

Skin Disinfection With A Quaternary Ammonium Salt Does Not Impact The Rheological Properties Of Mannitol-Modified Hyaluronic Acid Viscosupplements

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BACKGROUND

There is a known incompatibility between Hyaluronic Acid (HA) and quaternary ammonium salts (QAS) due to the risk of HA precipitation in the solution. Therefore, many instructions for use of HA viscosupplements recommend to avoid the use of QAS to disinfect the injection site. However, in the conditions of clinical practice, it has never been evidenced that QAS disinfectants exert a negative impact on the rheological properties of viscosupplements.

OBJECTIVES

To assess the rheological behaviour of two mannitol-modified HA viscosupplements after skin disinfection with QAS product.

MATERIAL & METHOD

- A cross-linked HA (16 mg/ml) HANOX-M-XL (HAppyCross® LABRHA SAS, Lyon, France).
- A linear HA (MW: 1-1.5 MDa; 15.5 mg/ml) HANOX-M (HAppyVisc® LABRHA SAS, Lyon, France).
- Both combined with high concentration of mannitol (35 mg/ml).
- HA was field on the rheometer plate using a 21Gauges x 1.5" L40 mm needle through a piece of pork skin previously disinfected with Biseptine®, an antiseptic from the QAS family.
- Controls :
 - 21G x 1,5" needle alone
 - 21G x 1,5" needle through a piece of pork skin not disinfected
 - 21G x 1,5" needle through a piece of pork skin previously disinfected with Betadine®, an iodinated derivative
- The dynamic viscosity η was measured according to the shear rate $\dot{\gamma}$ from 0.1 to 100 s⁻¹ using a cone-plate rheometer (RheoWin HAAKE Viscotester iQ Air, Thermo Electron SAS) at 20° C.

RESULTS

The dynamic viscosity η was not statistically modified according to the disinfection protocol.

		needle alone	needle pork skin	needle pork skin Betadine®	needle pork skin Biseptine®	p-value
HANOX-M-XL	Mean η (Pa.s) $\dot{\gamma} = 0.5 \text{ s}^{-1}$	110.8	118.2	106.8	119.4	0.84
	SD	9.2	5.9	2.8	4.9	
	Mean η (Pa.s) $\dot{\gamma} = 50 \text{ s}^{-1}$	5.2	5.7	5.8	5.4	0.81
	SD	0.1	0.3	0.1	0.4	
HANOX-M	Mean η (Pa.s) $\dot{\gamma} = 0.5 \text{ s}^{-1}$	34.2	41.2	35.4	33.8	0.61
	SD	3.3	1.7	1.8	0.1	
	Mean η (Pa.s) $\dot{\gamma} = 50 \text{ s}^{-1}$	4.1	4.2	4.1	4.0	0.97
	SD	0.2	0.1	0.1	0.1	

Table : Dynamic Viscosity of HANOX-M-XL and HANOX-M at a shear rate of 0,5 and 50 s⁻¹ according to skin disinfection protocol

Viscosity is related to both HA MW and concentration. Because HA concentration remains constant, the absence of change in the viscoelastic behaviour after skin disinfection with QAS indicates the lack in structural change of HA macromolecule.

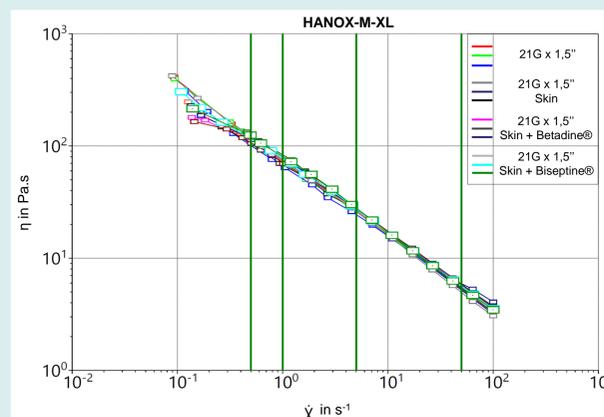


Figure 1 : Rheological Profile of HANOX-M-XL

HANOX-M-XL

- Mean η (SD) at a shear rate of 0.5 s⁻¹ : **114.0 (7.6) Pa.s**
- Mean η (SD) at a shear rate of 50 s⁻¹ : **5.0 (0.3) Pa.s**

HANOX-M

- Mean η (SD) at a shear rate of 0.5 s⁻¹ : **36.0 (3.6) Pa.s**
- Mean η (SD) at a shear rate of 50 s⁻¹ : **4.0 (0.1) Pa.s**

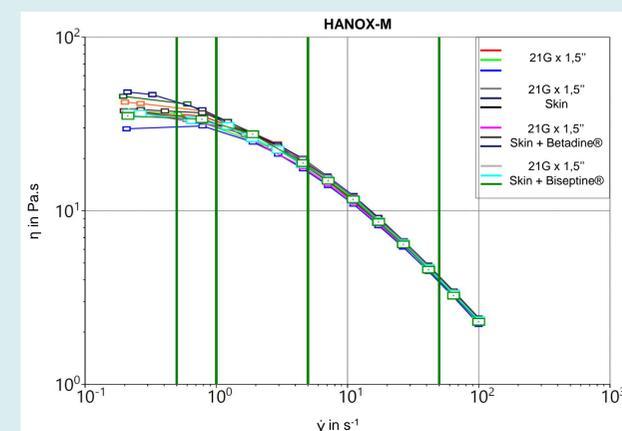


Figure 2 : Rheological Profile of HANOX-M

CONCLUSION

The rheological behaviour of HANOX-M-XL and HANOX-M is not impacted when an antiseptic from the family of QAS is used to disinfect the injection site before viscosupplementation. HANOX-M-XL and HANOX-M being mannitol-modified HA viscosupplements, the present results cannot be extrapolated with certainty to other HA viscosupplements not containing mannitol.