JET INJECTORS = JET INFECTORS

Inherent Problems With Jet Injectors
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- Splash Back
- Fluid Suck-Back
- Retrograde Flow
In 1966 an article titled, *Vaccination by Jet Injection*, published in the *British Medical Journal* stated,

“There is no risk of cross-infection unless the face of the injector is contaminated with blood or tissue juices.”
Samir Mitragotri, a chemical engineer, captured splash-back during jet injection through microcinematography. “The typical volume of the liquid splashed in the image at 400 μs is around 100 nl [i.e., Nanoliter].” (Mitragotri, 2006)

In the photograph below, the black region at the top is the nozzle of the jet injector. The black region at the bottom is human skin. The white region in the middle is open space. Herein the jet stream can be seen along with extensive splash-back.
Hoffman et al. (2001) observed the nozzle and internal fluid pathway became contaminated.

He termed this phenomena as *ballistic contamination*, whereupon the force of impact caused a release of pressure which expelled debris away from the site of impact.

With the jet injector being directly behind the site of impact it is a prime target to becoming contaminated as evidenced in Mitragotri’s photographs.
Fluid Suck-Back

Puffing Statement:

“Unlike most earlier hypodermic jet injection guns, the instant invention [the Ped-O-Jet] is free from danger of sucking fluid back from a patient either during or after the firing cycle is completed so that the danger of cross-infection is almost completely avoided.”


-Note: This patent divulged fluid suck-back was an issue amongst jet injection devices.

Fact:

“After injections, they [CDC] observed fluid remaining on the Ped-O-Jet nozzle being sucked back into the device upon its cocking and refilling for the next injection (beyond the reach of alcohol swabbing or acetone swabbing).”

Dr. Bruce Weniger, former Lead Researcher on Vaccine Technology within the CDC and leading expert on jet injection technology, recalled the CDC’s 1980s investigation into jet injectors.
Kale and Momin (2014) stated that during Phase 2 of the injection process there would be a backwards flow where the jet spray would shoot back-out of the hole towards the jet injector. This would be an expected phenomena in every injection due to the continuous depletion of pressure where the volumetric rate of hole formation would eventually be less than the volumetric rate of the jet impinging the skin. This continuous decrease in pressure would create a retrograde, or rather backwards flow, whereupon the jet injector’s nozzle, internal fluid pathway and drug reservoir would become contaminated.
Suria et al. (1999) found retrograde flow, as well:

“firing the jet injector onto a contaminated surface (gauze pad contaminated with 4 cm$^3$ of $10^8$ CFU/mL $S$ aureus) caused back flow of bacteria into the internal canal, as indicated by growth of bacteria after firing of sterile liquid through the contaminated device onto agar plates. The degree of back flow and resulting contamination increased with increasing ejection volume setting, from lowest (0.06 cm$^3$) to highest (0.30 cm$^3$).”
Retrograde Flow

Hoffman et al. (2001) found retrograde flow:

“some of the liquid injected form[ed] a pocket below the injection site. This will be under maximum pressure towards the end of the injection process, before sufficient dispersion into surrounding tissues has occurred to release pressure. This will coincide with a lessening of pressure from the injector. When the pressure from the injector is exceeded by the back-pressure from the tissue pocket, backflow through the pathway in the skin created by the injector could occur. This liquid will contain blood from the destruction of small blood vessels during the injection process and can have different pathways after it has emerged from the skin according to the type of injector. Injectors that have direct skin contact will form a continuous fluid pathway between the skin and injector. As the outward pressure from the injector dies away at the end of an injection, back-pressure from the fluid in the tissue pocket will cause blackflow out of the skin to inside the injector’s fluid pathway.”
Retrograde Flow

- Programme for Appropriate Technology in Health (PATH) works to develop jet injection technology.

- PATH ran parallel tests to Hoffman’s preliminary study. The in-vitro tests of the Ped-O-Jet (later known as Am-O-Jet) confirmed similar findings.

- PATH found “a correlation between the extent of contamination and the level of back-pressure in simulated skin models” (WHO, 1997).
Kelly et al. (2008) tested the potential cross-contamination of the hepatitis B virus via a new protector cap needle-free injector.

Table 1 demonstrates that cross-contamination of HBV occurred without any visible bleeding at the injection site. In 7 out of the 17 injections that tested positive for cross-contamination researchers observed no visible bleeding at the injection site. This indicates that cross-contamination of blood-borne viruses successfully occurred within microscopic levels of blood not visible to the human eye.

The study also demonstrated retrograde flow allowed blood-borne pathogens to permeate the single-use protector cap and enter the jet injectors internal fluid pathway.
<table>
<thead>
<tr>
<th>Study site-volunteer number</th>
<th>Post-injection sample positive(^a)</th>
<th>Serial number of fluid path used(^b)</th>
<th>ID number of jet injector used(^b)</th>
<th>Indications from injection site photograph(^c)</th>
<th>HBV on injection day (copies/mL)(^d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>001–006</td>
<td>First</td>
<td>#003</td>
<td>#003</td>
<td>Right: no visible blood, slight reflux</td>
<td>8.00E+07</td>
</tr>
<tr>
<td></td>
<td>Second</td>
<td></td>
<td></td>
<td>Left: inconclusive</td>
<td></td>
</tr>
<tr>
<td>001–020</td>
<td>Second</td>
<td>#003</td>
<td>#002</td>
<td>Left: no visible blood, moderate reflux</td>
<td>1.60E+09</td>
</tr>
<tr>
<td>001–029</td>
<td>First</td>
<td>#003</td>
<td>#002</td>
<td>Right: 8–10 mm intradermal wheal, no visible blood, no reflux</td>
<td>9.36E+08</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Right: single droplet of blood at the injection site, no reflux</td>
<td></td>
</tr>
<tr>
<td>002–002</td>
<td>First</td>
<td>#004</td>
<td>#004</td>
<td>Left: 6–8 mm intradermal wheal, no visible blood, significant reflux</td>
<td>6.31E+08</td>
</tr>
<tr>
<td></td>
<td>Second</td>
<td></td>
<td></td>
<td>Left: reflux with capillary bleeding</td>
<td>1.31E+09</td>
</tr>
<tr>
<td>002–005</td>
<td>Second</td>
<td>#014</td>
<td>#004</td>
<td>Right: 6–8 mm intradermal wheal, no visible blood, no bleed-back</td>
<td>1.63E+08</td>
</tr>
<tr>
<td>002–020</td>
<td>First</td>
<td>#006</td>
<td>#004</td>
<td>Right: no visible blood, very light reflux</td>
<td>3.76E+09</td>
</tr>
<tr>
<td>002–027</td>
<td>First</td>
<td>#005</td>
<td>#004</td>
<td>Right: 3–4 mm intradermal wheal, light reflux with light capillary bleeding</td>
<td>1.33E+09</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Left: no visible blood, no bleed-back</td>
<td></td>
</tr>
<tr>
<td>002–300</td>
<td>First</td>
<td>#014</td>
<td>#004</td>
<td>Right: capillary bleeding, no bleed-back</td>
<td>6.89E+08</td>
</tr>
<tr>
<td>003–011</td>
<td>Second</td>
<td>#007</td>
<td>#007</td>
<td>Left: no visible blood, very light reflux</td>
<td>2.10E+08</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Picture not available</td>
<td>2.21</td>
</tr>
<tr>
<td>003–013</td>
<td>First</td>
<td>#012</td>
<td>#007</td>
<td>Picture not available</td>
<td>E + 08</td>
</tr>
<tr>
<td></td>
<td>Second</td>
<td></td>
<td></td>
<td>Large 8–10 mm intradermal wheals and significant reflux observed.</td>
<td>4.25E+08</td>
</tr>
</tbody>
</table>

\(^a\) The first injection was delivered into the right deltoid, the second injection was delivered into the left deltoid.

\(^b\) Each fluid path and jet injector were individually numbered for identification.

\(^c\) Splash-back = injectate fluid on skin surface that did not penetrate the tissue. Injectate reflux = injectate fluid that flows back out of the tissue at the injection site. Bleed-back = capillary bleeding at the injection site after injection.

\(^d\) Quantities of HBV in participants' blood were confirmed to be above the eligible level of a \(>10^6\) copies/mL by PCR DNA assay after the study injections.
References
