Modeling, sensitivity analysis and parameter identification of a twin screw extruder

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Abstract: Following the recent success of hot-melt extrusion in the pharmaceutical field, monitoring and control are increasingly applied. In this study, a mathematical model consisting of mass and energy balance partial differential equations is developed and parameters related to material transportation are inferred from experimental data collected from a pilot plant. This data is relative to the output residence time distribution of active product. Parameter identification is complemented by a parametric sensitivity analysis and the computation of confidence intervals. Direct and cross-validation results demonstrate the good predictive capability of the model, which could probably be exploited for model-based control at a next stage.

Keywords: Mathematical Modeling, Partial differential equations, estimation, pharmaceuticals, process control

1. INTRODUCTION

Hot-melt extrusion is a forming technique well established in the industry since the 19th century. This thermomechanical process implies the transformation of several solid materials into a specific uniform product conveyed through the extruder thanks to the screw rotation [Gerrens (1994)]. Nowadays, more and more forming processes use this technique. Extruded products are numerous and range from metals to plastics through rubbers and clay composites. This method is also increasingly used in the pharmaceutical sector, for instance in drug manufacturing under the form of granules, pellets, tablets or implants [Crowley (2007)]. In this particular context, an active pharmaceutical ingredient (API) is generally heated with a thermoplastic polymer and different excipients like surfactants, salts, super disintegrants, plasticizers and antioxidants can be mixed together [Hughey (2013), Repka (2007)]. The main process complexity in a pharmaceutical context is linked to the strong constraints imposed to product manufacturing. An a priori optimization study of the characteristics and performances is generally achieved [Sarode (2012)], assessing the main physical parameters impacting on the final product quality (typically the temperature, the screw configuration and rotation speed, and the feed rate) [Thiry (2014)].

This work aims at modeling the extruder behavior when mixing a polymeric matrix and a active pharmaceutical ingredient for accurate quality control purpose. To this end, a distributed parameter model, based on mass and energy balance partial differential equations (PDEs), is proposed in the same spirit as [Kulshreshtha (1992)]. The contribution of this work is to consider an actual device made of different screw elements with specific geometry, and to propose appropriate PDE models for each sections complemented by continuity and boundary conditions. This dynamic model is based on several assumptions such as the mono-dimension of the flow, the distinct boundaries between the different screw zones, constant melting product density and specific heat capacity, and negligible heat loss in the screw shafts. Several transportation parameters are then inferred from experimental data. Parameter identification is achieved using the information from the residence time distribution (RTD), as suggested in [Li (2001), Choulak (2004), Baron (2010) and Eitzlmayr (2014)]. A sensitivity analysis is also carried out to analyze the information content of the experimental data.

This paper is organized as follows. Section 2 presents the proposed PDE model. The boundary conditions and rheological evolution laws of the material are discussed. Section 3 is dedicated to an identification procedure using the residence time distribution (RTD) whose degree of informativity about the unknown parameters is assessed by a sensitivity analysis. Experimental validations are achieved in section 4 and the good predictive capability of the resulting model is demonstrated. Conclusions are drawn in section 5.

2. EXTRUDER MODELING

The considered extruder is synthetically schematized by two screws as in Figure 1. The feed flow rate $Q_0$, screw
rotation speed \( N \) and the inlet active product concentration \( C_{\text{in}} \) are considered as the three system inputs while the filling ratio \( f \), pressure \( P \) and the material, barrel and screw temperatures, are considered as system states.

The spatial variation is considered along the \( z \) axis of the extruder screws, and two types of spatial elements are distinguished: elements of volume which are partially filled (conveying material) or completely filled (melting zone).

A PDE model is developed in this work, allowing the subsequent use of any higher-order discretization methods (finite differences, elements or volumes), thus decoupling modeling and numerical simulation.

### 2.1 Mass balances

#### Material Conveying Zone

A conveying zone is partially filled, and consequently, the filling ratio \( f \) is smaller than 1. Material is conveyed thanks to the screw rotation. The evolution of the filling ratio is defined by the following mass balance equation:

\[
\frac{\partial f}{\partial t} = -\frac{V_c N \partial f}{S} \frac{\partial z}{\partial f} + D \frac{\partial^2 f}{\partial z^2}
\]  
(1)

where \( \rho, S, N \) are respectively the material density, the cross section area for material transportation and the screw rotation speed. \( V_c \) is the shear volume and \( D \) is the diffusion coefficient which are considered unknown.

#### Melting Zone

A melting zone is completely filled (i.e., \( f = 1 \)). This occurs if there is a counter-current flow driven by a pressure difference. This flow obeys Poiseuille theory [Booy (1980)]. Inside a melting zone, the total mass flow \( Q_m \) is conserved and is given by

\[
Q_m = \rho V_c N - \frac{K_r}{\eta} \frac{\partial P}{\partial z}
\]  
(2)

where \( K_r \) is an unknown geometrical coefficient and \( P \) the pressure.

The pressure gradient can therefore be calculated as follows:

\[
\frac{\partial P}{\partial z} = \frac{(V_c N - \frac{Q_m}{\rho})}{K_r} \eta(z)
\]  
(3)

### 2.2 Energy balances

In this subsection, energy balance equations are established.

#### Material Temperature:

Energy balance for the material leads to a PDE involving convection, dissipation through viscous friction (Martelli’s theory [Martelli (1983)]) and heat exchange with the barrel and screws:

\[
f \frac{\partial T_m}{\partial t} = -\frac{1}{\rho S} Q \frac{\partial T_m}{\partial z} + \frac{f C_S N^2 \eta}{\xi \rho S C_m^p} + \frac{f U_b l_b (T_b - T_m)}{\rho S C_m^p} + \frac{f U_s l_s (T_s - T_m)}{\rho S C_m^p}
\]  
(4)

where \( C_m^p, T_m, C_S, N, \eta, \xi, U_b, l_b, T_b, U_s, l_s \) and \( T_s \) are respectively the material specific heat, material temperature, viscous zone geometry, screw rotation speed, dynamic viscosity, screw pitch, material/barrel heat exchange coefficient, material/barrel exchange perimeter, barrel temperature, material/screw heat exchange coefficient, material/screw exchange perimeter and screw temperature.

In equation (4), the total mass flow \( Q \) varies according to the filling ratio as

\[
f < 1 : Q = \rho f V_c N - \rho D S \frac{\partial f}{\partial z}
\]  
(5)

in a solid conveying zone and

\[
f = 1 : Q = Q_m
\]  
(6)

in a melting zone.

#### Barrel Temperature:

Energy balance applied to the steel barrel involves heat diffusion and exchange with the outside environment:

\[
\frac{\partial T_b}{\partial t} = \frac{\lambda}{\rho_s C_p S_{\text{steel}}^p} \frac{\partial^2 T_b}{\partial z^2} - U_{\text{ext}} l_{\text{ext}} (T_{\text{ext}} - T_b)
\]  
(7)

where \( \rho_{\text{steel}}, S_{\text{steel}}, C_p^p, \lambda, U_{\text{ext}}, l_{\text{ext}} \) and \( T_{\text{ext}} \) are respectively the steel density, the cross area of the barrel, steel specific heat, steel diffusion coefficient, heat exchange coefficient with outside environment, exchange perimeter and outside temperature.

#### Screw Temperature:

The screw energy balance involves heat diffusion and heat exchange with the material:

\[
\frac{\partial T_s}{\partial t} = \frac{\lambda}{\rho_s C_p S_{\text{steel}}^p} \frac{\partial^2 T_s}{\partial z^2} - f U_s l_s (T_s - T_m)
\]  
(8)

### 2.3 Active pharmaceutical ingredient concentration

The conveying material is composed of several elements. In this study, we assume that the material is a matrix in which an active product is inserted. Mass balancing leads to the evolution of the active pharmaceutical ingredient according to

\[
f \frac{\partial C}{\partial t} = -Q \frac{\partial C}{\partial z} + D \frac{\partial^2 C}{\partial z^2}
\]  
(9)
where \( C \) is the active pharmaceutical ingredient.

2.4 Kneading zone equations

An extruder consists of an arrangement of screw elements with different geometries and kneading elements, which involve rollers and allow an efficient material mixing. It is therefore assumed that these elements are always totally filled \((f = 1)\).

In [Werner (1976)], internal flow is due to a pressure gradient. In this study, as in [Eitzmayer (2014)], Poiseuille’s theory is used to characterize the flows.

\[
Q_k = -\rho K_{rk} \frac{\partial P}{\eta \frac{\partial z}{z}} \tag{10}
\]

where \( Q_k \) is the mixer mass flow and \( K_{rk} \) is a geometrical coefficient related to this flow (index \( k \) corresponds to the kneading zone).

2.5 Initial and Boundary Conditions

- Initial Conditions:

The system is considered in steady state at initial time.

- Boundary Conditions:

Boundary conditions are expressed at the inlet and outlet of the extruder, as well as at the edge between a partially and a completely filled zone. Indeed, these zones have different model structures according to the filling ratio. The system is therefore decomposed into subsystems, for which boundary conditions are expressed.

\[
z = 0 : f = f_0; P = P_0; T_m = T_{ext}; \frac{\partial T_b}{\partial z} = \frac{\partial T_x}{\partial z} = 0; C = C_{in} \tag{11}
\]

\[
z = l_{pc} : f = f_{pc}; P = P_0; T_m = T_{mpc}; T_b = T_{bpc}; T_x = T_{xpc}; C = C_{pc} \tag{12}
\]

\[
z = L : f = 1; P = P_{end}; T_m = T_{mend}; \frac{\partial T_b}{\partial z} = \frac{\partial T_x}{\partial z} = \frac{\partial C}{\partial z} = 0 \tag{13}
\]

The \( pc \) index corresponds to the boundary between a partially and completely filled zone. \( L \) is the extruder length.

Continuity conditions between two screw elements are:

\[
(\rho f V_r N - \rho DS \frac{\partial f}{\partial z})^+ = (\rho f V_r N - \rho DS \frac{\partial f}{\partial z})^- \tag{14}
\]

\[
P^+ = P^- \tag{15}
\]

\[
T^+_m = T^-_m \tag{16}
\]

\[
T^+_b = T^-_b; \frac{\partial T_b}{\partial z} = \frac{\partial T^-_b}{\partial z} \tag{17}
\]

\[
T^+_x = T^-_x; \frac{\partial T_x}{\partial z} = \frac{\partial T^-_x}{\partial z} \tag{18}
\]

\[
C^+ = C^-; \frac{\partial C}{\partial z} = \frac{\partial C^-}{\partial z} \tag{19}
\]

As in [Choulak (2004)], the extruder output is comparable to a tube in which a Poiseuille flow is considered:

\[
Q_{end} = \rho K_f (P_{end} - P_0) \tag{20}
\]

where \( Q_{end} \) is the extruder outlet flow, \( P_{end} \) is the outlet pressure and \( K_f \) is the output geometrical constant obtained as:

\[
K_f = \frac{\pi R_f^4}{8 L f \eta_{end}} \tag{21}
\]

where \( R_f \) is the output radius, \( L_f \) its length and \( \eta_{end} \) the output material dynamic viscosity.

- Moving interface equation:

A last variable that should be determined is the melting zone length (completely filled zone). In this work, the approach suggested in [Kulshreshtha (1992)] is followed, where a mass balance allows to calculate the quantity of material filling a solid conveying zone.

\[
S(1 - f_{pc}) \frac{\partial l_m}{\partial t} = Q_{pc} - Q_m \tag{22}
\]

where \( f_{pc} \) is the boundary filling ratio, \( l_m \) the melting zone length and \( Q_{pc} \) the boundary mass flow.

The melting zone length can be calculated following:

\[
\frac{\partial l_m}{\partial t} = \frac{Q_{pc} - Q_m}{S(1 - f_{pc}) \rho} \tag{23}
\]

Equation (23) applies at the extruder output and the kneading zone input (see figure 1).

2.6 Dynamic viscosity

Rheological properties of material are generally assumed to be such that the density \( \rho \) is constant but the dynamic viscosity \( \eta \) varies all along the extruder screws. Yasuda-Carreau’s law, often used in previous works (see, for instance, [Carneiro (2000), Choulak (2004) and Khalifeh (2005)]), is chosen to represent this variability:

\[
\eta = \eta_0(1 + (\lambda \dot{\gamma})^a)^{[\frac{n-1}{a}]} \tag{24}
\]

where \( \eta_0(t) \) is the viscosity without shearing, \( \lambda \) the characteristic matrix time constant, \( \dot{\gamma} \) the shear rate, \( a \) the Yasuda parameter and \( c \) the pseudo-plastic index. Most of these parameters can be determined with respect to the matrix properties that are generally a priori known. The dynamic viscosity without shearing \( \eta_0(t) \) is also varying with the material temperature following an Arrhenius law:

\[
\eta_0(t) = \eta_0 e^{(-b T_m)} \tag{25}
\]

3. PARAMETER IDENTIFICATION

Equations from 1 to 25 describing the dynamic model contain several model parameters. While the thermal properties are known, geometrical parameters such as \( V_r \) and \( K_r \) as well as the diffusion coefficient \( D \) (considered constant along the device) are a priori unknown. Figure 2 shows the role of 7 model parameters in the extruder configuration with 3 different screw elements (as parameters of the building pressure elements are assumed the same, the unknown parameters reduce to 5 \( (V_{c4} = V_{c2} \text{ and } K_{c4} = K_{c2}). \) Note that there is no counter-pressure flow in the conveying element, i.e. the parameter \( K_{r1} \) is not used.
3.1 Residence time distribution (RTD)

A possible source of information to estimate unknown parameters is measurement of the residence time distribution (RTD) of a specific component. As a reference, a tracer is injected via an input pulse when the system is assumed to be in steady-state. The concentration RTD is normalized in equation (27), where $E(t)$ is the residence time distribution and $c(t)$ the tracer concentration evolution at the extruder output.

$$E(t) = \frac{c(t)}{\int_0^t c(t)dt}$$  (26)

3.2 Parameter identification

Parameter identification is a difficult task since it exploits measurement signals corrupted by noise, resulting in uncertainties on the identified parameter values. Moreover, physical variations of parameters could occur, adding another source of uncertainty and degrading the predictive capability of the model. In this work, a simple least-square criterion measuring the deviation between experimental data collected from the pilot plant and model state trajectories is minimized as in:

$$J(\theta) = \sum_{i=1}^{n_m} \sum_{j=1}^{n_x} \left((x_{ij}(\theta) - x_{meas,ij}(\theta))^T (x_{ij}(\theta) - x_{meas,ij}(\theta))\right)$$  (27)

where $\theta$ is the parameter vector, $x_{ij}$ the $j^{th}$ output state variable at time $i$ and $x_{meas,ij}$ the corresponding output experimental measurements. In equation (27), $n_m$ measurements and $n_e$ experiences are considered.

3.3 Sensitivity analysis

The accuracy of the parameter set heavily depends on the information content of the experimental data, and the influence of the parameters on the measured variables. A sensitivity analysis is therefore useful in order to assess the consequence of parameter variations on model predictions. Starting from the general expression of a partial differential equation (PDE) model:

$$\frac{\partial x_i}{\partial t} = f_i(x, \theta)$$  (28)

the sensitivity of a state $x_i$ with respect to parameter $\theta_j$ can be expressed as:

$$S_{x_i, \theta_j} = \frac{\partial x_i}{\partial \theta_j}$$  (29)

Equation (29) requires the analytical expression of the states evolution following an API pulse experiment. Numerical solvers are a solution to this problem but equation (29) needs to be first rewritten in the following form:

$$\frac{\partial S_{x_i, \theta}}{\partial \theta} = \frac{\partial f_i(x, \theta)}{\partial \theta} = \theta \frac{\partial (\frac{x_{max}}{x_i})}{\partial \theta} = \theta \frac{S_{x_i, \theta}^{norm}}{x_{max}}$$  (31)

where $\theta^{norm}$ is the nominal parameter value.

3.4 Simulation study

In the simulation study, realistic operating conditions (i.e., comparable to the experimental ones) are considered: the system is assumed to be in steady-state at a specific operating point, an active product concentration pulse is injected and the resulting output is measured at the die. The experiment is repeated for different operating points in order to cover a sufficiently wide experimental field (in order to collect sufficiently informative data). To assess data information content (or parameter identifiability), a parametric sensitivity analysis is first achieved for each considered operating point (see Table 1). Figures 3 and 4 show the state sensitivities evolution for runs 1 and 6. Comparable results are obtained for the other runs. Obviously, the filling ratio $f$ and the material temperature $T_m$ are totally insensitive to the parameter variations, i.e. no information on the parameters is carried by those output profiles. Pressure $P$ displays constant sensitivity profiles for some of the model parameters. Unfortunately,
practical limitations occur when measuring the pressure in an experimental context: when applying operating conditions of Table 1 to the real plant, very small pressure variations are observed (pressure oscillating between 4.8 and 5 bar), meaning that even if this signal could theoretically be informative, no practical information can be drawn from it. The most interesting profiles are relative to the active product concentration: sensitivity variations are observed with respect to all parameters, i.e. this measurement is globally informative about the whole parameter set. The active product also appears to be the only informative state about $V_{c1}$.

This study leads to the conclusion that the output API is the most reliable signal in view of parameter identification. RTD, as suggested in subsection 3.1, will form the required data set.

4. EXPERIMENTAL RESULTS

This section is dedicated to parameter identification based on 6 experimental runs achieved on a pilot extruder, following operating conditions shown in Table 1. Different constant levels (i.e., the system is assumed to be in steady state since the beginning) of the rotation speed $N$ (RPM) and the feed rate $F_0$ (kg/h) are chosen (see Table 1). Once the system reaches steady-state, an API pulse of 0.085 kg/h is added and, for each experiment, RTD is measured using a colorimetric technique (API is actually replaced by iron oxide, see [Kumar (2006)]) with a sampling period of 4 s. However, for the sake of clarity in the next figures, measurements are represented every 32 s.

Table 1. Operating conditions for the 6 runs

<table>
<thead>
<tr>
<th>Run</th>
<th>$N$ (RPM)</th>
<th>$F_0$ (kg/h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>50</td>
<td>0.144</td>
</tr>
<tr>
<td>2</td>
<td>75</td>
<td>0.2724</td>
</tr>
<tr>
<td>3</td>
<td>100</td>
<td>0.3576</td>
</tr>
<tr>
<td>4</td>
<td>100</td>
<td>0.3576</td>
</tr>
<tr>
<td>5</td>
<td>100</td>
<td>0.3576</td>
</tr>
<tr>
<td>6</td>
<td>150</td>
<td>0.5576</td>
</tr>
</tbody>
</table>

4.1 Direct and cross validation

The 6 experimental data sets is partitioned for direct and cross validation. Parameter identification is achieved using runs 1, 2, 4, 6 and runs 3, 5. The minimization of the cost function (equation (27)) is performed using the `fminsearch` optimizer, implementing a Nelder-Mead algorithm [Gao (2012)] in MATLAB environment. This algorithm is local but generally more robust in the presence of local minima than gradient-based techniques. The absolute confidence interval at 95 % is also shown in Table 2 and is calculated on the basis of the Fisher Information Matrix (FIM) containing the state sensitivities with respect to the identified parameters. Standard deviations of parameter estimations can be obtained as follows:

$$
\sigma_{est} = \sqrt{FIM^{-1}}
$$

Table 2. Model parameter values and corresponding absolute confidence intervals

<table>
<thead>
<tr>
<th>Model parameter</th>
<th>Identified value</th>
<th>absolute confidence interval at 95 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>$V_{c1}$ (m/s)</td>
<td>$2.34 \times 10^{-8}$</td>
<td>$\pm 6.35 \times 10^{-9}$</td>
</tr>
<tr>
<td>$V_{c2}$ (m/s)</td>
<td>$6.96 \times 10^{-9}$</td>
<td>$\pm 5.11 \times 10^{-10}$</td>
</tr>
<tr>
<td>$K_{r1}$ (m/s)</td>
<td>$9.72 \times 10^{-11}$</td>
<td>$\pm 6.41 \times 10^{-12}$</td>
</tr>
<tr>
<td>$K_{r3}$ (m/s)</td>
<td>$2.24 \times 10^{-10}$</td>
<td>$\pm 3.22 \times 10^{-11}$</td>
</tr>
<tr>
<td>$D$ (m²/s)</td>
<td>$6.64 \times 10^{-6}$</td>
<td>$3.31 \times 10^{-7}$</td>
</tr>
</tbody>
</table>

Obviously, $V_{c2}$, $K_{r2}$ and $D$ are accurately identified (the relative confidence interval is around 6 – 7 %) while the two remaining parameters have more uncertainties. $V_{c1}$ presents a relative confidence interval of 27 %.

Table 3. Quantitative assessment of direct and cross validation, respectively for runs 1, 2, 4, 6 and runs 3, 5

<table>
<thead>
<tr>
<th>Run</th>
<th>Mean-square residuals</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>$1.25 \times 10^{-1}$</td>
</tr>
<tr>
<td>2</td>
<td>$1.71 \times 10^{-1}$</td>
</tr>
<tr>
<td>3</td>
<td>$1.12 \times 10^{-4}$</td>
</tr>
<tr>
<td>4</td>
<td>$2.26 \times 10^{-4}$</td>
</tr>
<tr>
<td>5</td>
<td>$3.80 \times 10^{-4}$</td>
</tr>
<tr>
<td>6</td>
<td>$3.38 \times 10^{-4}$</td>
</tr>
</tbody>
</table>

A first qualitative assessment of the direct validation can be observed in Figures 5 and 6 where the evolution of the model trajectories are in accordance with the experimental measurements. The resulting cost function (equation (27)) equal to $8.6 \times 10^{-4}$ confirms anyway the good identification accuracy. From a more quantitative point of view, Table 3 shows the mean-square residuals between the model and the measurements for each run separately and supports the previously drawn conclusions on the global quality of the results. Confidence intervals at 95 % are represented for each measurement in Figures 5 and 6, and are calculated on the basis of the a posteriori measurement error variances:

$$
\sigma_{exp}^2 = \frac{J}{M - P}
$$

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where $\sigma_{exp}$ is the measurement standard deviation, $J$ the final cost function value, $M$ the state number and $P$ the parameter number.

5. CONCLUSION

A distributed parameter model is develop to represent a pilot plant extruder. This model is based on mass and energy balances to represent the variations of variables such as filling ratio, pressure, material temperature, barrel temperature and screw temperature. The extruder has two kinds of spatial zones, some which are partially filled (solid conveying) and others which are completely filled (melting). This aspect is taken into account in the model by defining subsystems supplement by the appropriate boundary conditions. An identification procedure of the screw geometrical parameters and the diffusion coefficient is proposed in order to predict the behavior of a real pilot plant extruder. To this end, a sensitivity analysis of the model outputs with respect to the unknown parameters is achieved. The residence time distribution of the active product appears to be an informative signal and the experimental study confirms this observation. 6 experiments are achieved at different operating conditions, and are subdivided in an identification (and direct validation) set and a cross-validation set. The good results obtained in direct validation are confirmed by the predictive capability of the model in cross-validation. However, the accuracy of our dynamic model can be discussed since it only concerns the reproduction of the RTD using simple screw geometries. Moreover, only data in steady state are used and transient experiments should be performed to ensure that all dynamic effects are correctly modeled.

ACKNOWLEDGEMENTS

This paper presents research results of the Belgian Network DYSCO (Dynamical Systems, Control, and Optimization), funded by the Interuniversity Attraction Poles Programme, initiated by the Belgian State, Science Policy Office. The authors acknowledge the support of the WB-Green MYCOMELT project in the convention n° 1217716, achieved in collaboration with the University of Liege (ULg). The scientific responsibility rests with its author(s).

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