MedTech for Women: Lactide-releasing and, as a result, pH-regulating textiles for a healthy vaginal environment

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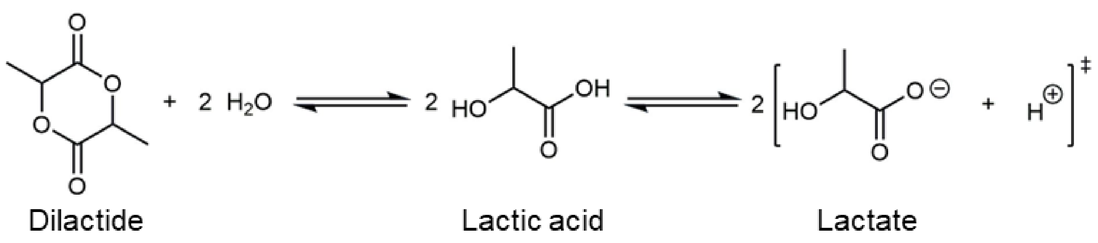
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Introduction

- 23 - 29 % of women in childbearing age suffer from bacterial vaginosis (BV). BV is the most common unbalance disorder of the vaginal flora and can cause many health problems. [1, 2, 3, 4]
- The abnormally high pH level disrupts the natural vaginal microbiome [1, 2]; therefore, a lactide-releasing fabric is intended to restore the natural pH level.
- In artificial vaginal secretion (AVS), the lactide is hydrolyzed into lactic acid and lactate [5], causing the pH to decrease from above 4.6 to a range of 3.0 – 4.0 within 3 hours.
- Three different textiles containing lactide were produced for use as potential panty liners.

Materials

- (Di)lactide hydrolyzes with water to lactic acid and than partially dissociates into a hydrogen cation (H+) and the lactate salt of lactic acid [5].



- Poly(lactic acid) (PLA) is used for the fiber formation. PLA is a polyester and biodegradable [6]. During the first few hours in the body environment, PLA releases only a negligible amount of lactide through hydrolysis and due to residual monomer content < 0.3 % [7].
- A viscose yarn (1220 dtex) was finished with Lactide. Viscose fibers have good moisture absorption, water retention and are gentle to the skin [8].

Textile production

Three different textiles are produced from these materials. A viscose yarn coated with melted lactide, wet spun fibers and air spun nonwovens (shown in fig. 1) from a solution of PLA/lactide in chloroform.

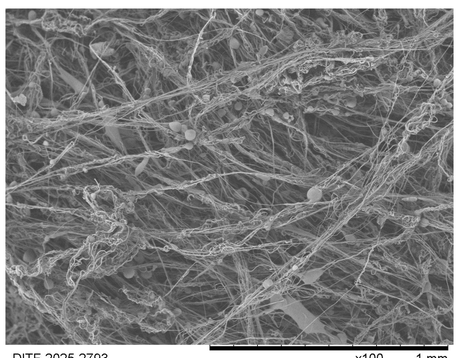


Fig 1: SEM-image of an air spun nonwoven

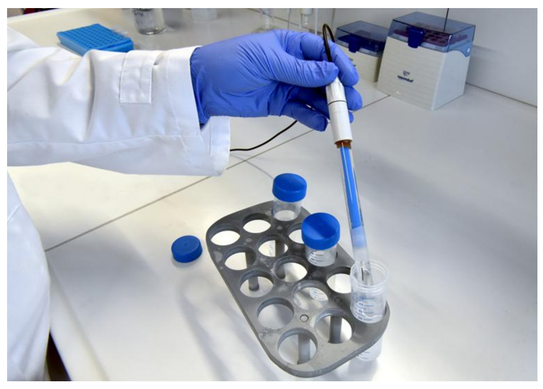


Fig. 2: pH value of samples inserted in artifical vaginal secretion

Sample testing

- AVS is used for the examination of the three textiles. The AVS has a pathogenic pH of 4.6 and a measurement temperature of 37 °C.
- The samples are characterized regarding their pH change over time.
- Since physiological secretion of vaginal fluid per day is only 1 – 5 ml [9], a detection method that requires a small amount of fluid had to be developed. For this reason lactate concentration over time was analyzed.
- Since panty liners are estimated to be used for a maximum of 16 hours, only the values for the first 24 hours are shown in fig. 2.

Results and Discussion

- The diagram in fig. 3 shows the change in the pH value and the lactate concentration of AVS, 0.1 g lactide in AVS, viscose yarn without coating and with lactide coating, an air-spun nonwoven of PLA/lactide and PLA/lactide/lactate and wet-spun fibers of PLA/lactide.
- The pH value of AVS and pure viscose yarn in AVS doesn't change. The 0.1 g lactide in AVS decreased the pH value in the first 3 h from 4.6 to 3.6, the lactide coating on the viscose fibers from 4.6 to 3.2, the nonwovens from 4.6 to 4.3 regardless of the addition of lactate, and the PLA/lactide fibers from 4.6 to 3.4.
- A larger amount of lactide on the surface of the fibers resulted in greater reduction in pH. The PLA in the fibers had no observable effect on the pH.

[1] Swidsinski 2023; [2] Chandrashekar, et al. 2023; [3] Plummer, et al. 2021; [4] Ma, et al. 2012;; [5] Cunha, et al. 2022; [6] Auras, et al. 2022; [7] Bian, et al. 2016; [8] Varnaite-Zuravlinova, et al. 2024; [9] Coleman 2025

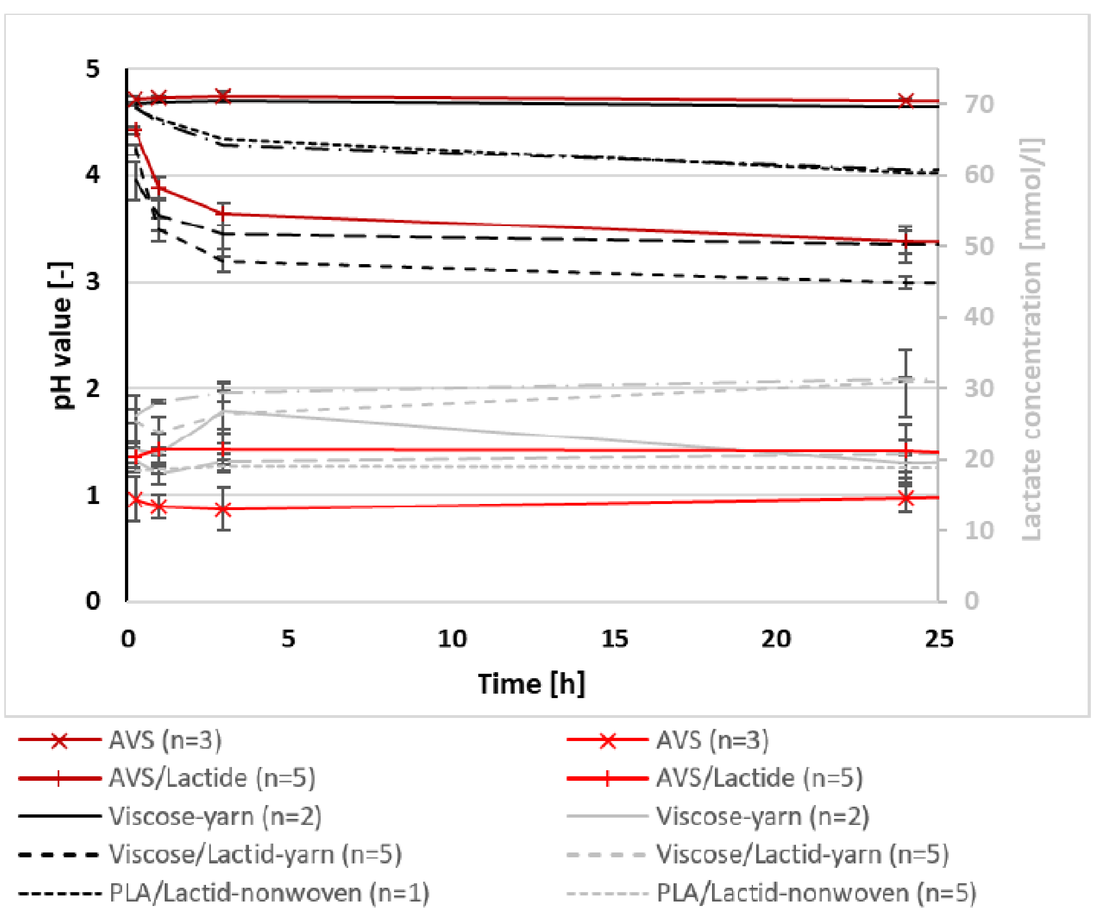


Fig 2: pH value and lactate concentration of AVS, AVS/Lactide and lactide loaded textiles in AVS at 37 °C

- The amount of 0.1 g lactide increased the concentration slightly. If the lactide was completely hydrolyzed in the AVS, the lactate concentration should be 44 mmol/l. All textiles with lactide showed a higher lactate concentration compared to the pure AVS, but they all remained below the expected values. This lower concentration occurs because lactide first hydrolyzes into lactic acid which inflected the pH value but not the lactate concentration and in a second step into the measurable lactate.
- The diagram in fig 3. shows that there is no correlation between the pH value and the lactate concentration.

Conclusion and Outlook

- All textile samples demonstrated that, upon contact with the AVS, they lowered the pH to a normal range within the first three hours.
- Lactate measurement is not a suitable method for determining the release of lactide.
- The textiles are to be further developed in following projects to improve confection, handling and storage.
- A suitable vaginal model has to be developed with focus on a fewer amount of fluid and that depicts natural conditions more realistically.
- The biocompatibility of the product has to be examined through cell toxicity and body tolerance studies.

Acknowledgement

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