



Vaginal dryness, meet your match

This K-Y® in-use clinical study is the **first of its kind**

The in-use clinical study **established the effectiveness** of five personal lubricants, three of which were **K-Y® Ultragel®**, **K-Y® Jelly** and **K-Y® Natural Feeling®***, in women who experienced intimate discomfort associated with vaginal dryness.

Each lubricant:

- ◆ improved sex for both pre- and post-menopausal women based on the Female Sexual Function Index (FSFI) without serious adverse events
- ◆ respected the vaginal microbiome
- ◆ did not disrupt the vaginal pH

K-Y® Ultragel®, K-Y® Jelly and K-Y® Natural Feeling® lubricants **are formulated to be within WHO osmolality guidelines while preserving efficacy.**

WHO=World Health Organization.

* The clinical study lists K-Y® Natural Feeling® as Durex® Naturals Moisture.

For the first time, K-Y® lubricants have been **clinically proven** to provide relief from intimate discomfort associated with vaginal dryness while not altering the vaginal microbiome.



The new and groundbreaking in-use clinical study explored the effectiveness of lubricant use for relief from vaginal dryness during sex

study design:

The study consisted of 174 pre- and post-menopausal women, aged 18 to 65, in an open label, five-arm, parallel-design, clinical investigation to determine the effectiveness and safety of five* water-based personal lubricants for the relief of intimate discomfort associated with vaginal dryness.

primary endpoint:

Change from baseline in total Female Sexual Function Index (FSFI) score assessed at the end of the 4-week lubricant-use period.

An increase of 4 points in the FSFI score from baseline to 4 weeks post lubricant use is considered a clinically significant change.

secondary endpoint:

A change from baseline in the six FSFI individual domain scores at 4 weeks post lubricant use was met:

all K-Y® lubricants indicated a positive change value across all domains.

The FSFI is a **clinically recognized tool** that is a self-reported measure of sexual functioning in six domains (desire, arousal, lubrication, orgasm, satisfaction and pain).

A clinically significant improvement of more than 4 points in the total FSFI score from baseline to 4 weeks post lubricant use was achieved for all K-Y® lubricants.

	K-Y® Ultragel	K-Y® Jelly	K-Y® Natural Feeling®
Investigational device			
Osmolality (mOsm/kg)	780 – 1180	780 – 1180	850 – 1200
pH range	3.5 – 4.5	3.5 – 4.5	3.5 – 4.5
Mean change in total FSFI score from baseline to 4 weeks post lubricant use	+ 5.7	+ 5.1	+ 5.4

*All K-Y® lubricants showed a statistically significant increase from baseline to 4 weeks ($p < 0.0001$).

mOsm/kg=milliosmoles per kilogram.

* All five lubricants include reformulated K-Y® Ultragel®, reformulated K-Y® Jelly, K-Y® Natural Feeling® (listed as Durex® Naturals Moisture in the clinical study), original and reformulated Durex Play Feel.

According to the WHO, lubricants with high osmolality may contribute to vaginal and anal epithelial disruption or damage.

This can lead to:

- ◆ irritated intimate tissue more susceptible to sexually transmitted infections (STIs)
- ◆ potential impact on the composition of the vaginal microbiota

K-Y® is committed to **respecting the intimate balance of the vaginal microbiome by reformulating the pH of personal lubricants to be in line with a healthy vagina (3.5-4.5) and within the WHO's osmolality recommendation without compromising performance.**

Osmolality is number of mmol of solute in solvent. WHO recommendation is ≤ 1200 mOsm/kg.



scan to read the published clinical study

Clinically proven good sex for your patients. Talk with your patients about K-Y® for enhanced pleasure and comfort.

Palacios S, et al. A randomized trial on the effectiveness and safety of 5 water-based personal lubricants. *J Sex Med* 2023. doi:10.1093/jsxmed/qdad005.



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