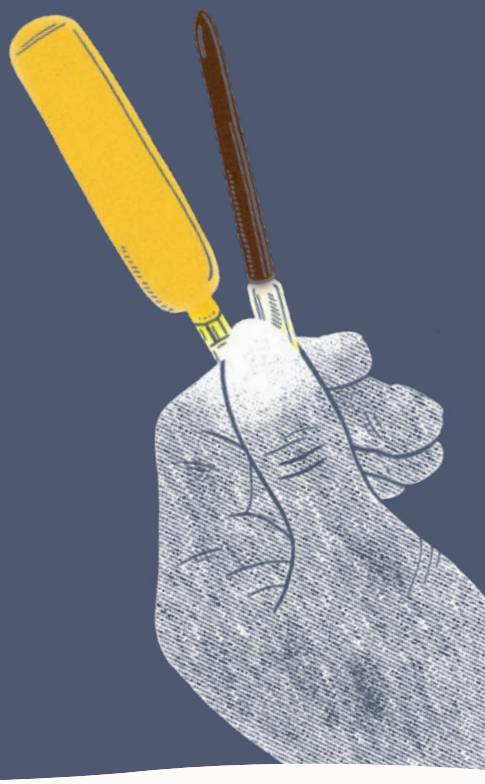
Dilapan-S®

A Randomised Controlled Trial of Dilapan-S® versus Foley Balloon for Pre-induction Cervical Ripening (DILAFOL Trial)



Study design

A single center, randomised, open-label trial.
419 women were randomised from November 2016 to February 2018.

Principal Investigator

Antonio F. Saad, MD, University of Texas Medical Branch, Galveston, Texas.

Objective

Confirm DILAPAN–S non-inferiority to the Foley balloon for pre-induction cervical ripening at term.

Baseline characteristics

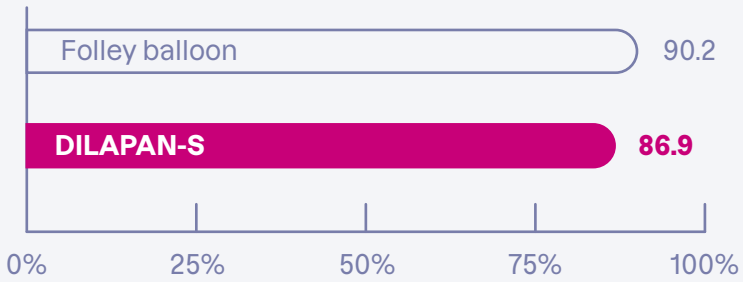
Nulliparous represented 41.9 % of subjects in DILAPAN-S group and 46.9 % in the Foley balloon group.

DILAPAN-S is a highly effective cervical ripening agent, with a vaginal delivery rate of 81%.

DILAPAN-S offered significantly higher maternal satisfaction over Foley balloon during cervical ripening. Induced women were better able to sleep, relax and perform daily activities without limitations.

First round cervical ripening success rate

High rate of successful cervical ripening was comparable between the groups



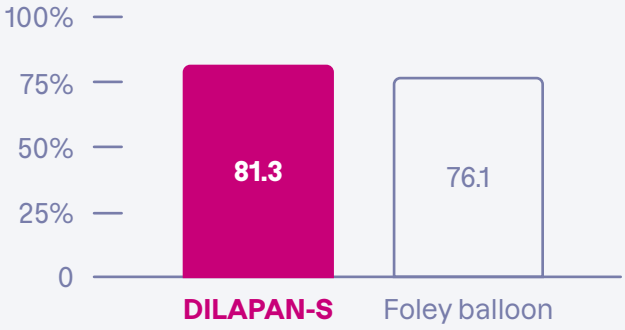
In the DILAPAN-S group the outcome was achieved by leaving 5 dilators in place for 13 hours.

5
dilators

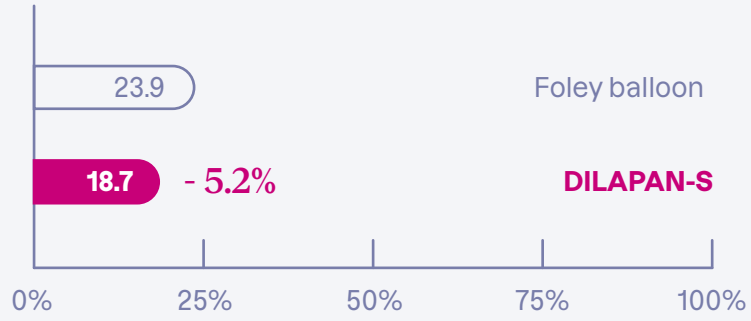
13
hours

The criteria for evaluation of successful ripening were primarily cervical dilation (>3cm) and effacement (>60%) rather than a complete Bishop score assessment.

Vaginal delivery rate



Caesarean section rate

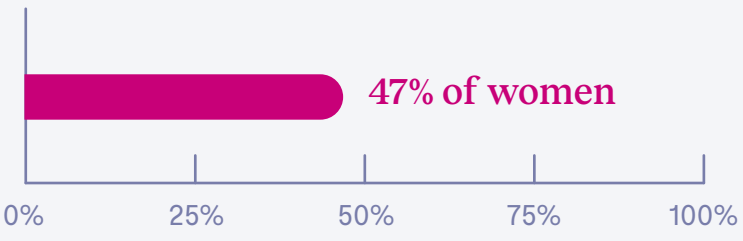


The results indicated a trend towards more vaginal deliveries and a lower Caesaeran section rate in DILAPAN-S group vs Foley balloon.

Vaginal delivery within 24 hours

Almost 50% of women delivered within 24 hours of DILAPAN-S insertion.*

*Data on file.



Dilapan-S®

Safety

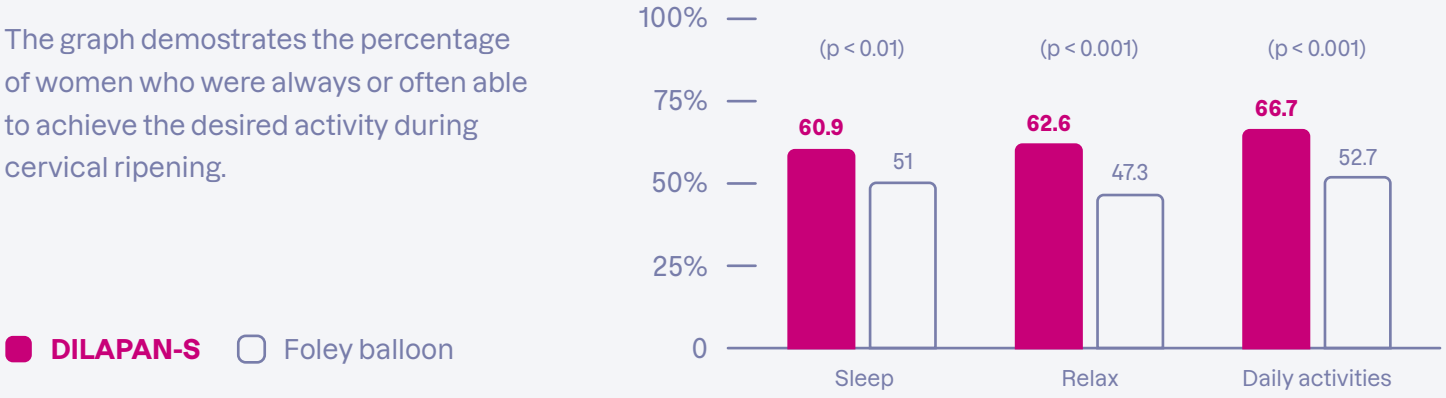
Low occurrence of adverse events confirmed DILAPAN-S favorable safety profile.

	DILAPAN-S	Foley Ballon
Vaginal bleeding*	3.1 %	0.9 %
Rupture of membranes*	0.9 %	0.9 %
Tachysystole*	0 %	0 %
Non-reassuring fetal status*	0.5 %	1.4 %
5 min Apgar < 7	0.5 %	0.5 %
Maternal infectious co-morbidity**	0 %	0 %

* During cervical ripening interval
** Related to device used

Maternal satisfaction

The graph demostrates the percentage of women who were always or often able to achieve the desired activity during cervical ripening.



DILAPAN-S offers greater maternal satisfaction during cervical ripening, compared with Foley balloon; induced women were significantly better able to sleep, relax and perform daily activities without limitations. Additionally, DILAPAN-S does not protrude from the introitus and does not need to be kept under tension.

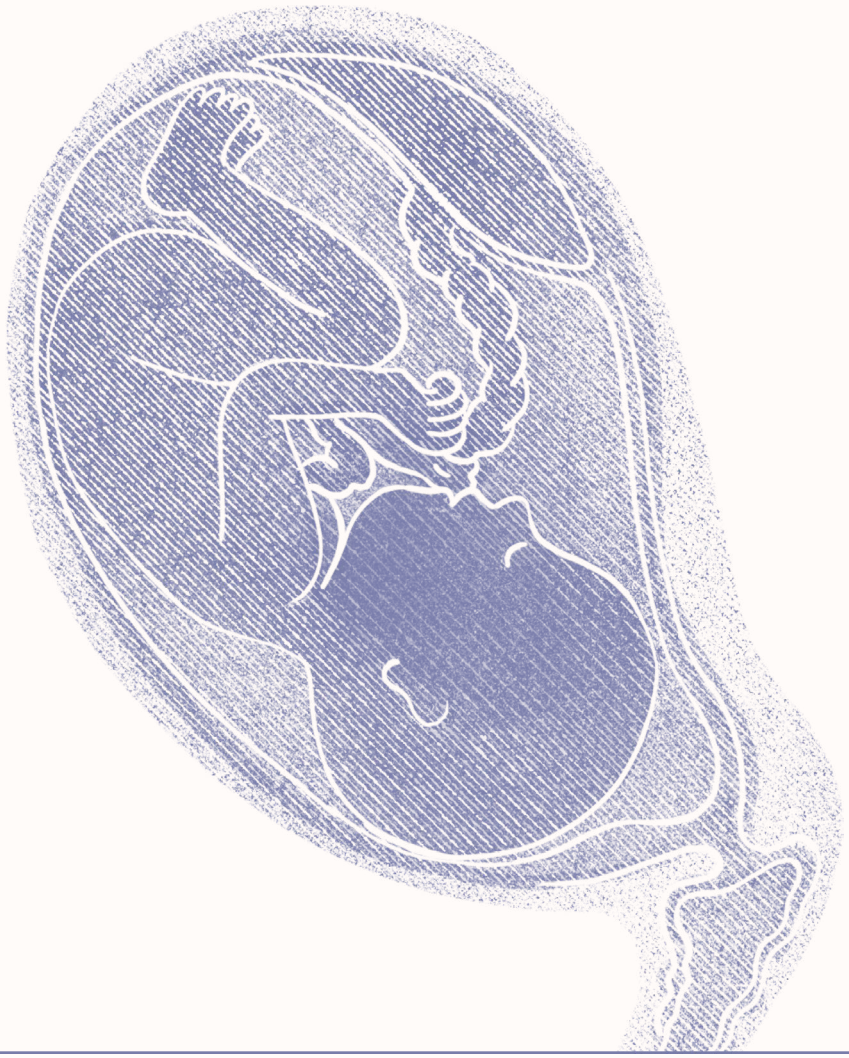
DILAFOL trial – DILAPAN-S key facts

87 %
first round cervical ripening success rate

81 %
vaginal delivery rate

47 %
vaginal delivery rate within 24 hours

0 %
serious maternal and fetal complications



REFERENCE: Saad A. et al. A randomized controlled trial of DILAPAN-S vs Foley balloon for preinduction cervical ripening (DILAFOL trial), Am J Obstet Gynecol 220(3):275.e1-275.e9., March 2019

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DILAPAN-S is manufactured by company MEDICEM Technology s.r.o., Czech republic (www.medicem.com)

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