless standard deviations from 4 to 15 µm for PMMA stapes and 8 to 20 µm for Al_2O_3 stapes indicate an extremely good reproducibility during the micro injection moulding process, see fig. 5. Thus the micro injection moulding is a versatile production process keeping tight tolerances in micro components manufactured from polymers, ceramics, metals or alloys [2].

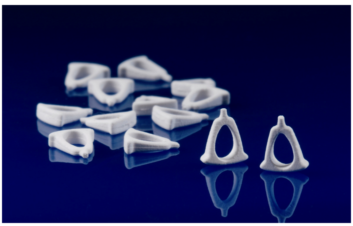

Figure 5: Series of Al_2O_3 stapes.

References:

[1] N. Salk, M. Schlüter, T. Seemann, M. Hoffmann, C. Harms, A. Rota, New Functions for Microfluidic Components by Using Micro Metal Injection Molding (µ-MIM), Chemical Engineering Communications, 194:859-866, 2007

[2] N. Salk, J. Haack, P. Imgrund,” Tolerances in the field of micro metal injection moulding”, Proceedings of the Euspen conference, San Sebastian, Spain, June 2009