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Determination of the release of wetting agents from nelfilcon A using a novel in vitro eye model

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PURPOSE: To measure the release of PEG (polyethylene glycol), HPMC (hydroxypropyl methylcellulose) and PVA (polyvinyl alcohol) from a daily disposable hydrogel contact lens material (nelfilcon A; Dailies AquaComfort PLUS; DACP) over 24 hrs using a novel *in vitro* eye model (Ocuflow).

METHODS: DACP lenses were mounted in a 2-piece eye model and exposed to a physiologically relevant flow of an artificial tear solution (ATS). The elute from the ATS flowing over the lenses was periodically collected for 24 hrs. The elution of PEG and HPMC from the lenses (n=5) were analyzed using LCMS (liquid chromatography mass spectrometry). The release of PVA was analyzed using a colorimetric method based on iodine-boric acid, which produces a black-blue color change in the presence of PVA. The amount of each wetting agent was also evaluated in the DACP blister packaging solution.

RESULTS: The total amounts of PEG, HPMC, and PVA in the blister pack were 153603536, 424384, and 28820 µg respectively. The release of all wetting agents from the lenses followed a burst-release pattern, which occurred within the first 1.5 hrs (p<0.05). PEG release was the highest, followed by HPMC, and then PVA (p<0.05). The release of HPMC and PVA from the nelfilcon A-based lenses was less than 5 and 1 µg respectively, at any measured time point and the amount of each wetting agent released at any given time was less than 1% of the amount in the blister pack.

CONCLUSION: The results suggest that the majority of the wetting agents are released within the first hour of exposure to the artificial tear film, using this *in vitro* mimic of the ocular environment.

