

APPROVED BY
Chief Doctor of Maternity Clinic #32
Monasheva G.M

22/05/2011
Moscow

**Report about clinical approbation of the
Wound covering Flamen[®]
produced by Scientific Company «Flamen»**

Executors:
Obstetrician-gynecologist Uzdenova S.A.

Report:

About clinical approbation of the *Wound covering Flamen[®]* produced by Scientific company "Flamen".

Research goal:

To evaluate efficiency of the *Wound covering Flamen[®] (vaginal set)* curing the cervix background deceases.

Research execution:

Approbation periods: 03.03.11-20.05.11

The cervix was treated by an antiseptic solution "Oktinisept", exposed in mirrors and *Wound covering Flamen[®]* was applied onto the cervix injured area. The woman had to stay in a supine position for 30 min afterwards. Procedure was carried out daily within 10 days.

The clinical research was carried out to analyze results of the therapy including: anamnesis, general and gynecological examination, cytological research, colposcopy, examination on sexually transmitted infections (Chlamydia, human papilloma virus HPV, herpes simplex virus HSV, cytomegalovirus disease CMV), cervical smear, studying of ovarian hormonal activity.

The control examination was carried on 11th day after the treatment was started.

The following factors were taken into account while anamnesis was done: earlier sexual activity onset- age before 15 years old; sexual partners number; burdened maternal obstetric and gynecological anamnesis (artifactual abortion; two and more abortions; embryotocia; non-developing pregnancy and therapeutic abortion); the cervical injury received at birth followed by suturing appropriate for parous women.

Gynecological exam was performed by using mirrors which help to find presence of pathological processes on the cervix of different diameter and localization visually.

Colposcopy was carried out in a simple way and in advanced way by using 3% acetic acid and Schiller's test (2-3% Lugol's iodine solution).

The *Wound covering Flamen[®]* was used for therapeutic purposes to cure cervical pathology after the complete examination.

There were performed the detailed examination and medical treatment of 23 women with the background deceases of the cervix. All women were with different pathology in a hospital treatment at the department of gynecology:

Disease	Number of patients	Part (%)
Dysfunctional uterine bleeding	9	39.13%
Ovarian apoplexy	4	17.40%
Ovulatory syndrome	3	13.05%
Embryotocia	1	4.35%
Salpingo-oophoritis (adnexitis)	1	4.35%
Ectopic pregnancy	1	4.35%
Induced abortion	2	8.70%
Non-developing pregnancy	2	8.70%

Patients' age varied from 15 to 61, average age was 28.4.

Aspiration of material for cytological research was carried out from the top of endocervix on the separate microslides using special brush.

Results of cytological research	Patients number
Cervix ectopia	17
Chronic exocervicitis	20
Dysplasia of 1-2 degree	1

Nicon350 was used for colposcopy

PCR-diagnostics of sexually-transmitted infections:

STIs	Patients number	Percentage (%)
Human papilloma virus (HPV)	9	39.13
16/18 type	1	4.35
Trichomonas vaginalis	3	13.04
Chlamidia trachomatis	2	8.70
Mycoplasma hominis	3	13.04
Genitalium	2	8.70
Ureaplasma parvum	3	13.04

Microbiology of Papanicolaou smear (cervical smear)

Microbes	Number of patients	Percentage (%)
Escherichia coli	13	56.52
Staphylococcus	4	17.39
Streptococcus	2	8.70
Quantity of microbes didn't change	4	17.39

Results:

There was noticed a complete recovery of 85% of patients after the full course of treatment (10 days). The recovery was characterized by the formation of ectocervix normal multilayered epithelium. The last 15% of patients noticed the partial response to treatment in a form of marginal epithelialization. A control gynecological examination to all patients was performed one month later after the beginning of treatment. There were no pathological processes noticed on the cervix.

There was observed a single case of effective patient's treatment with dysplasia of 1-2 degrees which suggests the possibility of using this treatment at this condition, but requires further and deeper research.

Conclusion:

The positive dynamics which led to full recovery was noticed in the main group of patients after the treatment with the *Wound coverings Flamen*a®. This fact demonstrated the effectiveness of this medical treatment curing the cervix background deceases.

Also, the significant reduction of treatment and recovery terms was noticed using above mentioned therapy curing cervix pathologies.

Cervix cicatrisation risk and its tissue change were minimized due to reparative regeneration (angenesis).

Repeated examination revealed no backsets and pathologies.