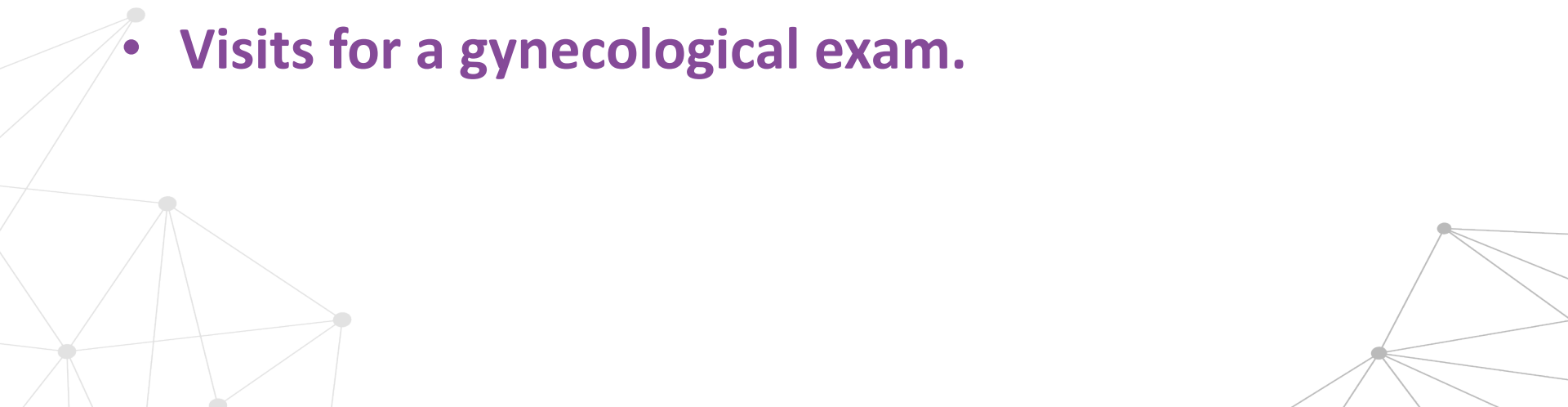


Case 7

**Woman vaccinated against HPV with
cervical intraepithelial lesion**

Dr. Javier Cortés

- 35 years of age. 2 children. Has an IUD in place since 4 years ago.
 - No relevant pathological history.
 - Visits for a gynecological exam.
- 

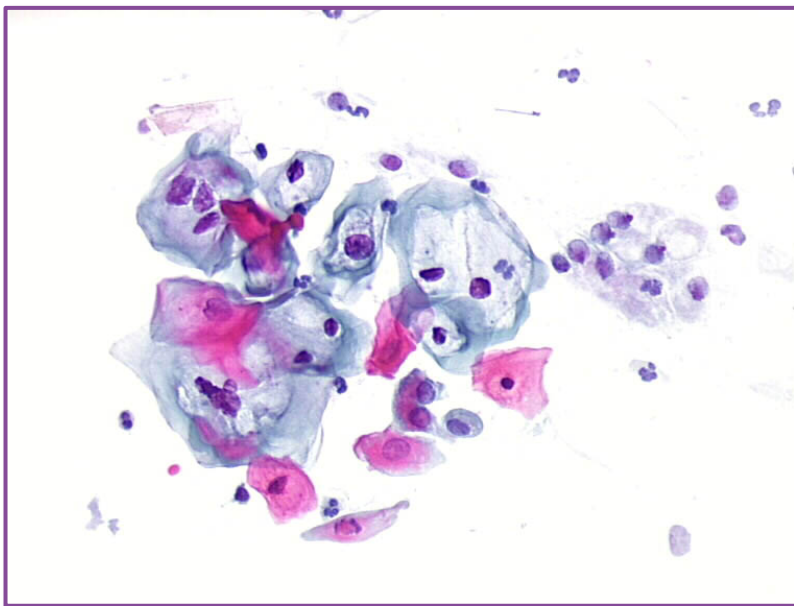
- Stable sexual partner for last 7 years.
- Previously, open sexual relations, always heterosexual, often without protection.
- Annual gynecological exams, always with negative cytology.
- Vaccinated with Gardasil 9® 14 months ago.

Action

- A gynecologic examination is performed and a sample is obtained for HPV determination.

- Clinically normal gynecologic examination
- HPV Determination: **Positive for HR types not 16/18**
- Platform used: Cobas[®] 4800 HPV Test.

Cytology indicated

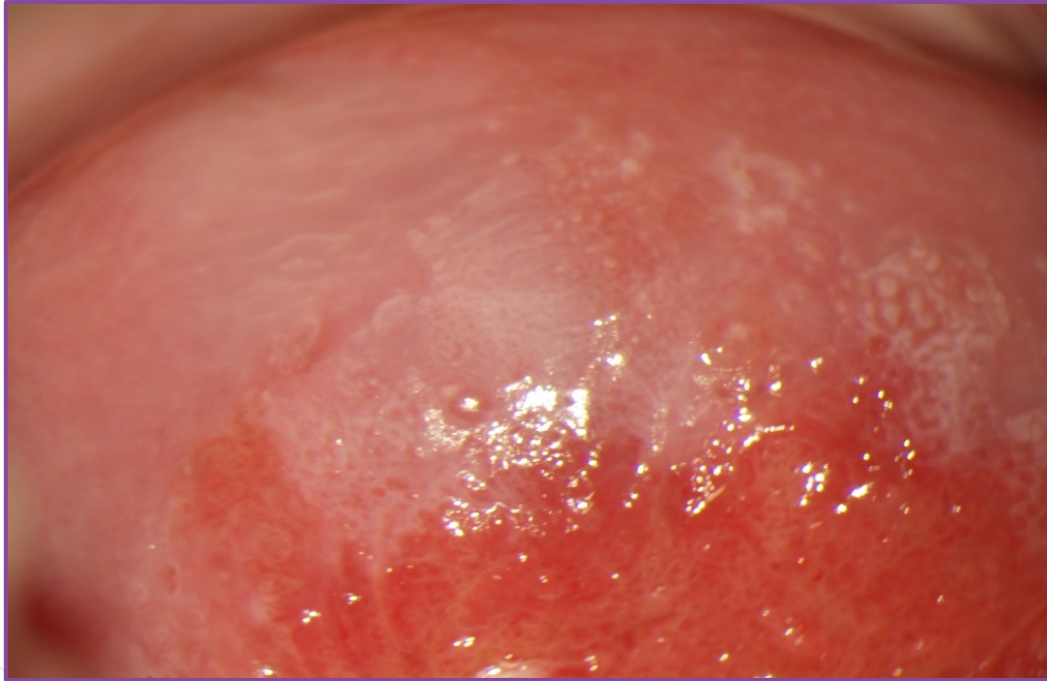


LSIL¹

COLPOSCOPY INDICATED²

1. <https://screening.iarc.fr/atlasclassifbethesda.php>

2. Oncoguía SEGO: Prevención del cáncer de cuello de útero [SEGO Oncoguides: Cervical cancer prevention]. Guías de práctica clínica en cáncer ginecológico y mamario [Practical clinical guidelines in gynecological and breast cancer]. Publicaciones SEGO, October 2014.



G1 Changes³

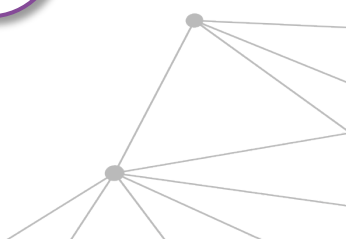
3. Bornstein J.: 2011 colposcopic terminology of the International Federation for Cervical Pathology and Colposcopy. Obstet Gynecol. 2012;120:166-72.

- **No biopsy. Follow-up²**

- **Recommended:**

- **Treatment with Papilocare[®].**
- **New check-up in 6 months.**

2. Oncoguía SEGO: Prevención del cáncer de cuello de útero [SEGO Oncoguides: Cervical cancer prevention]. Guías de práctica clínica en cáncer ginecológico y mamario [Practical clinical guidelines in gynecological and breast cancer]. Publicaciones SEGO, October 2014.



HPV vaccination is strictly prophylactic, with no therapeutic effect on HPV infections present at the time of vaccination.

HPV vaccine efficacy data*

Gardasil 9®

Efficacy: 95% CI

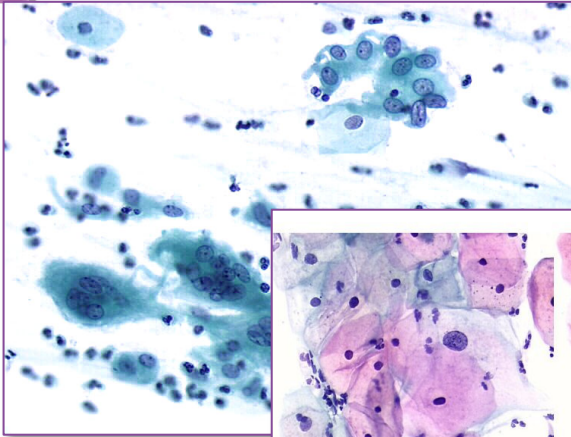
- **CIN 2/3, AIS, Cervical Cancer, VIN 2/3, VaIN 2/3, Vulvar Cancer and Vaginal Cancer** related to HPV 31, 33, 45, 52, 58:
 - **97.4** (85.0; 99.9)
- **CIN 2/3, AIS** related to HPV 16, 18:
 - **98.2** (93.5; 99.8)
- **VIN 2/3** related to HPV 6, 11, 16, 18:
 - **100.0** (67.2; 100.0)
- **VaIN 2/3** related to HPV 6, 11, 16, 18:
 - **100.0** (55.4; 100.0)
- **Genital Warts** related to HPV 6, 11, 16, 18:
 - **99.0** (96.2; 99.9)

Cervarix®

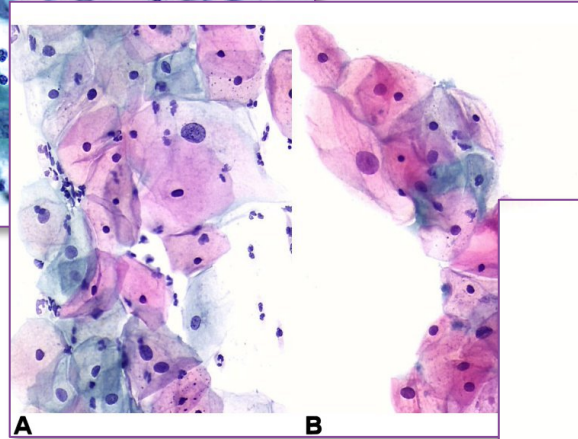
Efficacy: 95% CI

- **CIN 2/3 Efficacy** related to HPV 16, 18:
 - **94.9** (87.7; 98.4)
- **CIN 2/3** related to:

• HPV 31	87.5	(68.3;96.1)
• HPV 33	68.3	(39.7;84.4)
• HPV 39	74.9	(22.3;93.9)
• HPV 45	81.9	(17.0;98.1)
• HPV 51	54.4	(22.0;74.2)

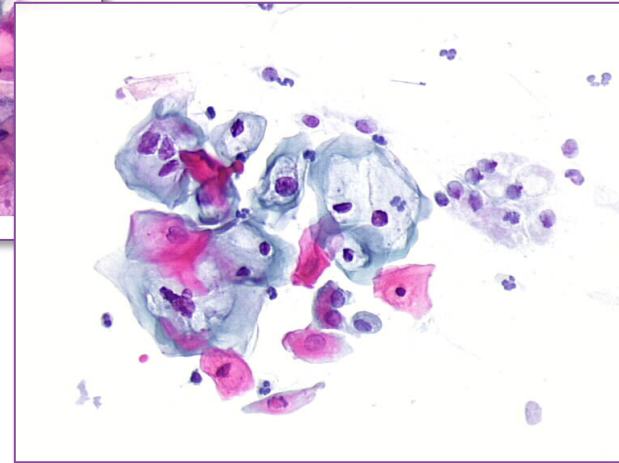


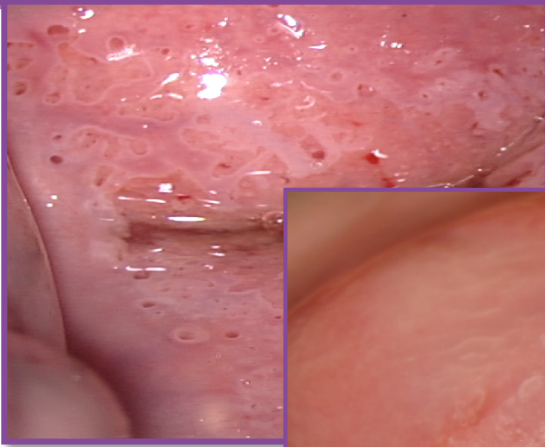
Changes due to IUD



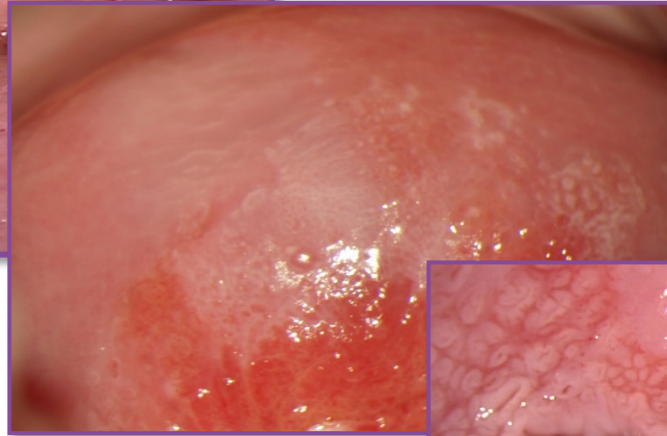
ASC-US

LSIL

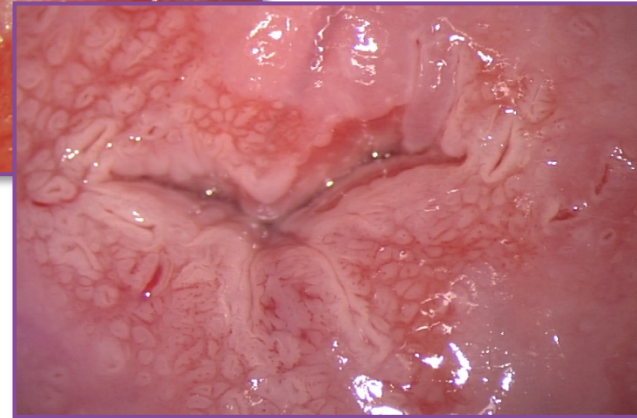




Normalcy



G1 Changes



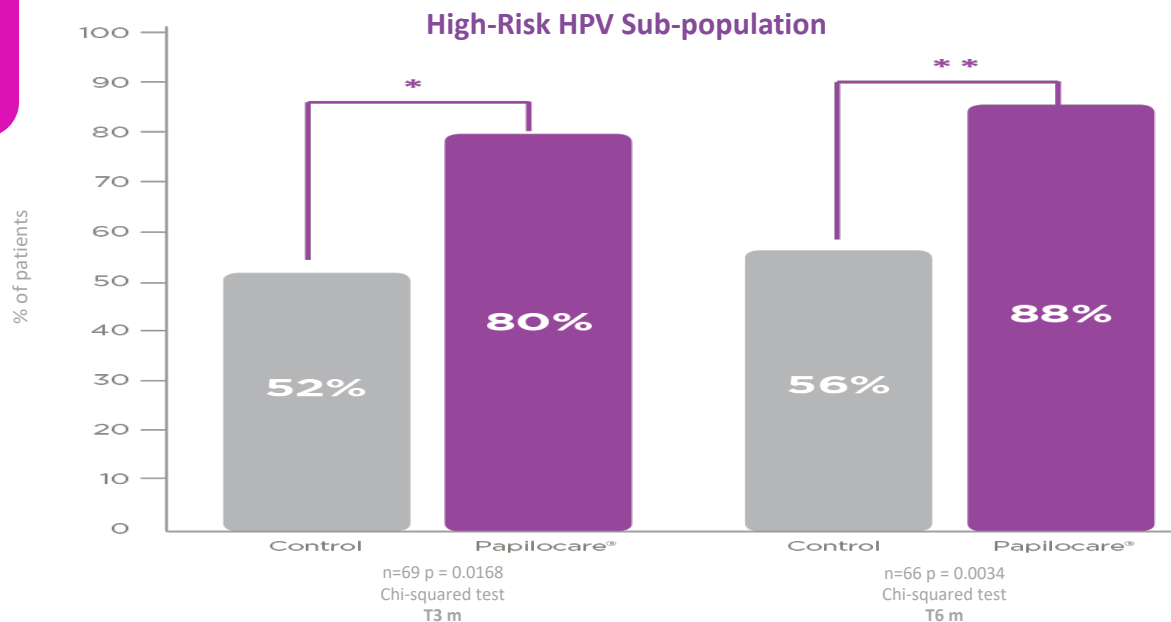
G2 Changes

PAPILOCARE®

Paloma Clinical Trial*.

Final results

CYTOLOGICAL NORMALIZATION LSIL / ASC-US AT 3 AND 6 MONTH WITH CONGRUENT COLPOSCOPY



Spontaneous regression to normalcy of LSIL: **59.1%** at 2 years

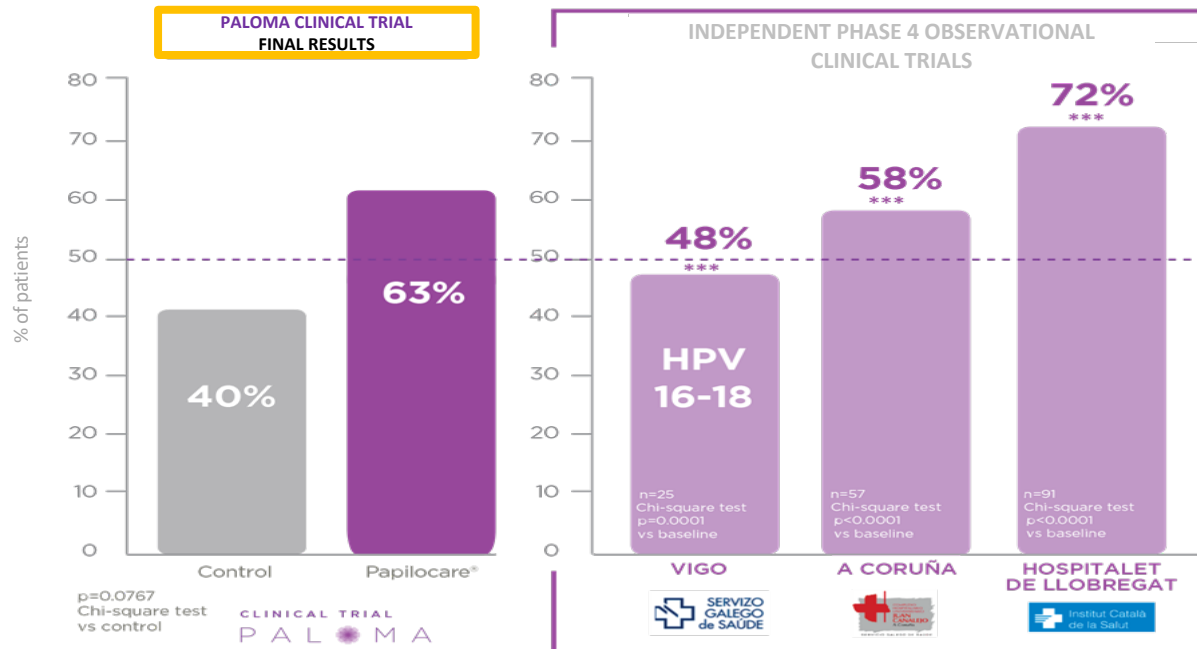
Matsumoto IJC 2011

PAPILOCARE®

Paloma Clinical Trial.

Final results &
independent studies

HIGH-RISK HPV CLEARANCE AT 6 MONTHS

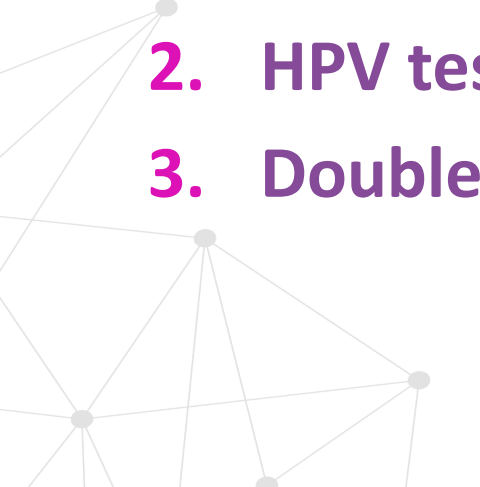
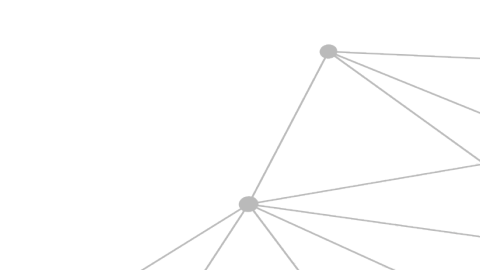


HPV-HR Clearance: 29% at 6 months

Bulkman BJC 2007

PALOMA: Cortés J et al. ASCCP 2020 Orlando
VIGO: Gil Andrés M et al. ASCCP 2018, Las Vegas
CORUÑA: Gajino C. IPCV 2018. Sydney,
HOSPITALET: Riera M et al. J Low Genit Tract Dis. 2018.

What is the preferred cervical cancer screening test?

- 
- 
1. Cytology.
 2. HPV test.
 3. Double test, cytology + HPV test.

For a low-grade cytological lesion with congruent colposcopy, what action should be taken?

- 1. Biopsy.**
- 2. Monitoring.**
- 3. Monitoring with Papilocare[®] treatment and vaccination against HPV.**

After six months of follow-up, what rate of regression to normalcy can be expected for a low-grade lesion after treatment with Papilocare®?

1. 88%.

2. 68%.

3. 48%.