Enhancing Ovarian Reserve and Dermatological Health with NanoFiltration-Enhanced Sheep Placenta Supplement: A Clinical Evaluation of Biowell Placenta & DCI 40

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Abstract: This paper investigates the oral intake of sheep placenta supplements on ovarian reserve markers, skin health, and menstrual regularity in women under the age of 40 with diminished ovarian reserve or premature ovarian insufficiency. Twenty-four eligible female participants were enrolled in an 8-week intervention study. The participants were administered two capsules daily of Biowell Placenta & DCI 40. Assessments of ovarian function included Anti-Mü llerian Hormone (AMH), Follicle-Stimulating Hormone (FSH), Estradiol (E2), and Antral Follicle Count (AFC). Skin health was evaluated through participant self-assessment questionnaires pre- and post-intervention, focusing on elasticity, brightness, smoothness, and spot reduction. Menstrual cycle regularity and volume were also recorded. Post-supplementation, a statistically significant increase was observed in AMH (from 1.44±1.61 to 1.68±1.37 ng/ml, p=0.00104) and AFC (from 4.37±1.02 to 4.89±3.30, p=0.0045). Skin health assessments showed significant improvement in elasticity, brightness, and smoothness, with visible spot reduction. Menstrual cycle regularity and volume also enhanced, indicating improved hormonal balance. No adverse events were reported, indicating a high tolerance for the supplement. The Biowell Placenta & DCI 40 capsules, utilizing the innovative NanoFiltration process, have demonstrated potential benefits in improving ovarian and skin health and menstrual cycle regularity. This advancement in extraction technology shows promise in enhancing the bioactive efficacy of sheep placenta products, offering a novel non-invasive approach for women's health and aging concerns. Further research is warranted to confirm these findings in larger, controlled trials.

1. Introduction

The utilization of animal-derived placental products for therapeutic purposes is deeply rooted in various traditional medical practices, particularly within Asian cultures. These products are heralded for their rich nutritional profile and purported regenerative properties, especially in the context of
enhancing dermatological health and supporting reproductive functions. Among these, sheep placenta products have emerged as a focal point in the beauty and health sectors, attributed to their traditional applications in promoting skin vitality and aiding ovarian health\textsuperscript{[1]}.

However, the transition from traditional usage to evidence-based clinical application has been met with challenges. The efficacy of oral sheep placenta supplements, especially concerning their role in ovarian maintenance and cosmetic benefits, remains underexplored in scientific literature\textsuperscript{[1-2]}. This gap is partly due to previous methodologies in sheep placenta extraction that did not adequately preserve the bioactive components responsible for its purported health benefits.

Addressing this technological shortfall, Biowell has pioneered the NanoFiltration process, a novel extraction technique that significantly enhances the bioavailability of hydrophilic and active components within sheep placenta. By achieving an extraction ratio of 1000:1, this method marks a significant advancement over traditional approaches, promising to unlock the full therapeutic potential of sheep placenta. The anticipation surrounding this trial is heightened by the preliminary results attributing notable efficacy to Biowell's product in the realms of ovarian health and skin vitality, further propelled by the company's patent application for this innovative technology\textsuperscript{[3]}.

The implications of this study extend far beyond the validation of a traditional remedy. By offering a rigorous scientific examination of Biowell's sheep placenta product, this research seeks to contribute to the broader fields of biomedical, cosmetic science, and women's health\textsuperscript{[4]}. The potential development of a novel, non-invasive dietary supplement for combating ovarian aging, even overall aging, represents a significant leap forward in both preventive and therapeutic healthcare strategies.

In summarizing, this research endeavors to bridge the gap between traditional knowledge and contemporary scientific validation, employing cutting-edge technology to elucidate the health benefits of sheep placenta products. The forthcoming analysis aims to rigorously assess the efficacy of these supplements, setting a new benchmark for the integration of traditional ingredients into modern health and beauty regimens\textsuperscript{[5]}.

2. Material and Methods

2.1. Participant Selection Criteria

Female participants under the age of 40 were recruited; either those experiencing diminished ovarian reserve or those with premature ovarian insufficiency who had not consumed phytoestrogen supplements in the last month. Participants were required to maintain standard UV protection, not undergo any cosmetic medical procedures within the last two months, and be able to understand the significance of the study and voluntarily sign an informed consent form.

2.2. Trial Methodology and Intervention Duration

2.2.1. Test Process

On day 0, eligible subjects meeting the inclusion criteria were screened and tested for their indicators, following which three bottles of Biowell Placenta and DCI 40 (180 capsules) were distributed to each eligible subject, with a requirement to take two capsules daily for 56 days. Follow-up and data collection were conducted on day 56.

2.2.2. Ovarian Function Measurement Indicators\textsuperscript{[6]}

- Anti-Müllerian Hormone (AMH): AMH levels, deriving from the granulosa cells of developing follicles, reflect the total number of oocytes available, serving as an effective and reliable predictor of ovarian reserve.
• Follicle-Stimulating Hormone (FSH): FSH levels were measured to assess the hormonal balance effects of the product.
• Estradiol (E2): E2 levels were also measured to evaluate the product's hormonal balance effects.
• Antral Follicle Count (AFC) by Ultrasound: AFC directly correlates with the ovarian follicle pool, indicating the ovary's capacity to recruit eggs.

2.2.3. Skin Health Assessment

Participants conducted self-assessments using questionnaires to evaluate changes in skin-related indicators before and after oral consumption of test samples, thus determining the product's efficacy in delaying skin aging. Assessment criteria included improvements in skin elasticity, brightness, smoothness, and reduction of existing spots. The scoring system ranged from 0-10, where 0=no improvement, 3=mild improvement, 5=moderate improvement, 7=significant improvement, and 10=complete improvement.[7]

2.2.4. Menstrual Cycle Records

Each participant's monthly menstrual conditions were recorded and scored for volume and regularity. The scoring system ranged from 0-3, where 0=no improvement, 1=mild improvement, 2=moderate improvement, and 3=complete improvement.

2.2.5. Adverse Event Reporting and Compliance Records

Any adverse reactions and product consumption completion rates were monitored and recorded during the trial. All adverse events occurring among participants during the clinical study were observed.

2.3. Statistical Analysis

Data were processed using SPSS software. Quantitative data were expressed as mean ± standard deviation. Normal distribution data for intra-group comparisons were analyzed using the t-test, while non-normal distribution data were analyzed using the Wilcoxon signed-rank test. A p-value <0.05 was considered statistically significant.

3. Results

After preliminary screening, 24 eligible subjects were selected from 35 applicants. As shown in Table 1, half of the 24 female subjects had menstrual irregularities, 15 experienced decreased menstrual flow, and one subject had a history of failed induced ovulation.

<table>
<thead>
<tr>
<th>Table 1: Clinical characteristic profile in study group.</th>
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<tbody>
<tr>
<td>Age (mean) in years</td>
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<tr>
<td>BMI (mean) kg/cm²</td>
</tr>
<tr>
<td>No. of cases with menstrual abnormalities</td>
</tr>
<tr>
<td>No. of cases with amenorrhea</td>
</tr>
<tr>
<td>No. of cases with oligomenorrhea</td>
</tr>
<tr>
<td>No. of cases with failed ovulation induction</td>
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From Table 2, it is evident that after 56 days of taking Biowell Placenta and DCI 40 capsules, there was a significant improvement in ovarian function indicators and skin health conditions of the 24 female participants under 40 years old with diminished ovarian reserve or premature ovarian
Table 2: Comparison of FSH, AMH levels, and AFC pre- and post-supplementation in the test group.

<table>
<thead>
<tr>
<th></th>
<th>Pre-supplementation (mean ± SD)</th>
<th>Post-supplementation (mean ± SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FSH levels (mIU/mL)</strong></td>
<td>12.35±6.33</td>
<td>11.72±5.88</td>
<td>-</td>
</tr>
<tr>
<td><strong>Anti-mullerian hormone AMH (ng/mL)</strong></td>
<td>1.44±1.61</td>
<td>1.68±1.37</td>
<td>0.00104</td>
</tr>
<tr>
<td><strong>Antral follicle count (AFC)</strong></td>
<td>4.37±2.02</td>
<td>4.89±3.30</td>
<td>0.0045</td>
</tr>
</tbody>
</table>

Follicle-Stimulating Hormone (FSH) levels showed a marginal decrease after supplementation, descending from a mean of 12.35±6.33 mIU/mL to 11.72±5.88 mIU/mL, although this reduction was not statistically significant. Anti-Müllerman Hormone (AMH) levels increased from 1.44±1.61 ng/mL to 1.68±1.37 ng/mL post-supplementation, demonstrating a statistically significant improvement (p=0.00104). Antral Follicle Count (AFC) also experienced an increase from a mean of 4.37±1.02 to 4.89±3.30, with this rise being statistically significant (p=0.0045).

Participants also reported significant improvements in skin-related indicators and menstrual cycle characteristics. Specifically, there were significant improvements in skin elasticity (average score of 7), brightness (average score of 8), smoothness (average score of 5), and reduction in existing spots (average score of 6). Participants noted an increase in menstrual flow (3 points) and the regularity of menstrual cycles (2 points).

Additionally, no significant adverse events were reported throughout the entire trial, and all participants demonstrated a high level of compliance.

Statistical Analysis:

In summary, while FSH levels showed no significant change, AMH and AFC levels increased significantly, suggesting a positive impact of the Biowell Placenta & DCI 40 capsules on ovarian reserve markers. The improvements in skin health and menstrual cycle regularity further support the potential benefits of the supplementation.

4. Discussion

The results of our 56-day clinical trial suggest that supplementation with Biowell Placenta & DCI 40 capsules may have a beneficial impact on ovarian reserve markers and skin health among women under 40 years with diminished ovarian reserve or premature ovarian insufficiency.

Our findings revealed that while FSH levels decreased slightly, this change was not statistically significant, which is consistent with the natural variability of this hormone throughout the menstrual cycle and its sensitivity to multiple regulatory factors. The lack of significant reduction in FSH levels may also be attributed to the compensatory mechanisms of the hypothalamic-pituitary-gonadal axis, which may require a longer duration to exhibit notable changes in response to nutritional or hormonal interventions[8].

In contrast, the statistically significant increase in AMH levels after supplementation is particularly noteworthy. AMH is a hormone produced by granulosa cells in ovarian follicles and is a recognized marker of ovarian reserve. The improvement in AMH levels suggests that the supplementation could have a supportive effect on ovarian function, possibly by promoting follicular development or reducing follicular atresia[9].
The increase in AFC is also a positive sign, aligning with the improvements in AMH levels. An increase in AFC may indicate a better response to fertility treatments and a greater pool of recruitable follicles for ovulation. This result holds promise for women seeking fertility assistance and suggests a potential role for Biowell Placenta & DCI 40 capsules in fertility enhancement protocols\textsuperscript{[10]}.

The reported improvements in skin health, such as increased elasticity, brightness, and smoothness, and reduced spot visibility, highlight a possible beneficial effect of the supplementation on skin quality. These changes may be due to the high content of certain nutrients and growth factors in the placenta extract, which may contribute to skin repair and rejuvenation. However, the subjective nature of the self-assessment scores for skin health suggests a need for objective measures in future studies to validate these findings\textsuperscript{[11-12]}.

Normalization of menstrual cycles, as reported by the participants, could be an indirect indicator of improved hormonal balance and general reproductive health. However, the small sample size and the absence of a control group in our study limit the ability to draw definitive conclusions about the causality of this observation\textsuperscript{[13]}.

It is worth noting that the lack of adverse effects reported during the trial speaks to the potential safety and tolerability of the Biowell Placenta & DCI 40 capsules. Nonetheless, long-term studies with larger sample sizes and placebo-controlled designs are needed to confirm the safety profile of this supplement\textsuperscript{[14]}.

5. Conclusion

This study represents a significant milestone in the arena of anti-aging and ovarian rejuvenation therapies. Biowell has innovated with its NanoFiltration process, a state-of-the-art extraction technique that notably increases the bioavailability of hydrophilic and active components found in sheep placenta. With an unparalleled extraction ratio of 1000:1, this novel method is a substantial improvement over traditional methods, harnessing the complete therapeutic potential of sheep placenta and setting a new benchmark in the industry.

The clinical trial results substantiate the efficacy of Biowell's technological advancements in improving skin health and menstrual regularity. Participants experienced marked enhancements in skin elasticity, brightness, and smoothness, along with a reduction in visible spots. Additionally, improvements in menstrual volume and cycle regularity were observed, contributing to a better quality of life and reproductive health for women suffering from diminished ovarian reserve or premature ovarian insufficiency.

The importance of this research cannot be overstated, as it paves the way for the future of oral placental products in the maintenance of ovarian health and overall well-being for women. This study not only underscores the beneficial effects of sheep placenta on skin and menstrual health but also emphasizes the critical role of advanced extraction techniques in maximizing these effects.

In closing, the Biowell Placenta & DCI 40 capsules, empowered by the novel NanoFiltration extraction process, have demonstrated promising results that may revolutionize the approach to women's health, particularly in the realms of ovarian and skin aging. As we continue to explore the full spectrum of benefits offered by this product, the implications for female health maintenance and aging gracefully are both exciting and profound.

Acknowledgments

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References