Implantable ports & power injection of contrast media : in-vitro evaluation of feasibility and security

Dr P. Mavoungou, ICO René Gauducheau, Nantes

Institut de Cancérologie de l'Ouest
René Gauducheau

Problems

- Injection of contrast media (CM) via a central venous catheter:
  - Viscous drugs + High flow rates
  - May generate an excessively high pressure in the injection line
- Consequent risks:
  - Catheter disconnection or rupture[1],
  - CM extravasation[2] or injector failure.
- Lower flow rates (0.5 to 2.5 mL/s)
  - may be insufficient to achieve good contrast enhancement.[3,4]
- The objective of this in vitro study :
  - to assess the feasibility of injecting CM into implantable ports (IP)
  - to establish safety guidelines.

1. *Macha DB et al. Radiology 2009;253:870-878.*
2. *Wong H et al. Clin Radiol Extra 2005;60:13-15.*
3. *Herts BR et al. AJR 2001;176:447-453.*
4. *Rigsby CK et al. AJR 2007;188:726-732.*

Materials

- 11 IP models from 4 different manufacturers were tested:
  - Polysite® micro (2005, 2015), (Perouse Medical)
  - Polysite® mini (3007, 3008, 3017), (Perouse Medical)
  - Polysite® standard (4008), (Perouse Medical)
  - Polysite® High Flow (4019, 40010) (Perouse Medical)
  - PowerPort® (Bard)
  - T-Port LP k-set (PFM medical)
  - Celsite® ST215 (B. Braun)

All are CE marked for this specific indication

- IP were punctured 50 times before the tests
  - to simulate real-life conditions of use
  - CM being rarely injected into a newly inserted IP

Materials and Methods

- Catheters used
  - Silicone and polyurethane
  - 25 cm long
    - this length being seldom exceeded in clinical practice
- Non-coring needles for IP access:
  - 20Ga and 19Ga curved non-coring needle for adult IP
    - Polysite® 3007, 3008, 3017, T-Port®, Celsite® ST215
  - 22Ga and 20Ga curved non-coring needle for pediatric IP
    - Polysite® 2005, 2015
  - PowerLock® 19Ga (Bard) with tubular validated for High Pressure CM injection for biggest sized IP
    - Polysite® 4008, Polysite® High Flow 4019 et 40010, Power Port®
- HP Injector Injektron® 82HP (MedTron),
  - CT mode
  - Injection pressure limit of 22 bar (320 psi)

Materials

- 200ml Pelicangio syringe (Perouse Medical) equipped with a 150cm long spiral connector
- Contrast media, pre-heated to 37°C before injection :
  - Xenetix® 350 (laboratoires Guerbet) for adult IP :
    - Viscosity (37°C) = 10cP
  - Xenetix® 300 (laboratoires Guerbet) for pediatrics IP
    - Viscosity (37°C) = 6cP
- Pressure measurements thanks to MESUREX datalogger (Graphtec GL800).

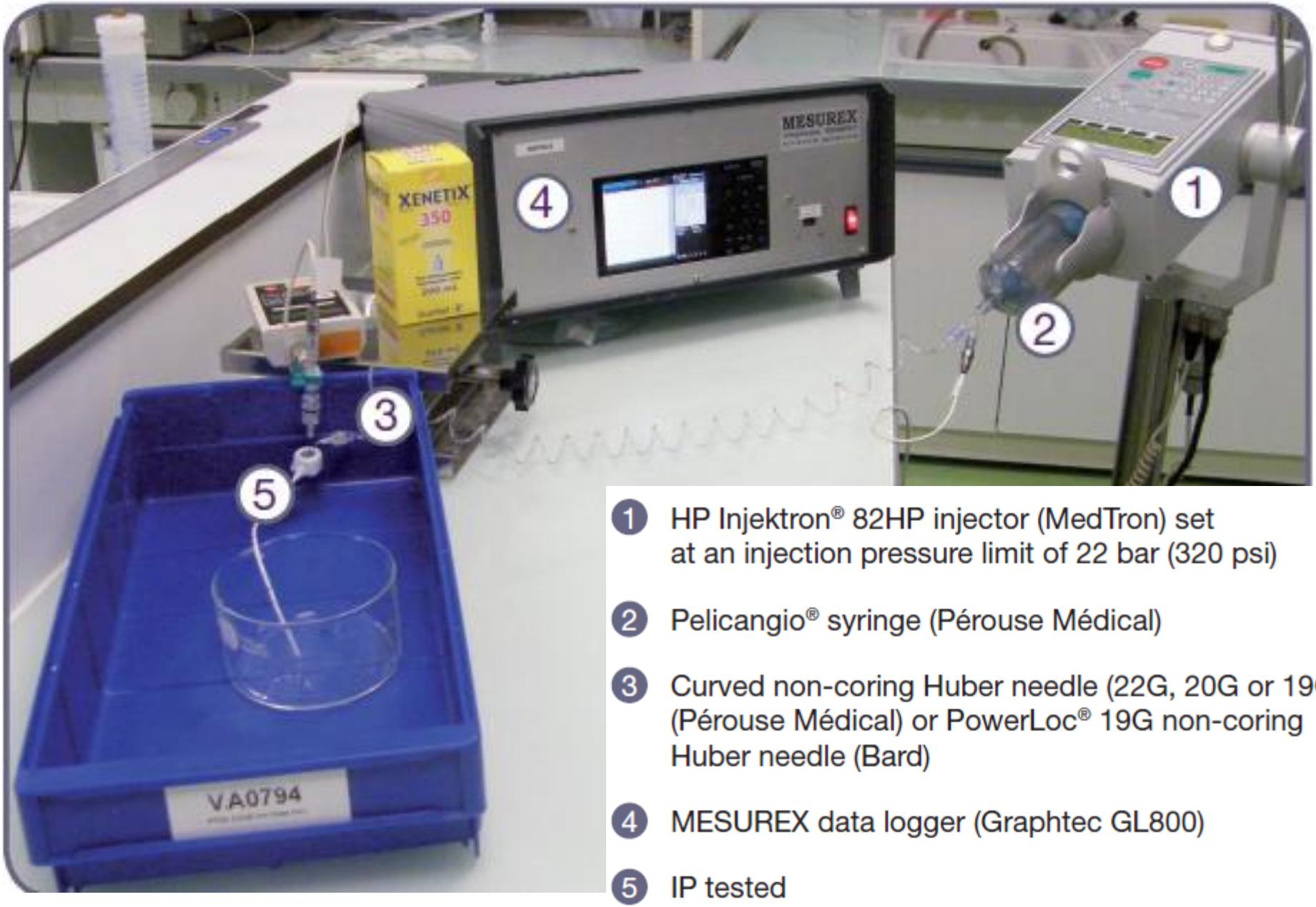
Methods

- The pressure during injection was measured by means of sensors connected to a central data logger :
  - at the injector outlet
  - in the reservoir of the IP tested
- Contrast Media were pre-heated to 37°C before injection in accordance with the recommendations of the IP manufacturers
- Flow rates tested:
  - 1 to 5 mL/s for pediatric IP (Polysite® micro and mini models);
  - 4 to 5 mL/s for adult IP

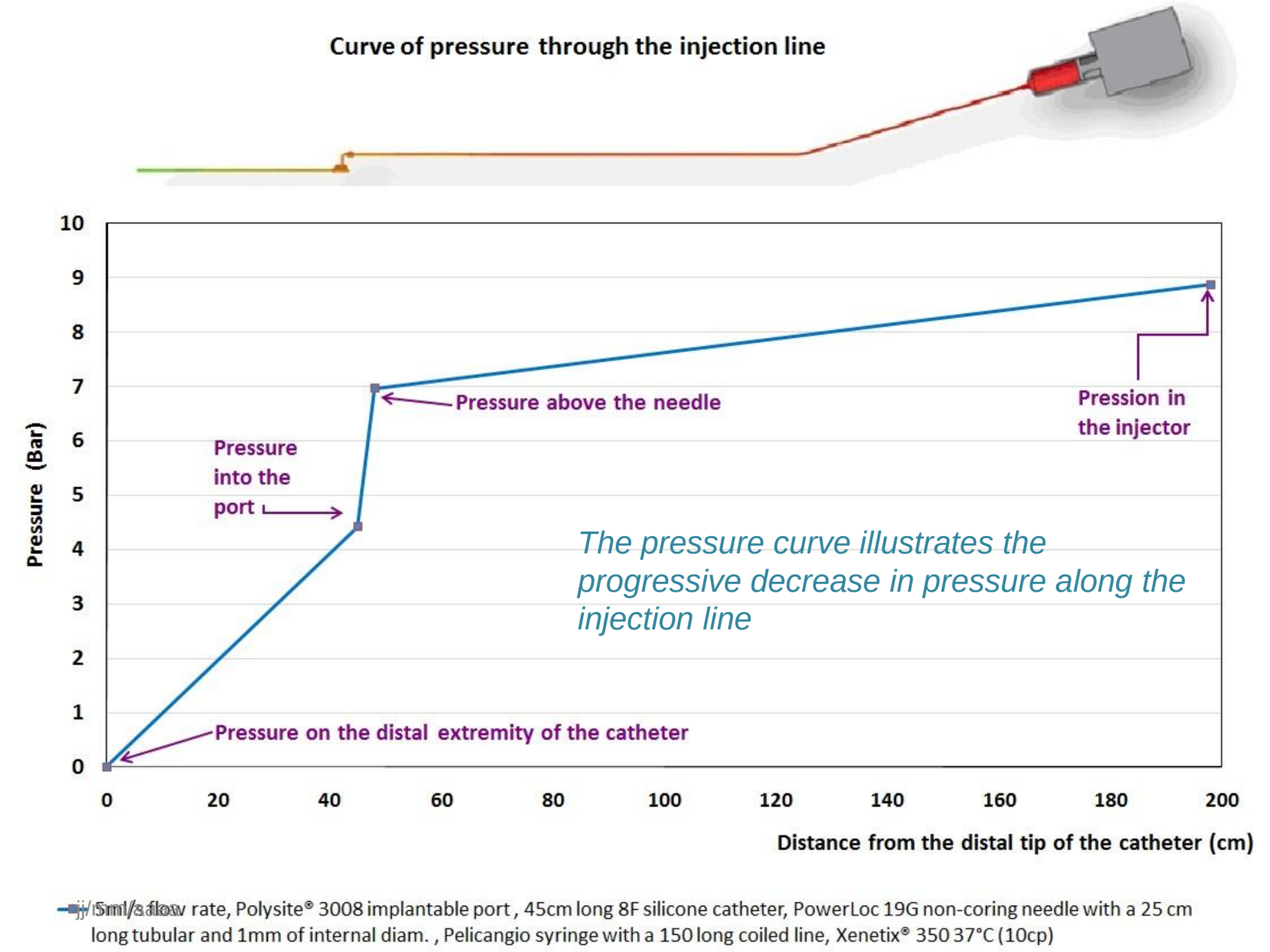
Methods

- The safety of the system was evaluated by the absence of
  - injector failure
  - leakage of the IP
  - catheter disconnection or rupture
- Specifications :
  - Do not exceed 4.5 bars of pressure into IP reservoir (in accordance with manufacturer recommendations)

Methods : Experimental set-up



1. HP Injektron® 82HP injector (MedTron) set at an injection pressure limit of 22 bar (320 psi)
2. Pelicangio® syringe (Pérouse Médical)
3. Curved non-coring Huber needle (22G, 20G or 19G (Pérouse Médical) or PowerLoc® 19G non-coring Huber needle (Bard)
4. MESUREX data logger (Graphtec GL800)
5. IP tested



jj/ 5ml/s flow rate, Polysite® 3008 implantable port , 45cm long 8F silicone catheter, PowerLoc 19G non-coring needle with a 25 cm long tubular and 1mm of internal diam. , Pelicangio syringe with a 150 long coiled line, Xenetix® 350 37°C (10cp)

Results (1)

Average Pressure values measured during injection :

- *At the injector outlet*
- *In the IP reservoir*

<4.5 bars

<22 bars

IP model / catheter caliber and composition	Injection conditions (25 cm catheter)	Injection flow rate (mL/s)	Mean pressure in IP reservoir (bar)	Mean pressure at injector outlet (bar)
Polysite® micro 2005 / 5F SI	Xenetix® 300 preheated to 37°C (viscosity: 6 cP)	1 *(n = 18)*	3.09	5.31
Polysite® micro 2015 / 5F PU		2 *(n = 18)*	4.38	9.80
Polysite® mini 3007 / 7F SI	Xenetix® 350 preheated to 37°C (viscosity: 10 cP)	3 *(n = 18)*	3.58	10.82
Polysite® mini 3008 / 8F SI		5 *(n = 18)*	3.39	13.61
Polysite® mini 3017 / 7F PU		5 *(n = 21)*	2.59	15.58
Polysite® standard 4008 / 8F SI		5 *(n = 21)*	3.94	14.13
Polysite® High Flow 4019 / 9F PU		5 *(n = 21)*	1.12	12.41
Polysite® High Flow 40010 / 10F SI		5 *(n = 21)*	1.24	12.62
PowerPort® / 9F PU		5 *(n = 9)*	1.38	12.62
PFM T-PORT LP k-Set® / 8F PU		5 *(n = 1)*	1.38	10.70
Celsite® ST215 / 6.5F SI		4 *(n = 1)*	2.88	18.44

Results (1)

- During injection of CM according to the recommendations (*CM pre-heated to 37°C, into an IP connected to a patent catheter, respecting the maximum flow rate per IP model*) at flow rates of 1 to 5 mL/s :
  - Pmean measured at the injector outlet of 5.31 to 18.44 bar
  - Pmean measured in the IP reservoir ranged from 1.12 to 4.38 bar
- At the flow rates recommended by the manufacturers of the IP models tested :
  - no leakage detected
  - no catheter disconnection detected
  - no injector failure was observed
  - the recommended maximum pressure (4,5 bars) in the IP reservoir was not exceeded

Complementary tests : out of recommendations

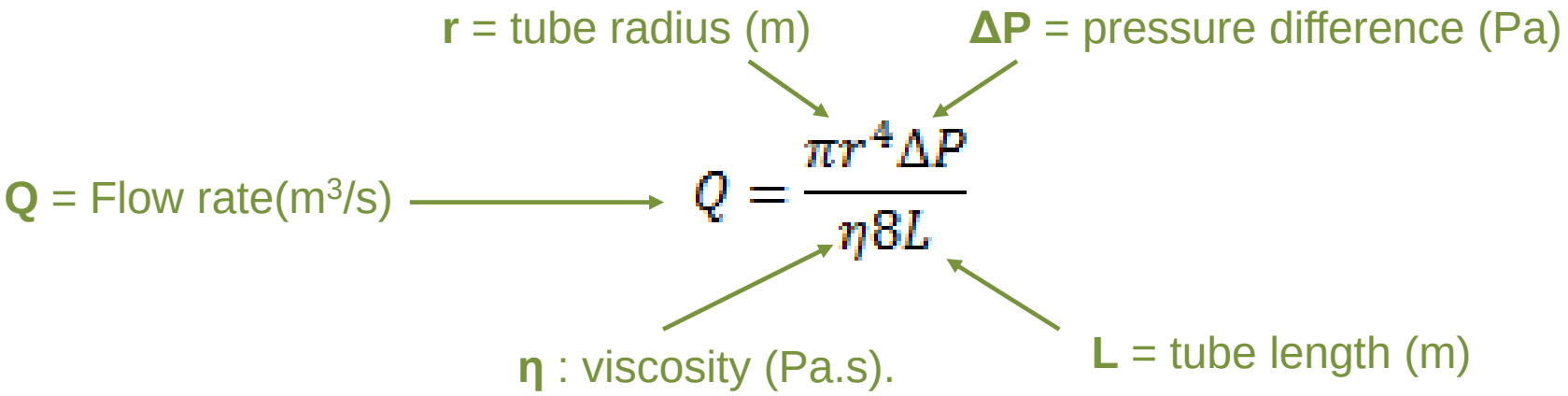
- Materials and Methods
  - Effect of not pre-heating the CM:
    - injection of Xenetix® 350 **at 20°C** at **5 mL/s** into a Polysite® mini 3008 ISP port connected to an 8F silicone catheter
    - N=3
  - Effect of total obstruction of the catheter:
    - injection of Xenetix® 350 preheated to **37°C** at **5 mL/s** into a Polysite® High Flow 4019 ISP port connected to a **clamped** 9F polyurethane catheter
    - N=3

Results(2)

- Effect of not pre-heating the CM (at 20°C) :
  - the Pmean measured in the IP reservoir was increased by 30%
  - approaching the safety limit specified by the manufacturer (4.5 bar)
- Effect of total obstruction of the catheter:
  - the Pmean in the IP reservoir reached > 9 bar, leading to:
    - Catheter rupture (n = 2)
    - Injector failure (n = 1)

Poiseuille's Law

- In the case of smooth flow (laminar flow), the volume flow rate is given by the pressure difference divided by the viscous resistance.
- This resistance depends linearly upon the viscosity and the length, but the fourth power dependence upon the radius is dramatically different.
- Considering the venous pressure to be negligible, the maximum pressure inside the IP reservoir depends on the pressure drop associated with the passage of liquid through the catheter.
  Being in a laminar flow, Poiseuille's law applies :



Conclusion

- All the IP models tested can be used for injection of CM at high flow rates on condition that the following precautions are respected:
  - **Preheating of the CM to 37°C** to reduce their viscosity
  - **Verification of the patency of the catheter** (in clinical practice, by obtaining blood reflux).
- The recommendations of the IP manufacturers concerning other parameters, such as
  - The maximum length of the catheter,
  - the choice of a non-coring (Huber) needle adapted to the IP and to power injection,
  - and the maximum flow rate of injection

  should of course also be respected.
- If these conditions are respected **all the tested adult IP withstand at least a 3 mL/sec flow rate.**