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Vaginal formulations containing prebiotics and probiotics for treatment of bacterial vaginosis

Caixuan Wang^a, Vickey Kett^b, Deirdre Gilpin^c, R. Karl Malcolm^{a*}

^aSchool of Pharmacy, Queen University of Belfast BT9 7BL, United Kingdom, ^bSchool of Pharmacy, Queen University of Belfast BT9 7BL, United Kingdom, ^cSchool of Pharmacy, Queen University of Belfast BT9 7BL, United Kingdom, ^{a*}School of Pharmacy, Queen University of Belfast BT9 7BL, United Kingdom

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*Corresponding author.
Tel.: +44 (0)28 9097 2319
Fax: +44 (0)28 9097 2319
E-mail:
K.Malcolm@qub.ac.uk

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SUMMARY

MED-4870 matrix-type VRs containing four different lyoprotectants of three concentrations were manufactured by reaction injection molding, and Shore M Hardness test, compression test and twist test were applied to determine the impact of incorporation of lyoprotectants on mechanical characteristics of VRs. Results indicated that incorporation of lyoprotectants can increase the resistance force and decrease the rotational angles of the VRs. As the category and concentration of incorporated lyoprotectant also have impact on the releasing profile of metronidazole (MET) and protecting ability of lactobacillus in freeze-drying process, more research will be needed.

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INTRODUCTION

BV is a disease that widely affects women's health (Broeckx et al., 2017). Lactobacilli are being actively developed as a treatment option for BV (Murina and Vicariotto, 2019). Here, we report preliminary formulation work as part of our efforts to develop sustained – release VR formulations for simultaneous release of MET, a prebiotic lyoprotectant and lactobacillus. Specifically, the influence of lyoprotectants on mechanical properties of matrix-type silicone elastomer VRs are investigated.

MATERIALS AND METHODS

Matrix-type VRs (~ 8.0g) loaded with micronized four categories of lyoprotectants (mannitol (MT), maltodextrin (MD), sucrose (SC) and polyethylene glycol 4000 (PEG)) at three concentration (5%w/w, 10%w/w and 20%w/w) were prepared from medical

grade addition-cure silicone elastomer dispersion (MED-4870, NuSil). Blank VRs were also prepared (13 formulations totally). For mechanical tests, four VRs were selected from each formulation. Shore M Hardness was tested by Checkline RX-DD-M digital durometer. The resistance force and rotational angle were tested by Texture Analyzer (TA-XTPPLUS, Stable Microsystem, UK).

RESULTS AND DISCUSSION

The compression test results are presented in *Fig. 1*. The results of Shore M Hardness and twist test of lyoprotectants-containing VRs are presented in *Fig. 2* and *Fig. 3*, respectively. As the increase of the concentration of lyoprotectants, the resistance force of VRs increases, while the rotational angle decreased. However, there are only limited differences between the Shore hardness values

CONCLUSIONS

Addition of lyoprotectants can affect the mechanical properties of MED-4870 matrix type VRs. The results can support us to determine the category and amount of lyoprotectant to incorporated into the VRs in the future.

ACKNOWLEDGEMENTS

All authors declare no actual or potential conflicts of interest.

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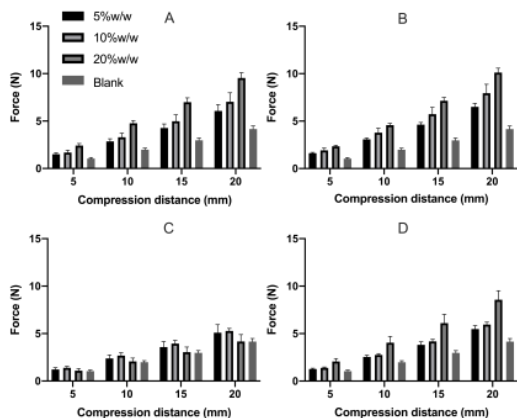


Fig. 1. The resistance force of MED-4870 VRs containing different %w/w of MT (A), MD (B), PEG (C) and SC (D) at 5, 10, 15 and 20 mm compression distances.

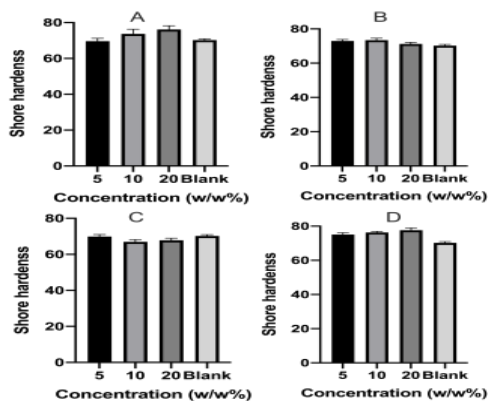


Fig. 2. The Shore M Hardness of MED-4870 VRs containing MT (A), MD (B), PEG (C) and SC (D) at 0, 5, 10, 20 %w/w loadings.

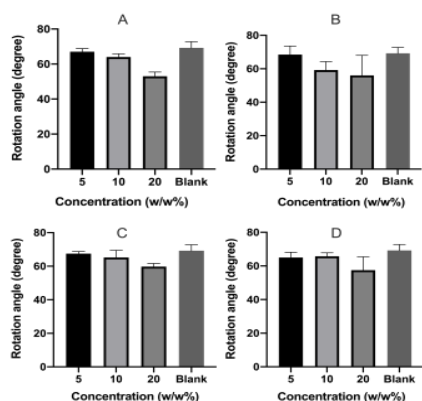


Fig. 3. The rotational angle of MED-4870 VRs containing different concentration of MT (A), MD (B), PEG (C) and SC (D).