Clinical Trial Results of Topical Growth Factor Gel for Vaginal Atrophy Treatment

Clinical results of Cellese Growth Factor topical vaginal rejuvenation treatment, containing human growth factors. The results of the trial proved the efficacy of a home-care solution to improve symptoms of vaginal atrophy.

Abstract:

A four-week clinical study was conducted at the Urogynecology Unit Hospital Universitario in San Jorge Pereira, Colombia from April 2018 to June 2018.

To evaluate the effectiveness of a topical treatment for atrophic vaginitis, 10 post-menopausal female volunteers ranging in age from 53–66 participated in a 4-week trial. All of the subjects exhibited genito urinary symptoms related to Genito Urinary Syndrome of Menopause (GSM) within the previous 24 months. Two gynecologists carried out the clinical evaluations.

Volunteers received 12 take-home specially formulated growth factor gel in a nozzle crimp tube applicator. The formulation was comprised of multiple human growth factors including hyaluronic acid.

One tube applicator was to be self-administered by the volunteer prior to bedtime every three days for one month. Volunteers were instructed to apply the contents of the tube applicator into the vagina cavity and wall, discarding the empty tube following treatment.

During the 4-week period, 8 of the 10 women completed the clinical trial. The symptoms used in the study to evaluate before and after results were: Dryness, itching, dyspareunia, pressure, dysuria, urgency, urinary tract infection, and stress incontinence. The results were calculated and averaged using a scale of zero to five, with zero being no symptoms, and five being severe symptoms.

Introduction:

Vaginal atrophy also known as genitourinary syndrome of menopause (GSM), attributed to estrogen deficiency, (common at the end of reproductive years) is estimated to affect 50% of women, yet 90% fail to seek treatment.

Often related to a wide range of uro-gynecological symptoms, GMS involves the thickening of collagen fibrils and disorganization of total collagen content, mainly due to decreased collagen I synthesis and increased fibrilragmentation.

The most common symptoms associated with vulvo-vaginal atrophy are dyspareunia, vaginal dryness, irritation, recurrent urinary tract infection, and urinary incontinence, which negatively affect the patient's quality of life and sexuality.

The homecare vaginal rejuvenation utilized is a non-hormonal and non-surgical rejuvenation topical product that appeared to be safe, effective, and a convenient treatment for vaginal atrophy.

Current pharmaceutical treatments such as systematic estrogen therapy, laser, topical estrogens, laser, dilators, vaginal inserts, rings, and patches have undesired side effects, can be costly, and may cause discomfort during the treatment process. Despite the numerous treatment options, many women, maturing and menopausal, continue to suffer with symptoms of vaginal atrophy.

Following the onset of vaginal atrophy, and without treatment, symptoms often increase as estrogen levels naturally decrease. A four-week clinical study was conducted at the Urogynecology Unit Hospital Universitario in San Jorge Pereira, Colombia from April 2018 to June 2018.

To evaluate the effectiveness of a topical treatment for atrophic vaginitis, 10 post-menopausal female volunteers ranging in age from 53–66 participated in a 4-week trial. All of the subjects exhibited genito urinary symptoms related to Genito Urinary Syndrome of Menopause (GSM) within the previous 24 months. Two gynecologists carried out the clinical evaluations.

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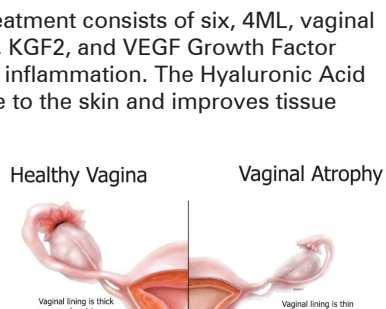
The psychological aspect and sensitive nature of this condition can negatively impact one's emotional and physical well-being.

The proprietary bio-signal treatment consists of six, 4ML, vaginal rejuvenation tubes. The KGF, KGF2, and VEGF Growth Factor support healing and mitigate inflammation. The Hyaluronic Acid a natural humectant, is native to the skin and improves tissue proliferation.

Each ingredient has peer reviewed literature and documented proof of efficacy in improving vaginal atrophyconditions commonly caused by low estrogen and the natural aging process.



Method:

A 4-week study was conducted of female 10 post-menopausal female volunteers ranging in age from 53-66, with clinically evaluated vaginal atrophy symptoms.

Vaginal Atrophy Characteristics
- Difficult or painful sexual intercourse, (Dyspareunia)
- Vaginal dryness, irritation and burning
- Urinary symptoms include urgency, dysuria, nocturia and urinary incontinence
- Recurrnt urinary tract infections.

Two gynecologists enrolled five patients each for the purpose of testing a topical non-pharmaceutical and non-hormonal vaginal rejuvenation gel to restore a natural micro-environment, and to improve vaginal atrophy symptoms caused by low estrogen.

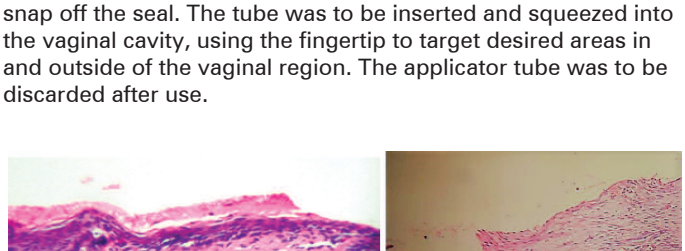
The volunteers provided written consent to participate and share before and after experiences. During the study, two subjects elected to end their participation.

Biopsies of the vagina were obtained before and after 12 weeks of growth factor treatment. The vaginal samples were subjected to basic and special histological studies performed by a blinded pathologist to identify trophic changes after treatment.

The pathologist used both Hematoxylin and Eosin (H&E) and modified Masson's trichrome staining.

Each subject was given 12 vaginal rejuvenation tubes containing human stem-cell growth factors (Recombinant human growth factors.) and cytokines that were synthesized in a laboratory. The volunteers were instructed to use one tube of the vaginal rejuvenation gel every three days for one month prior to bedtime.

To administer the vaginal rejuvenation product, the female volunteers were instructed to hold the applicator tube at the wide end, shake the product downward toward the narrow tip, and snap off the seal. The tube was to be inserted and squeezed into the vaginal cavity, using the fingertip to target desired areas in and outside of the vaginal region. The applicator tube was to be discarded after use.



Histological analysis of the vaginal mucosa by Hematoxylin and Eosin staining. Pre: Flattened epithelium and atrophic stroma with dense small cells (100x). (Right) Post: Epithelium with extra cell layers, stroma growth and more fibroblasts

Results Summary:

A total of nine symptoms of vaginal atrophy from were assessed over a four-week period.

Subjects who completed the four-week trial evaluated the convenience of the at-home, self-administered treatment, the ease of its application, as well as the physical and cosmetic results.

All patients reported high levels of satisfaction with the results regarding symptoms related to GSM as well as cosmetic improvement in the labia majora and perineal area. No side effects were reported by any of the subjects. Upon clinical examination at the end of the treatment period, the quality and trophism of both the vaginal mucosa and the vulvar skin and perineal area showed dramatic improvement.

Primary Outcome

Clinical changes related to vaginal atrophy as evaluated by clinical examination, and changes in the VHI and FSFI score.

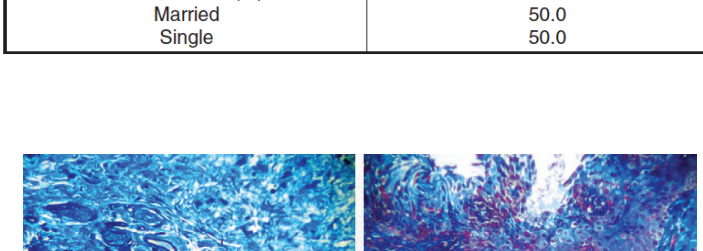
Secondary Outcomes

Cosmetic improvement of the vulvar and perineal area as evaluated by a Vulvar Symptoms Questionnaire (VSQ).12 Treatment satisfaction as evaluated using a visual analogue scale (VAS) from the baseline conditions to the end of treatment.

All 10 subjects completed the protocol (Table I).

Table I
Demographic variables of the subjects (n=10)

Age (± SD) (years)	56.9 (± 3.19)
BMI (± SD) (kg/m2)	24.4 (± 1.55)
Parity (± SD)	2.5 (± 0.6)
Marital Status (%)	
Married	50.0
Single	50.0



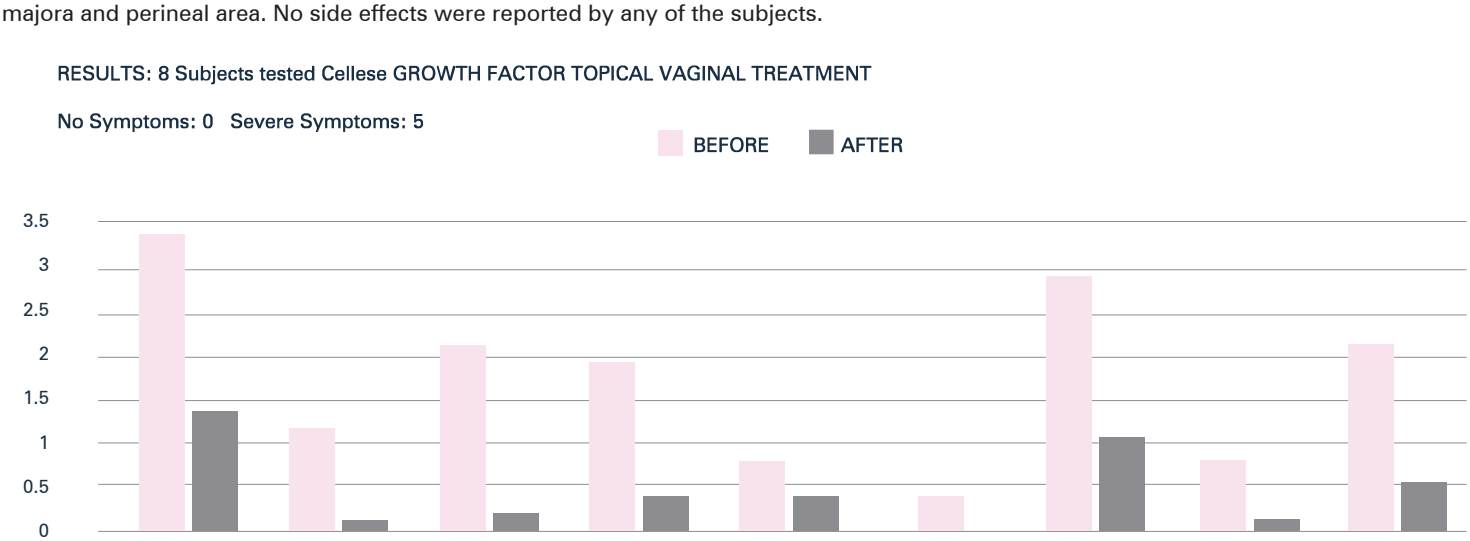
Histological analysis of the vaginal mucosa by modified Masson's trichrome staining. Pre: Dense and disorganized collagen and atrophy (4x). Post: Epithelium with several layers of cells of stromal maturation with an increase in collagen (4x).

Results Summary Cont.:

Important clinical and histological changes were seen during the 12-week course of treatment.

All 10 subjects completed the protocol (Table I). Important clinical and histological changes were seen during the 12-week course of treatment. All of the subjects who were treated with topical growth factors showed improvements according to scores on the visual analogue scale (VAS) and vaginal health index (VHI).

All patients reported high satisfaction with the results regarding symptoms related to GSM as well as cosmetic improvement in the labia majora and perineal area. No side effects were reported by any of the subjects.



Professional rating: Score of subjects showing improvements over 9 key categories

Discussion:

Topical Bio-Signals

The relationship between estrogen receptor activation and influence on downstream cytokine/growth factor cascades is well established.

As signaling proteins, growth factors work at the cell-transcription level to up-regulate sex steroid receptors.
They can also induce cellular proliferation, differentiation, and apoptosis without the side effects sometimes reported by patients using topical estrogen therapy.

Hence, application of selective offer a non-hormonal option for peri and post-menopausal GSM.

(Before treatment) (After treatment)

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Don't ignore vaginal dryness and pain. The condition is treatable, although treatments likely won't provide complete relief.
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