Do Bevacizumab solutions interact during an infusion through implantable venous access ports with silicone or polyurethane catheters ?

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Supplementary material

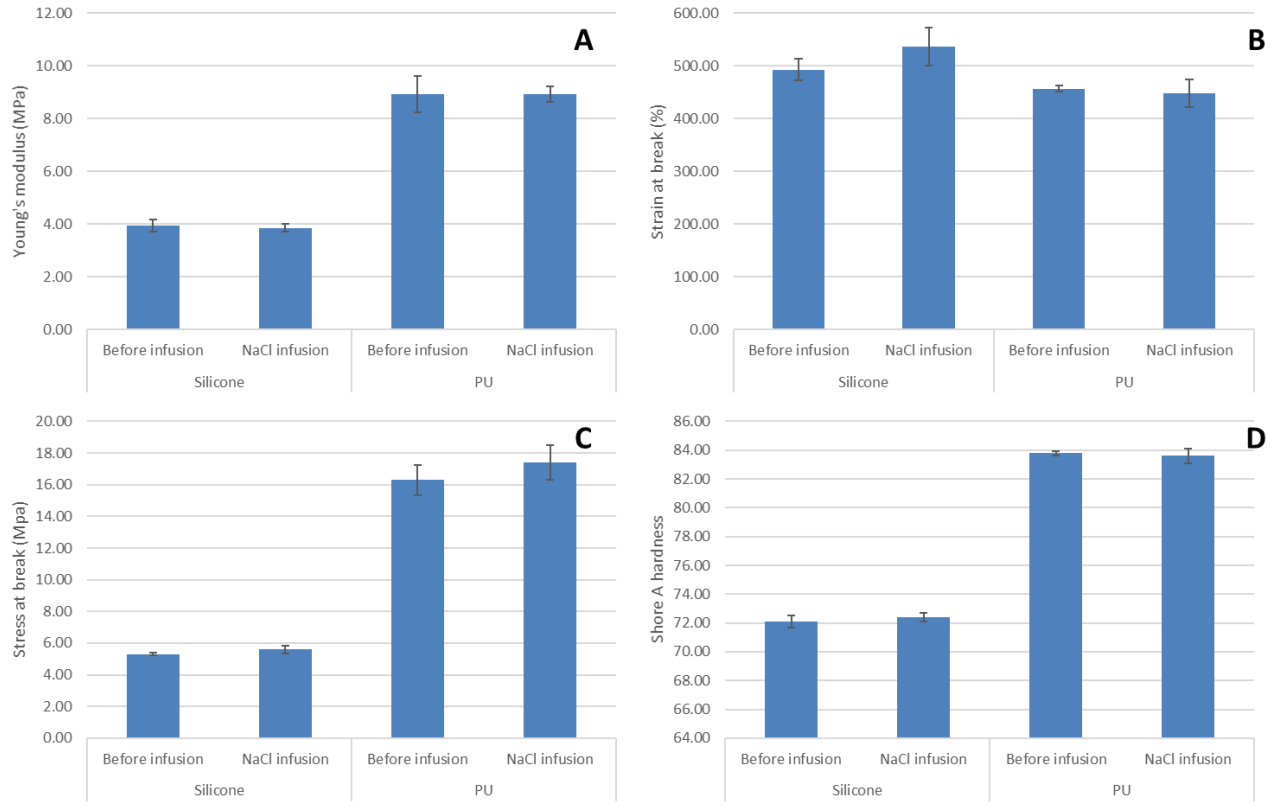

Figure A : Mechanical properties (A = Young's modulus; B = strain at break; C = stress at break; D = Shore A hardness) of polyurethane (PU) and silicone catheters before and after infusion of a 0.9% NaCl solution (Mean ± 95% confidence interval, n = 3).

Validation of the analytical methods used for bevacizumab analysis:

Concerning analysis of the bevacizumab solution, analytical methods were validated as being stability-indicating. Five different conditions of intentional degradation were performed (1: Acidic, HCl 10-2N 24h at 40°C; 2: Basic, NaOH 10-2N 72h at 40°C; 3: Oxydative, H_2O_2 1% (v/v) 72h at room temperature; 4: high temperature; 168h at 40°C; 5: light : exposure to 1.2M lux/hour in a climatic chamber). All degraded samples were analyzed with UV spectroscopy (turbidity assessment), DLS, SEC, CEX, peptide mapping and SD-UV. Each analytical techniques was able to highlight modification resulting from at least one degradation condition. Moreover, SEC method was validated by separating a standard mix of protein and also by separating bevacizumab after digestion by papain. SD-UV method was also validated by highlighting shift of maxima and minima after degradation by guanidine. The effect of a high concentration or longer time exposure could not have been studied due to the very cost of the monoclonal antibody.