Robot-Assisted Bone Cement Injection

Nicole LEPOUTRE, Laurence MEYLHEUC, Gabriela I. BARA, François SCHMITT, Laurent BARBÉ and Bernard BAYLE
ICube - University of Strasbourg - UMR 7357 CNRS - INSA Strasbourg
1, place de l'Hôpital, 67091 Strasbourg - Tel : +33 (0)3 88 11 91 11
Contact: nlepoutre@unistra.fr

Percutaneous vertebroplasty is a minimally invasive intervention that involves injecting bone cement, under fluoroscopic guidance, into the vertebral body [1]. It consolidates the fractured vertebra and reduces pain [2]. However, some drawbacks must be considered. The major difficulties are related to the cement that is injected during its polymerization phase. It is very liquid at the beginning of the injection, which introduces a high risk of leakage outside the vertebra and, thus, potential severe complications [3]. During the injection, the reaction progresses and the cement hardens suddenly, leaving a short working phase. Finally, the operator is permanently exposed to X-rays. Our work aims to provide a new teleoperated injection device with haptic feedback that allows a fine supervision of the cement injection by including a viscosity control system. The aim of this abstract is to prove the ability of computing the bone cement viscosity on the injection device.

1 Bone cement rheology

1.1 Rheological study

During its exothermic polymerization reaction, orthopedic bone cement shows a complex behavior, which mainly depends on shear rate $\dot{\gamma}$, time t and temperature T. To understand and quantify these dependencies, a rotational rheometer study has been performed for Osteopal V® bone cement. As an example, Figure 1 shows the complex viscosity evolution over time at 20 °C where the shear rate, ranging from $0.1 \times 2\pi\ \mathrm{s}^{-1}$ to $15 \times 2\pi\ \mathrm{s}^{-1}$, has been changed from one trial to another. These experiments have been repeated for other temperatures going from 10 °C to 37 °C.

1.2 Identified model

Based on the acquired data, an original rheological model has been identified. The most widespread model for characterizing these pseudoplastic fluids is the Ostwald – de Waele law [4], which gives the following relationship between viscosity η and shear rate $\dot{\gamma}$:

$$\eta\left(\dot{\gamma},t\right) = K(t)\dot{\gamma}^{n(t)-1} \tag{1}$$

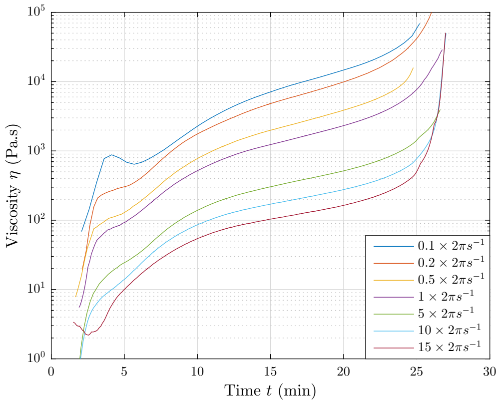

Figure 1 – *Evolution of viscosity along time from mixing at* $T_0 =$ 20 °C *for several shear rates.*

where K represents the flow consistency in $\mathrm{Pa \cdot s^n}$ and $n \in [0;1]$ is the flow index of the sample. According to the literature [5, 6], this well-known law is valid for acrylic bone cements, from the mixing to the end of the injection.

In order to consider all three dependencies, this model has been improved as follows:

$$\eta\left(\dot{\gamma}, a_{T_{\mathrm{ref}}\to T}t, T\right) = b_{T_{\mathrm{ref}}\to T} K(t, T_{\mathrm{ref}})\, \dot{\gamma}^{n(t,T_{\mathrm{ref}})-1} \tag{2}$$

with $T_{\mathrm{ref}} = 20\ ^\circ\mathrm{C}$ the chosen reference temperature. In the same way, $K(t,T)$ and $n(t,T)$ can be express as a function of $K(t,T_{\mathrm{ref}})$ and $n(t,T_{\mathrm{ref}})$ respectively. At T_{ref}, the flow index n has been identified as a linear function of time and the flow consistency K as a sum of two exponential functions. Parameters $a_{T_{\mathrm{ref}}}$, a scale factor, and $b_{T_{\mathrm{ref}}}$, a shift factor, follow the known Arrhenius law [7]. The corresponding activation energies have been identified by solving the optimization problem that shifts the fitting of equation (2) to the curves acquired on the rotational rheometer. This curve fitting problem has been solved by applying a nonlinear least-squares solver. This identified model will be beneficial to validate the online viscosity estimation (see Section 3). In a future work, it will be exploited to design an appropriate controller for an effective viscosity control.

2 S-Tronic injection device

2.1 Injection device

A new injection device has been developed in order to provide a reliable setup that preserves the current procedure conditions while addressing the issues of vertebroplasty interventions. Therefore, the injection of cement with a high viscosity, the measurement of the injection parameters and the teleoperation of the system were the main considered goals throughout the design of the system. Illustrated in Figure 2, the injection device is based on a syringe pusher. Thanks to the control of the servo-motor, the carriage in translation imposes the speed of the piston which pushes the cement from the syringe of radius R_s inserted in a sheath, into the treated vertebra via the needle. In order to control the flowing bone cement temperature, a dedicated heat exchanger has been implemented. It is composed of a central regulated block on which are fixed symmetrically two stacks including a Peltier module, a heat sink and a fan.

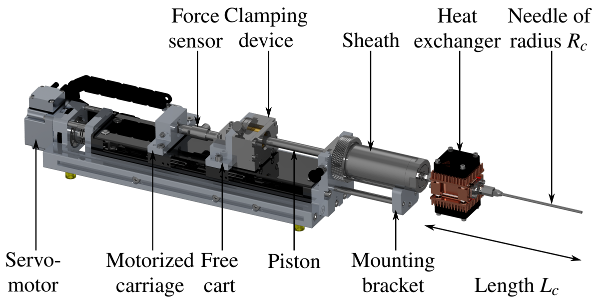

Figure 2 – *CAD view of the injection device.*

A haptic interface has also been designed in order to provide the practitioner with force feedback resulting from the cement hardening.

2.2 Online viscosity estimation

In order to estimate the online viscosity, our approach assumes that the bone cement behavior can be described by equation (1). Since the flow involved in the injection can be assimilated to a Poiseuille flow, the principle of mass conservation coupled to the resolution of the Navier-Stokes equation provide the following relationship over time between the pressure drop ΔP and the flow rate Q:

$$Q(t) = \left(\frac{\Delta P(t)}{2K(t)L_c}\right)^{\frac{1}{n(t)}} \frac{\pi n(t) R_c^{3+\frac{1}{n(t)}}}{3n(t)+1} . \qquad (3)$$

An adapted instrumentation has been included to the injection device as depicted in Figure 2. A linear position sensor has been mounted on the carriage, which allows to measure its position and, thus, to compute the bone cement flow rate Q. The force sensor in the transmission provides the measurement of the injection force F, which helps to assess the pressure drop as $\Delta P(t) = F(t)/(\pi R_s^2) - P_{\text{atm}}$. This implies the assumption that the bone cement flows out at atmospheric pressure P_{atm}.

According to the offline identification of the Ostwald-de Waele law, K is by far the most influencing parameter on the viscosity evolution. For the online viscosity computation, the flow behavior index n is supposed to be a known linear function of time. With this hypothesis, K can be computed through equation (3) and the appropriate instrumentation. Viscosity is finally estimated by evaluating equation (1) where, according to the framework of the medical application, the highest shear rate $\dot{\gamma}_w$, is reached at the fluid domain wall.

3 Results and conclusion

Two experiments have been performed with the device in conditions similar to the ones of an Interventional Radiology room. The temperature set point has been fixed at 24 °C with the heat exchanger. At the outlet of the needle, the bone cement flows into a L5-phantom vertebra, either hollow (experiment 1) or with a cancellous insert (experiment 2). This foam simulates the bone tissue inside a human vertebral body, which renders the cement spread more complex. In Figure 3, the method developed in section 2.2 has been applied to compute the parameter K over time for both experiments. Moreover, the offline identified function describing K, at the same temperature, has been superimposed on this figure (dashed purple curve).

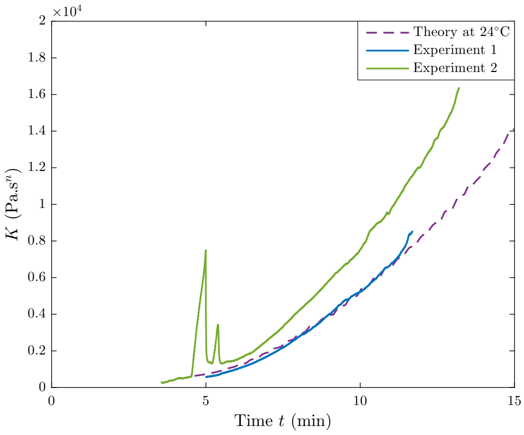

Figure 3 – *Evolution of the parameter K of the power law for two experiments.*

The blue curve that outlines experiment 1 is very close to the one identified offline, which shows that the flow consistency K and, thus, the viscosity can be computed online with an appropriate instrumentation. For the second experiment, one can notice two sharp peaks because of the formation of a plug at the needle tip, which is a common phenomenon during vertebroplasty procedures. Moreover, the distortion between both experiments questions the assumption of the bone cement outlet at atmospheric pressure.

In conclusion, the proposed estimation of the bone cement viscosity online by settling its temperature allows us to progress towards our goal, which is to manage the cement viscosity during the injection thanks to a suitable temperature control. Such a control will allow to address the issues of bone cement leakages and short working time.

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