AUTOINJECTOR DESIGN ADJUSTMENT TO CONTROL NEEDLE INSERTION AND INJECTION SPEED

Pascal Dugand, Technology Product Manager, Nemera, relates a study conducted by Nemera to determine a way to optimise the transition from needle insertion to syringe emptying for parenteral devices. This piece was originally presented as a poster at PDA Vienna 2017.

INTRODUCTION

Subcutaneous is a common route of administration for parenteral drug delivery. Injection is performed by patients or healthcare professionals using syringes or other delivery devices, such as autoinjectors. Due to the increasing number of marketed and in development biologics, more treatments require subcutaneous injection of a larger dose, greater than 1 mL.

It is observed that larger doses of viscous formulations lead to higher viscous back forces. Usage of higher energy levels to deliver viscous formulations could result in higher shocks on the syringe, especially at the end of syringe insertion and start of syringe emptying.

Controlling needle insertion speed can reduce these shocks. Lowering this shock will allow a smooth transition to syringe emptying.

OBJECTIVE

Nemera conducted a study with the objectives to:

• Estimate needle insertion speed and energy level transmitted to the syringe by calculation.

• Propose a practical way to optimise injection devices allowing smooth transition between needle insertion and syringe emptying, especially for viscous, large dose formulations and thin needles.

METHOD

Firstly, the theoretical calculation approach was based on a 2.25 mL syringe. Insertion speed, and energy transmitted to the syringe were calculated.

In the case of stiff spring usage, it is possible to lower the speed and energy by:

• Specific cam profile for needle insertion
• Using a counter spring back force.

In a second step, tests were performed to verify the theoretical calculation approach (Figure 1).

THEORETICAL APPROACH

First part of calculation is aiming to predict needle speed during the insertion phase. After this phase, the plunger pusher is colliding with the plunger rod and injection begins. Calculations are based on the models shown in Figures 2-4 and the equations:

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Figure 1: Injection sequences for injection force measurements.

$$\begin{cases} m.\dfrac{\partial^2 \lambda}{\partial t^2} = -z.k + F_z \text{ Translation on } \vec{z} \text{ axis } Eq_1 \\ J.\dfrac{\partial^2 \theta}{\partial t^2} = R.F_\theta \qquad \text{Rotation on } \vec{z} \text{ axis: } \quad Eq_2 \end{cases}$$

With:

- J, inertia of parts in rotation,
- R, radius of the cam shaft
- m, mass of translating part
- k, stiffness of the equivalent spring
- λ, distance from equilibria position $\lambda = (L0 - z)$.

Friction was not taken into account.

With the equation of the cam:

$$\begin{cases} \theta(z) = f\big(z(t)\big) \ Eq_3 \\ F_\theta = F_z.\dfrac{\partial z}{R.\partial\theta} \quad Eq_4 \end{cases}$$

By combining the three previous equations:

$$m.\frac{\partial^2 \lambda}{\partial t^2} = -\lambda.k + J.\frac{\partial^2 \theta}{\partial t^2}.\frac{\partial\theta}{\partial z} \ Eq_1 + Eq_2 + Eq_4 \Rightarrow Eq_5$$

The final differential equation is:

$$m.\ddot{z} = J.(f'(z).\ddot{z} + f''(z).\dot{z}^2).f'(z) - \lambda.k$$
$$Eq_5 + Eq_3 \Rightarrow Eq_6$$

Solving this differential equation by numerical calculation provides solutions for the axial position and axial speed at each step of needle insertion stroke. Figure 5 shows that the device with a cam shaft shows a 23% theoretical reduction of needle insertion speed.

PRACTICAL APPROACH

Physical tests were then carried out and the results compared with the theoretical approach.
Test sample properties:

- 2.25 mL
- 27G ½" TW
- Filled with water
- 30N drive spring.

Needle insertion speed was measured with a camera:

- Without cam: up to 3.5 m/s
- With cam: 0.9 m/s.

Compared with the theoretical calculation, the needle insertion speed decreased due to friction in prototype parts, not considered in the mathematical model.
Without a cam, jetting is observed at the start of injection. This jetting can be explained by the high impact energy
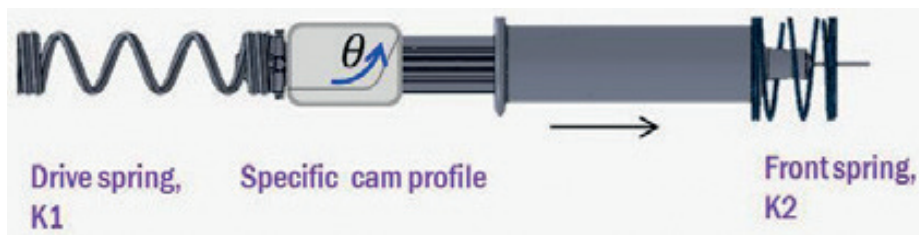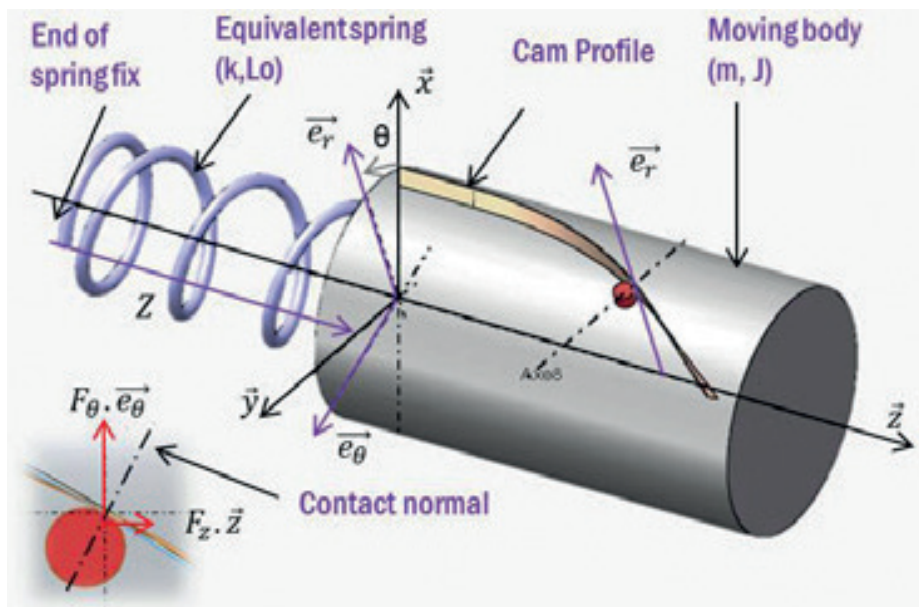

Figure 2: Real model.

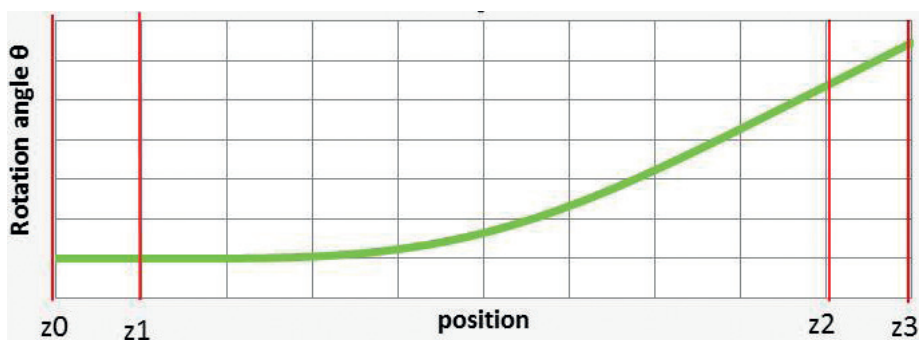
Figure 3: Mathematical model.
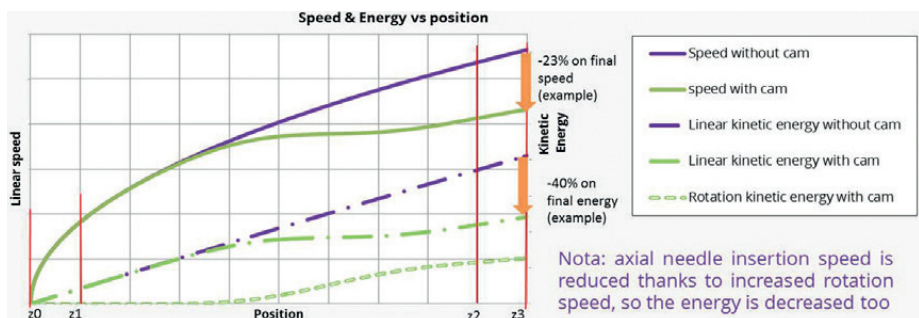

Figure 4: Rotation angle by syringe position.

Figure 5: Needle insertion speed and energy, with and without a cam.

transmitted by the plunger rod to the plunger stopper at start of injection, once the needle is inserted.

With a cam, jetting is not observed at the start of injection. This can be explained by the lower impact energy transmitted by

the plunger rod to the plunger stopper at the start of injection.

CONCLUSION

- Needle insertion speed profile can be tailored to minimise the shock on a syringe, which can consequently reduce initial peak injection flow.
- New generations of autoinjectors have to deliver larger volumes, often of highly viscous formulations. Controlling needle insertion speed is a way to have a smoother transition to injection.

ABOUT THE COMPANY

Nemera is a world leader in the design, development and manufacturing of drug delivery devices for the pharmaceutical, biotechnology and generics industries.

Nemera's services and products cover several key delivery routes:

- Parenteral (autoinjectors, pens, safety devices & implanters)
- Ophthalmic (multidose, preservative-free eyedroppers)
- Nasal, buccal, auricular (pumps, valves and actuators for sprays)
- Inhalation (pMDIs, DPIs)
- Dermal and transdermal (airless & atmospheric dispensers).

ABOUT THE AUTHOR

Pascal Dugand graduated as a Polymer Engineer from EAHP (Strasbourg, France). He holds a Master's in Polymer mechanics and joined Plastic Omnium in 1990 where he started in Development and Innovation. In 2004, the medical division of Plastic Omnium was acquired by Rexam, and more recently the four drug delivery devices plants, including the Innovation Centre became Nemera. Today, Mr Dugand is an experienced medical device developer engineer specialised in the development of parenteral drug delivery devices. He worked on the development of Nemera's own IP products, including the Safe'n'Sound® safety device and Safelia® autoinjector, as well as working on several customer injectable product developments.
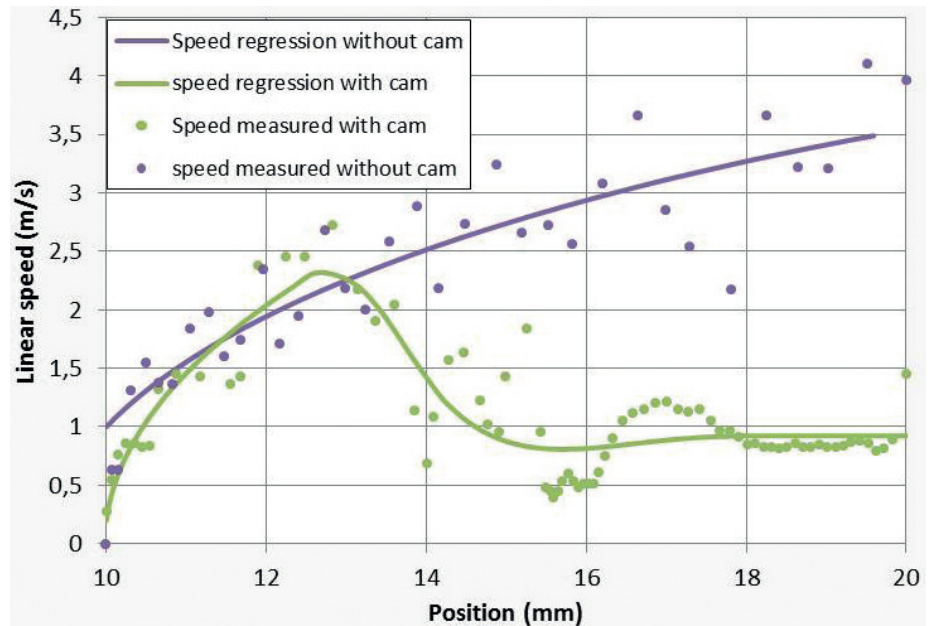

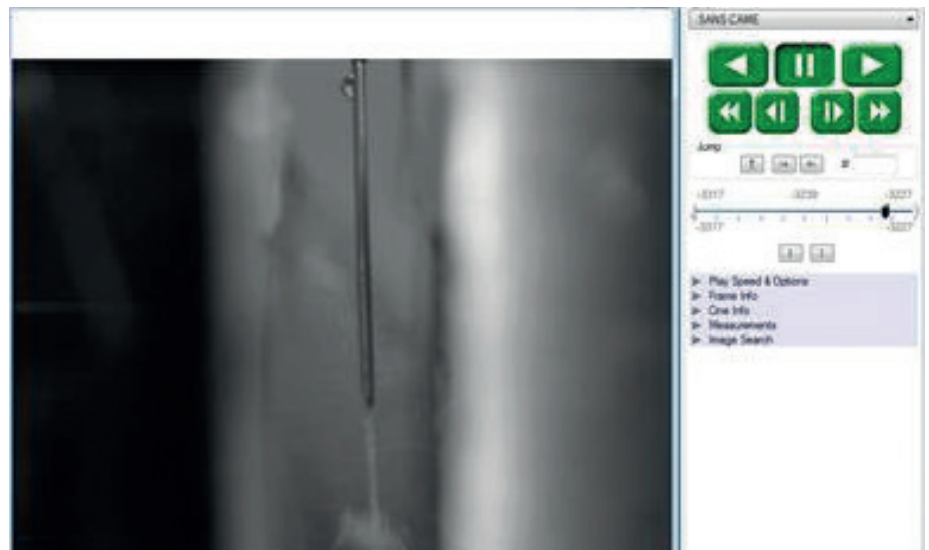Figure 6: Measured needle insertion with and without a cam.

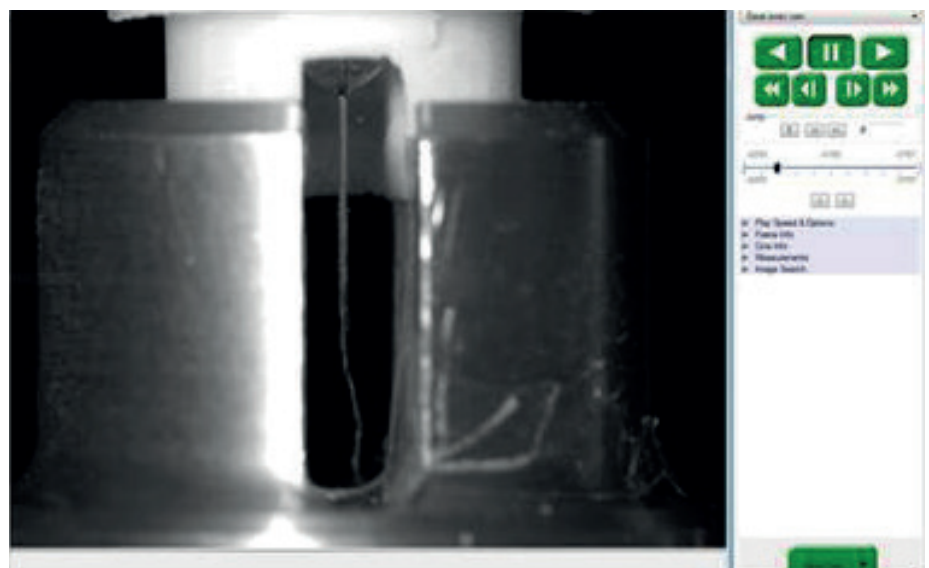Figure 7: Start of injection just after needle insertion without a cam.

Figure 8: Start of injection just after needle insertion with a cam.

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