Evaluation of injection forces of VAX-ID to maximize usability, minimize pain & cell death

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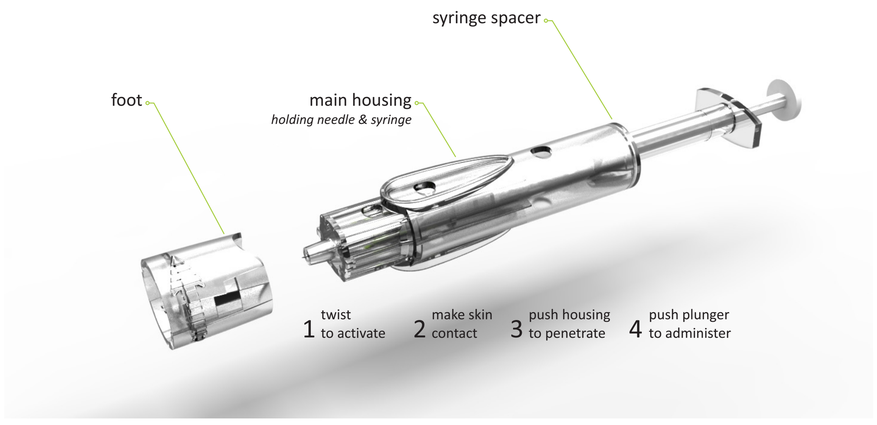
Introduction

The pressure drop through a hypodermic needle is directly related to the injection force needed to inject fluid. This has implications on usability for healthcare workers, the amount of pain for patients next to the possibility of inducing cell death. In this regard, the validity of the Hagen-Poiseuille law was explored for predicting injection forces for small hypodermic needles used in the VAX-ID device platform which is suited for accurate injection of small volumes in the dermal layer of the skin.



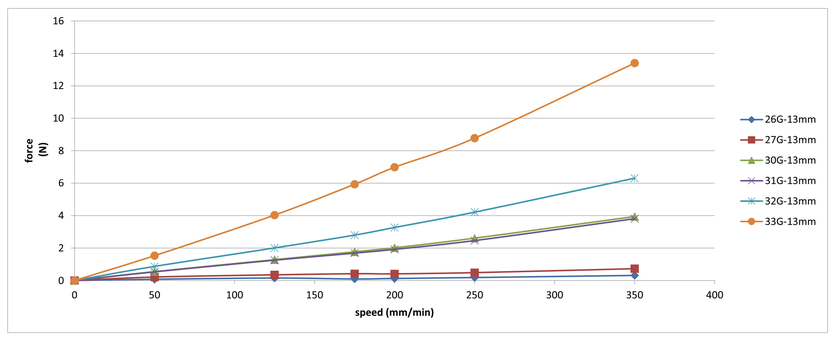
VAX-ID™ Device | PCT/EP2013/057990

Method

A mathematic model was designed to take parameters, including length and inner diameter of needle and syringe, and viscosity that determine the injection force of any device of the VAX-ID platform into account. This study is confined to the non-prefilled VAX-ID variant, composed of a foot for controlled intradermal injection depth, a commercially available syringe and hypodermic needle. The model allows calculation of the force needed for an injection at a given injection rate.
Microscopy was used to evaluate flow irregularities possibly caused by raggedy of the inner wall of the needle.

A compression bench (accuracy of 0.02N) was used for recording of: 1) friction force of the plunger moving in the syringe and 2) overall force, at various volume flows and different injection speeds. These data allow calculation of the force needed to pass liquid through the needle.

Tests were conducted at room temperature using water as a dummy solution. Different hypodermic needle gauges (26G up to 33G) and lengths (14.3mm up to 54.6 mm) were investigated. Total needle length was measured, inner diameter was adopted from specification sheets and confirmed by microscopic inspection. The injection speed ranged from 50mm/min up to 350 mm/min and injection force was recorded as a dependent variable.

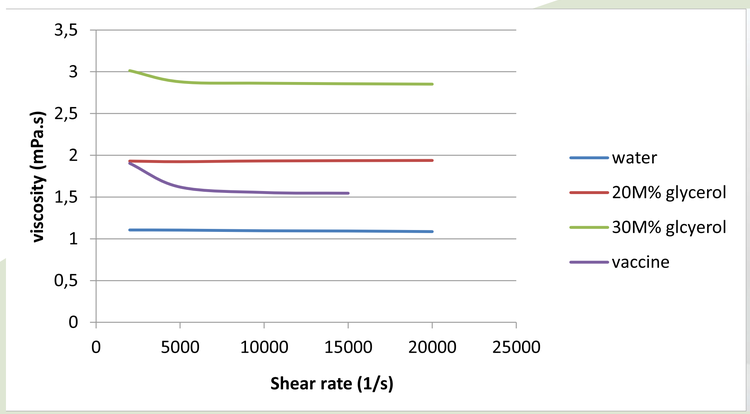


Speed-force of 13mm needles ranging from 26 to 33G. A smaller diameter requires a greater force.

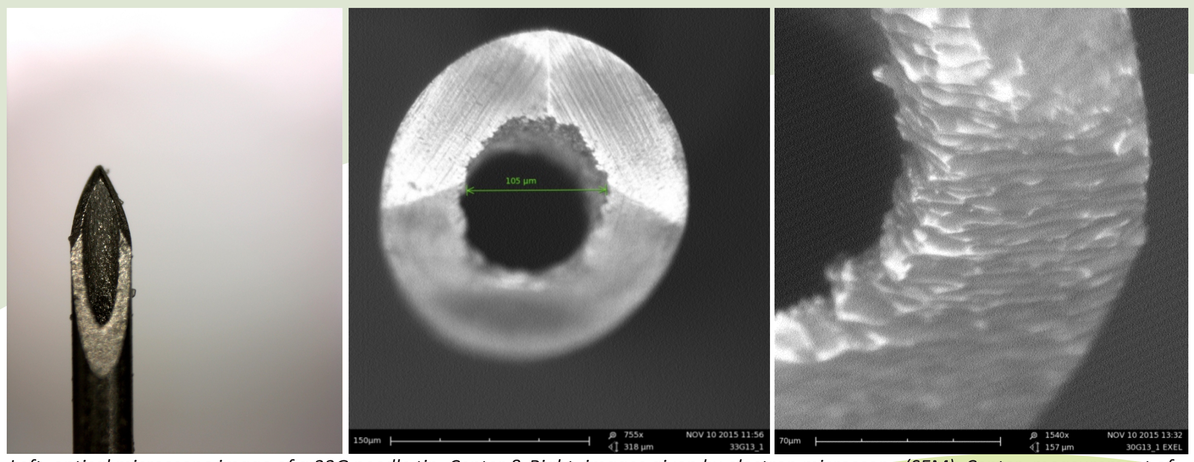
Results

The friction force of the VAX-ID needle and syringe combination mounted up to 9N depending on the type of needle used and injection rate, knowing that the friction force of the plunger is about 2N. The narrower the inner diameter of a needle and the longer, the higher the pressure drop and thus the higher the needed injection force.

Inter-relationships between volume flow, diameter and length of the needle was shown to increase the friction force with 5N up to 7N.



Viscosity measurements taken by m-VROC (Rheosense apparatus) of water, 20M% glycerol, 30M% glycerol and a vaccine.



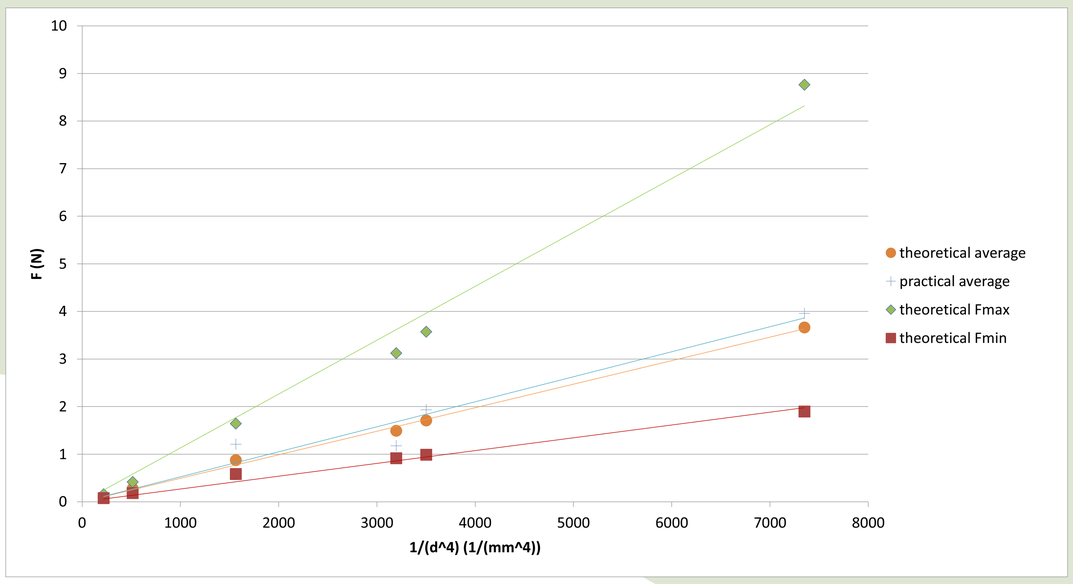
Left: optical microscope image of a 33G needle tip; Center & Right: images given by electron microscope (SEM). Center: measurement of inner diameter 33G needle; Right: surface roughness of the same 33G needle caused by needle grinding

Conclusion

Results showed that the Hagen-Poiseuille formula can be used to estimate the impact on the injection forces with a given hypodermic needle. However, for medical substances with viscosities higher than water additional research will be needed to confirm the current findings.

The insights gained in force needed for inserting the needle and injecting the fluid into the skin allows for customization of needles depending on the application and the fluid to be injected.

Next to accurate intradermal injections, optimizing the VAX-ID device based on acceptable injection forces will result in a user friendly device, while minimizing injection pain and cell death.



Hagen-Poiseuille relation between the inner diameter and its monitored force for a 32G needle. This graph represents the applicable force range in function of the upper and lower needle diameter tolerance (d_{min}/d_{max}).

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