



# The impact of the number of pieces of osmotic dilator Dilapan-S<sup>®</sup> used for cervical ripening on the course and outcome of labor



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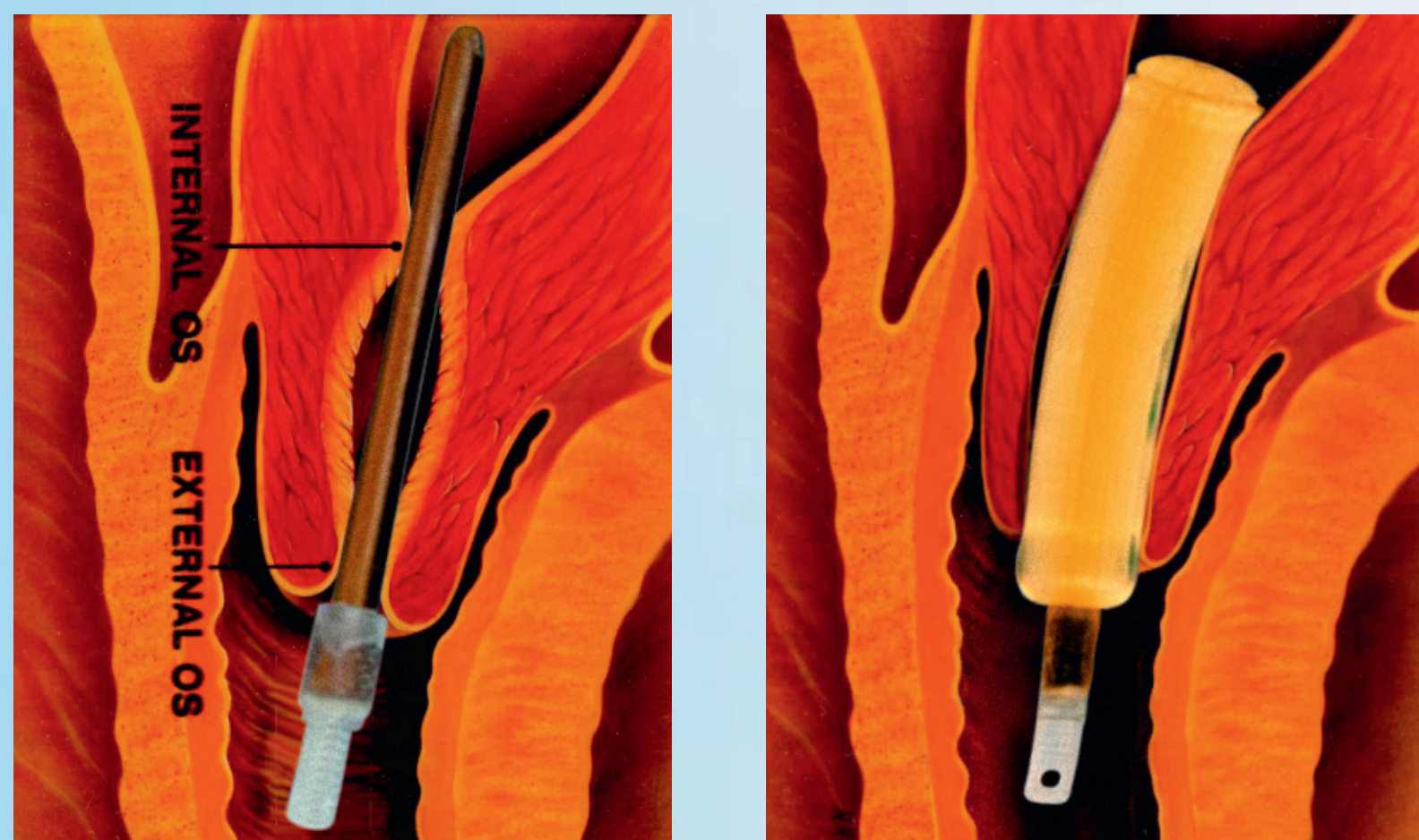
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## Introduction:

Patients indicated for termination of the pregnancy by vaginal delivery having an immature cervix (Bishop score less than 5) usually require preparation for labor induction by cervical ripening. Considering cervix characteristics mechanical and medicamentous methods have been used for cervical ripening. These methods are based on exogenous application of prostaglandins or stimulation of their endogenous secretion. In case of mechanical methods mechanism of action is based on generating local pressure which stimulates endogenous prostaglandin release. Synthetic hydrogel dilators such as Dilapan-S<sup>®</sup> combine osmotic and radial expansion. Gradual anisotropic swelling generates radial pressure against cervix and, therefore, causes gentle dehydration and softening. Absorption of water from cervical tissue causes its further dehydration and softening. Combined expansion and water absorption softens and gradually dilates the cervix. Simultaneously, Dilapan-S initiates endogenous prostaglandin release causing collagen degradation. Patented sterilized hydrogel AQUACRYL guarantees consistency of action, predictability of the clinical outcome and safety of the use. Published study data on the impact of the number of pieces of osmotic dilator Dilapan-S<sup>®</sup> used for cervical ripening on the course and outcome of labor are missing.



**Fig. 1:** Anisotropic swelling of Dilapan-S<sup>®</sup> osmotic cervical dilator

## Objective:

The purpose of this sub-analysis is to evaluate the impact of the number of pieces of osmotic dilator Dilapan-S<sup>®</sup> used for cervical ripening on the course and outcome of labor.

## Material and methods:

The study was designed as an observational, prospective, multicentre, data collection, performed between 15. May 2013 and 31. October 2013. The 96 female patients were included in the data analysis. 35 patients (36,5 %) had a caesarean section reported in their medical history, while the group of patients without previous caesarean section involved 61 patients (63,5 %). Assessment of the primary objective and success of cervical ripening procedure was based on the Bishop (cervical) score. Reported numbers of used Dilapan-S<sup>®</sup> dilators were analyzed in all 96 women. We evaluated answers about satisfaction from patient's questionnaire.



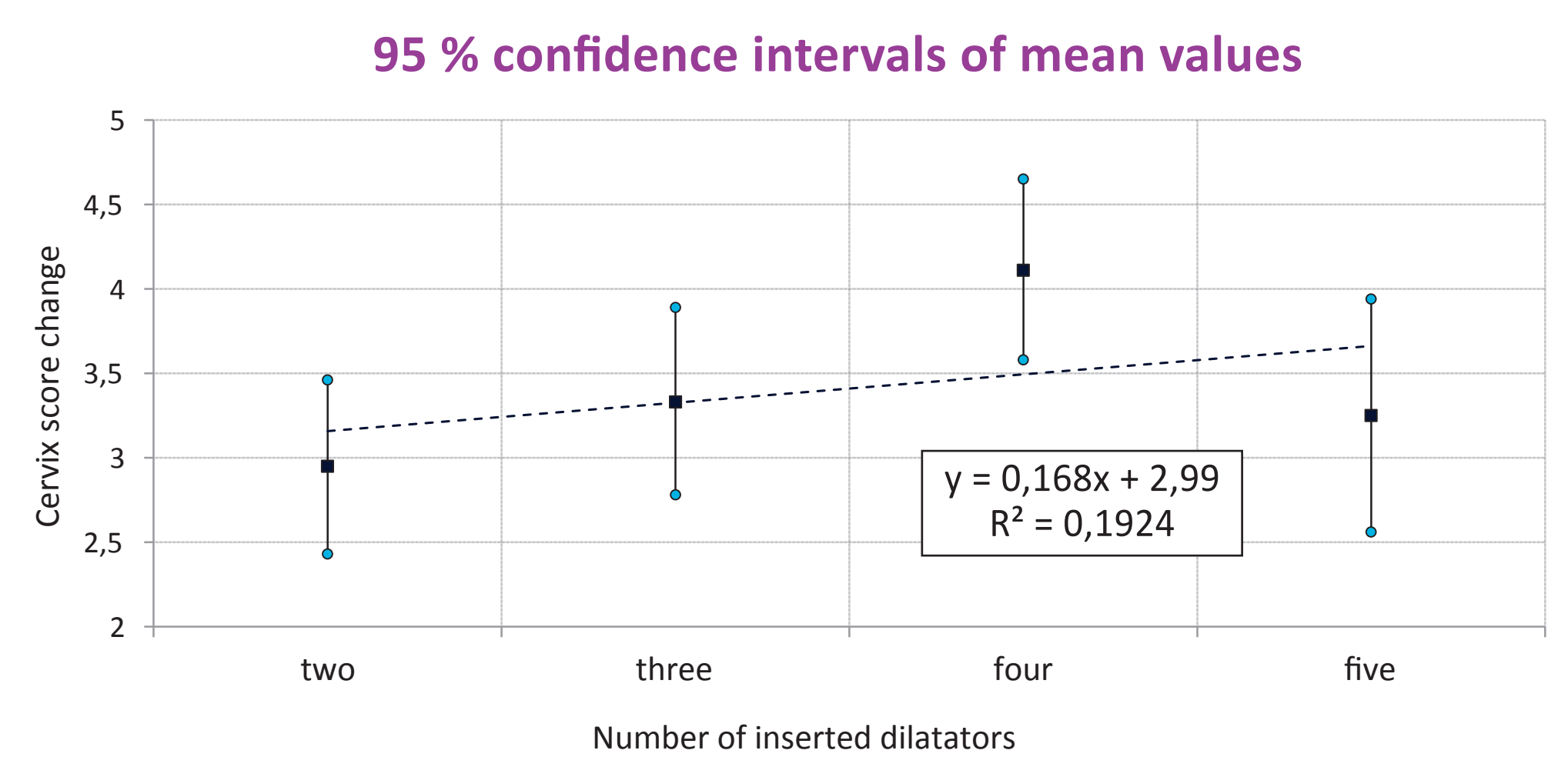
**Fig. 2:** Consistency of swelling of Dilapan-S<sup>®</sup> dilators enables clear predictability of their action

## Results 1:

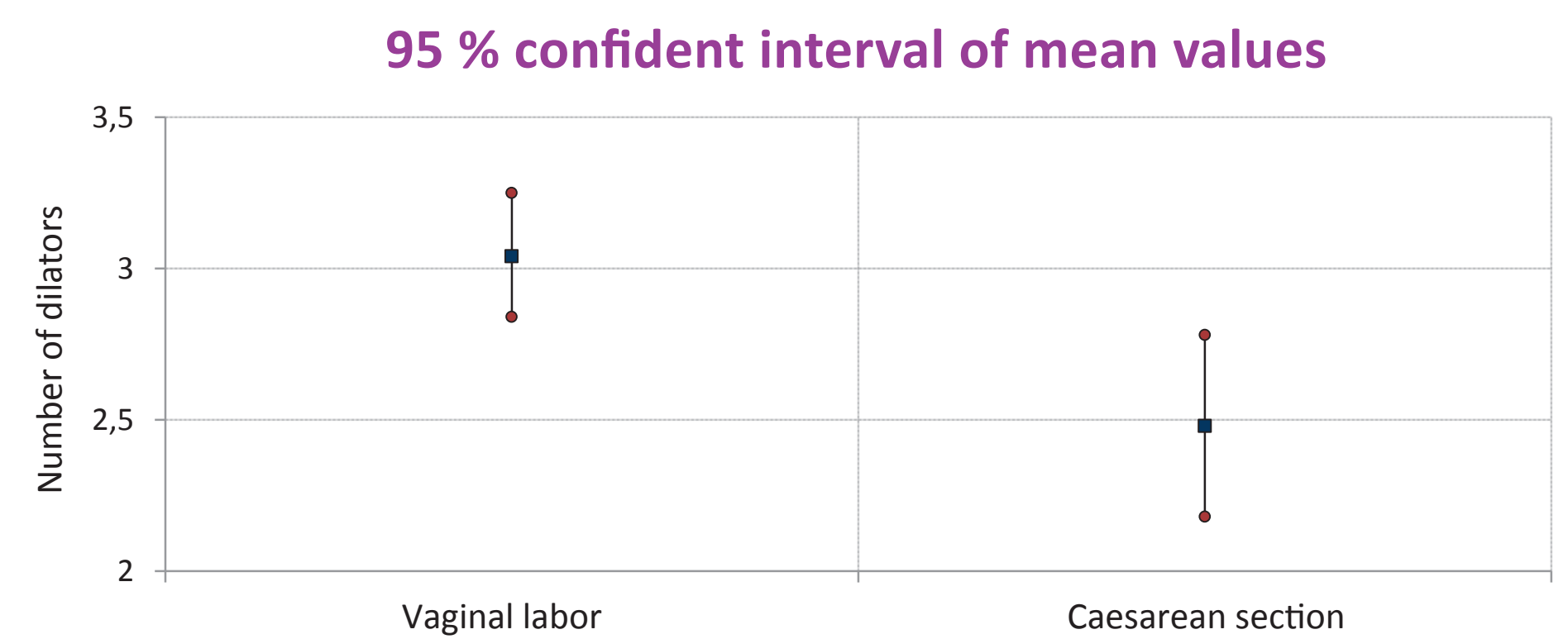
The evaluation of efficacy of Dilapan-S<sup>®</sup> in labor pre-induction showed that the application was effective in terms of the Bishop cervix score progression with the increase from a mean of 2,81 to 6,13. In total, the mean number of used dilators was 2,9 (range: 2 to 5). Successful pre-induction (Bishop score 5 and more) was achieved in 86.5 % of women. 68 females (71.6 %) delivered vaginally, 27 females (28.4 %) delivered by Caesarean section. When comparing the subgroup of women with a Caesarean section in their medical history and the subgroup of women without previous CS, there was no significant difference in the ratio of completed vaginal births.

## Results 2:

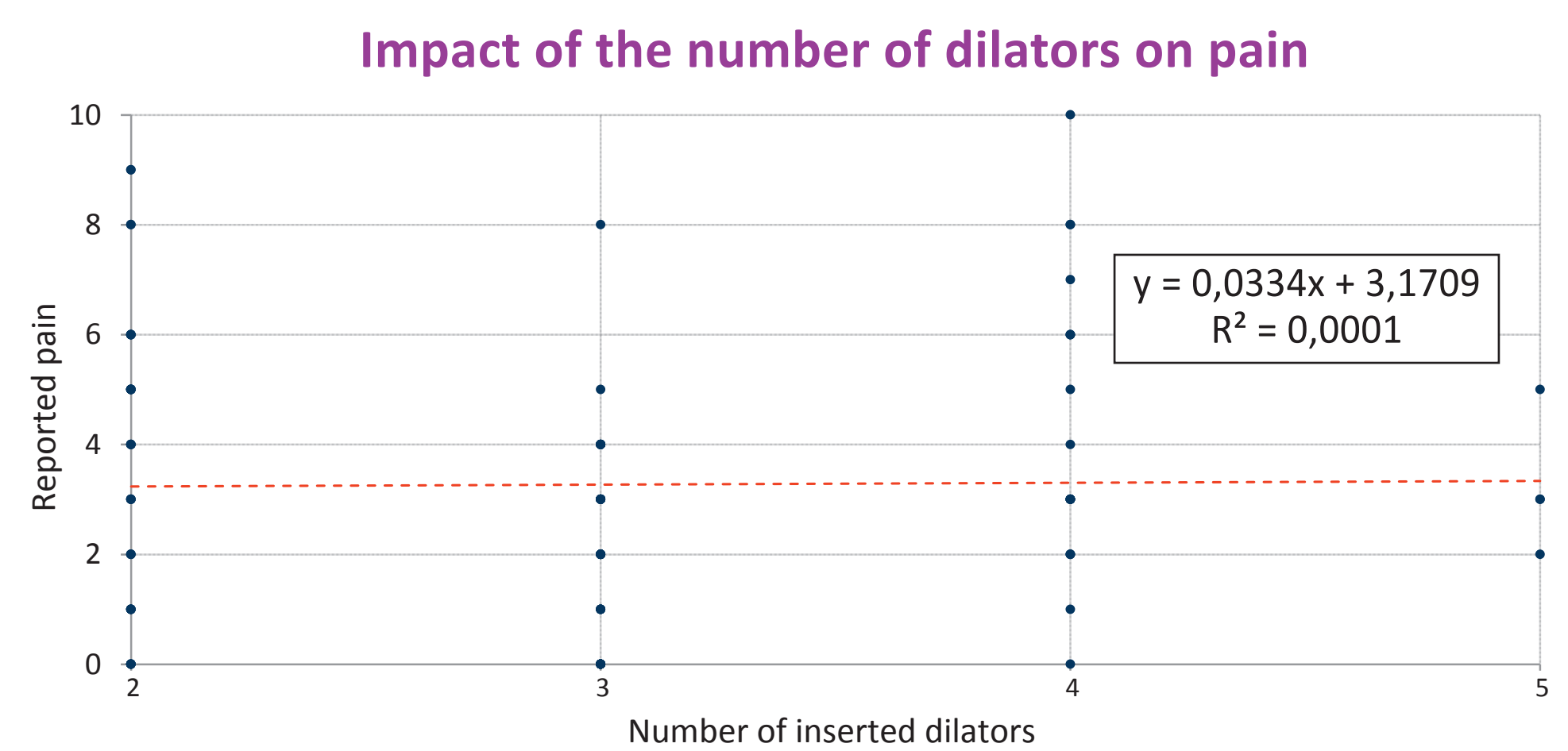
A statistically significant difference in the mean values of the cervix score change between groups of females with 2 and 4 inserted dilators was confirmed ( $p$  value  $\leq 0,002$ ). The analysis also showed that there is a statistically significant difference in the mean values of number of inserted dilators between patients with subsequent vaginal delivery and Caesarean section ( $p$  value  $\leq 0.0019$ ). The analysis didn't show that the number of inserted dilators had an impact on pain during insertion and the women's ability to sleep and relax during the pre-induction.



**Graph 1:** Cervix score change in relation to the number of inserted Dilapan-S<sup>®</sup> dilators in all females



**Graph 2:** Effect of the number of inserted dilators Dilapan-S<sup>®</sup> on outcome of delivery in all females



**Graph 3:** No impact of the number of inserted Dilapan-S<sup>®</sup> dilators on the pain during insertion in all females

## Conclusion:

The use of higher number of Dilapan-S<sup>®</sup> dilators were more efficient in terms of efficiency of cervical dilation and also in terms of achieving a vaginal birth. Higher number of inserted Dilapan-S<sup>®</sup> dilators was not accompanied by more pain during their insertion or worsening of rest for women during pre-induction. Achieving shorter pre-induction time was not among the objectives of this study, but from the presented impact of number of Dilapan-S<sup>®</sup> dilators on Bishop score we can assume that the introduction of a higher number of dilators could potentially lead to a shortening of the pre-induction time.

**References:** 1. Jozwiak, M. et al.: Mechanical methods for induction of labour (Review), The Cochrane Library, 2012  
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3. Gilson, J. et al: A prospective randomised evaluation of hygroscopic cervical dilator, DILAPAN, in the preinduction ripening of patients undergoing induction of labor, AJOG, 1996