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Safety and Efficacy Testing of External Natural Belief Mask

Sponsor : Thomp'Son Enterprise Co., Ltd.

**Testing Institute : Center for Cosmetology Research and Testing ,
Chia Nan University of Pharmacy and Science**

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Wei Jing Hung 

1. Abstract

Completed by Thompson enterprises limited development of functional External Natural Belief mask(ENB Mask) safety and efficacy assessments, the assessment results provided with Thomp'Son company, for the development and maintenance of cosmetics with high added-value market basis. For the safety assessment, there was no evidence of any irritant effect for the patch test of ENB mask and Bio-Cellulose mask, as shows in table 1. For the efficacy of the ENB mask, the results showed significant improvement in TEWL, skin moisture , skin sebum , skin surface pH, skin color, skin elasticity and firmness, skin texture, porphyrins and sensitive skin after 14 days of use by the subjects . Efficacy comparison of ENB mask using for two weeks and four weeks, after four weeks of use on uv spots and wrinkles, skin will have better improvement. For the efficacy of the reused ENB mask(ENB mask after repeated use for a week; and then using it for another one week), the results showed significant improvement in sensitive skin. ENB mask also showed significant improvement in skin acne after 3 days of use by the subjects.

2. Preface

Efficacy of ENB mask included (1) skin moisture, and skin sebum and skin surface pH (2) skin colour (3) skin elasticity (4) skin firmness (5) skin spots (6) uv spots (7) skin texture (8) skin pores (9) porphyrins (10) skin wrinkles (11) sensitive skin improvement (12) sensitive skin (reused ENB mask) (13) skin acne improvement (14) cosmetic efficacy (using four week) (15) color spot.

Safety parts of the product included (1) skin patch test (2) usage test.

3. Materials and Methods

A. The safety and efficacy of assessment products are shown below:

1. ENB mask (reuse week)
2. For Beloved One Bio-Cellulose mask (can only be used once, discarded)

B. Equipment and methods are as follows:

1. Safety assessment

a) Testing material:

Skin patch (Finn Chamber, SmartPractice, U.S.A.)

b) Process :

- 1) skin patch testing : Subjects applied the products for 48 hours patch test under occlusion. The subjects removed the patches approximately 3 hours after application for occlusive patch conditions. A clinical observation of skin irritation evaluation was conducted after removing the occlusive patches.
- 2) Usage test : Subjects used the product on a daily basis, once a day for 14 or 28 days. A clinical observation of skin irritation evaluation was conducted during 14 or 28 days.

2. Cosmetic efficacy

a) Instrumentation:

1) Skin Color (DSIII, Wo Toyoharu, Taiwan)



2) Multifunctional Skin Detection Apparatus (MPA580, Courage + Khazaka electronic GmbH, Germany)

i) Skin Moisture ii) Skin Sebum iii) Skin Surface pH

iv) Skin elasticity



3) Skin surface Topography (VISIA Complex Analysis, Canfield Scientific, Inc , USA)



b)Test Area: Face (Ages from 20 to 40)

c)Test Time:

- 1) Before applying cosmetics (Baseline) 2)Applied the cosmetics for 4 hours
- 3) Applied the cosmetics for 3 days 4) Applied the cosmetics for 7 days
- 5) Applied the cosmetics for 14 days 6)Applied the cosmetics for 28 days(2 subjects)

d)Subjects:

17 Taiwanese females; ENB mask,14 subjects (4 subjects measuring only acne); reused ENB mask,1 subject; Bio-Cellulose mask, 2 subjects.

e)Test Environment:

Temperature 23 ± 2 °C; Relative humidity $46 \pm 2\%$

4.Results

A. Skin safety assessment results

1.Patch test:

Subjects applied the products for 48 hours patch test under occlusion. The subjects removed the patches approximately 3 hours after application for occlusive patch conditions. A clinical observation of skin irritation evaluation was conducted after removing the occlusive patches. There was no evidence of any irritant effect for the patch test of ENB Mask and Bio-Cellulose mask. The results were shown in Table 1.

2.Usage test:

All 10 subjects used them throughout a period of 14 or 28 days. All 10 subjects used both ENB Mask and Bio-Cellulose mask on a daily basis, once a day for 14 or 28 days. There was no evidence of any irritant effect for ENB Mask and Bio-Cellulose mask. The results were shown in Table 1.

Table1. Safety Evaluation of ENB Mask

| Safety Evaluation | Patch test (X/Y)* | Usage test (X/Y) |
|-------------------|-------------------|------------------|
| Skin irritation | | |
| Itch | 0/4 | 0/10 |
| Sting or Erythema | 0/4 | 0/10 |
| Eczema | 0/4 | 0/10 |
| Scaliness | 0/4 | 0/10 |
| Acne | 0/4 | 0/10 |
| Discontinued | 0/4 | 0/10 |

*: (X/Y), X, Number of irritant effect subjects; Y, Number of total testing subjects

B. Cosmetic efficacy results

1. For the efficacy of the ENB mask, the results showed significant improvement in TEWL, skin moisture, skin sebum and skin surface pH after 14 days of use by the subjects; the Bio-Cellulose mask showed significant improvement in TEWL and skin moisture as shown in Figure 1~4 and table 2.
2. ENB mask and Bio-Cellulose mask showed significant improvement in skin color, as shown in table 2, Figure 1 and Figure 5.
3. ENB mask and Bio-Cellulose mask showed significant improvement in skin elasticity as shown in table 2 and Figure 1 and Figure 6.
4. ENB mask showed significant improvement in skin firmness after 14 days of use by the subjects; the Bio-Cellulose mask showed no significant improvement in skin firmness as shown in table 2 and Figure 1 and Figure 7.
5. ENB mask and Bio-Cellulose mask showed no significant improvement in skin spots, as shown in Figure 8 and Figure 11.
6. ENB mask and Bio-Cellulose mask showed no significant improvement in uv spots, as shown in Figure 8 and Figure 11.
7. ENB mask and Bio-Cellulose mask showed significant improvement in skin texture, as shown in Figure 9 and Figure 12.
8. ENB mask and Bio-Cellulose mask showed no significant improvement in skin pores, as shown in Figure 9 and Figure 12.
9. ENB mask showed significant improvement in porphyrins after 14 days of use by the subjects; the Bio-Cellulose mask showed no significant improvement in porphyrins as shown in Figure 10 and Figure 13.
10. ENB mask and Bio-Cellulose mask showed no significant improvement in skin wrinkles, as shown in Figure 10 and Figure 13.

11. Efficacy comparison of ENB mask using for two weeks and four weeks, after four weeks of use on uv spots and wrinkles, skin will have better improvement, as shown in Figure 14 to 16.
12. ENB Mask showed significant improvement in sensitive skin after 14 days of use by the subjects ; the Bio-Cellulose mask showed no significant improvement in sensitive skin as shown in Figure 17 and Figure 18.
13. For the efficacy of the Reused ENB mask(ENB mask after repeated use for a week; and then using it for another one week), the results showed significant improvement in sensitive skin as shown in Figure 19.
14. ENB mask showed significant improvement in skin acne after 3 days of use by the subjects as shown in Figure 20.
15. ENB mask showed no significant improvement in color spots after 28 days of use by the subjects as shown in Figure 21.

Figure 1. Efficacy of ENB mask after 14 days of use by subjects

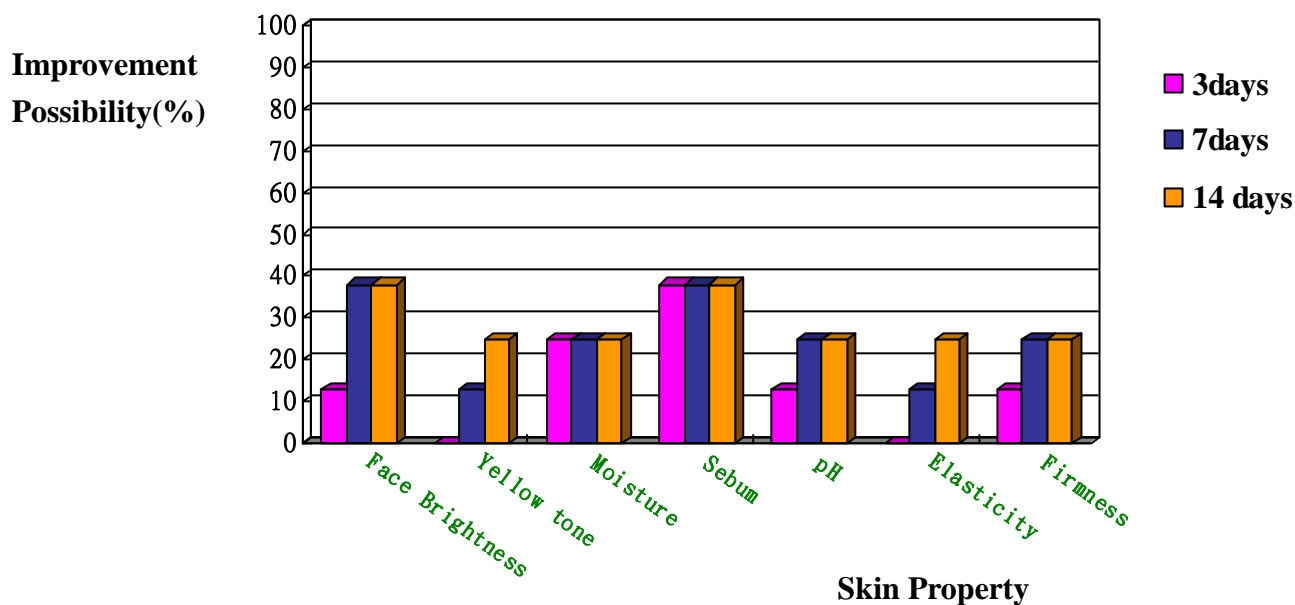


Table 2. Efficacy of both ENB mask and Bio-Cellulose mask after 14 days of use by subjects

| Product property | | ENB mask | Bio-Cellulose mask | Product property | | ENB mask | Bio-Cellulose mask |
|------------------|-------|------------------|--------------------|------------------|-------|----------------------|----------------------|
| Skin Moisture | 4hr | +1(3/8) | +1(1/2) ;+2(1/2) | Face Skin color | 3day | L: +1(1/8);b:+1(0/8) | L: +1(0/2);b:+1(0/2) |
| | 3day | +1(2/8) | +1(1/2) | | 7day | L: +1(3/8);b:+1(1/8) | L: +1(0/2);b:+1(0/2) |
| | 7day | +1(2/8) | +1(1/2) | | 14day | L: +1(3/8);b:+1(2/8) | L: +1(1/2);b:+1(0/2) |
| | 14day | +1(2/8) | +1(1/2) | Skin elasticity | 3day | +1(0/8) | +1(0/2) |
| Skin sebum | 4hr | +1(2/8) ;+2(1/8) | +1(0/2) | | 7day | +1(1/8) | +1(1/2) |
| | 3day | +1(3/8) | +1(0/2) | | 14day | +1(2/8) | +1(1/2) |
| | 7day | +1(3/8) | +1(0/2) | Skin firmness | 3day | +1(0/8) | +1(0/2) |
| | 14day | +1(3/8) | +1(0/2) | | 7day | +1(2/8) | +1(0/2) |
| Skin surface pH | 4hr | +1(0/8) | +1(0/2) | | 14day | +1(2/8) | +1(0/2) |
| | 3day | +1(1/8) | +1(0/2) | | | | |
| | 7day | +1(2/8) | +1(0/2) | | | | |
| | 14day | +1(2/8) | +1(0/2) | | | | |

*: L, expressing color brightness ;b, expressing a yellow tone.

Parameter Definition :

※ Symbol Definition : $\pm A$ (B%); $\pm A$ expressing -2 ~ 0 ~ +2 etc. 5 scale grades,
(B%) expressing the possibility of this scale grade.

※ Skin type

a) Skin moisture:

+2, the relative value of higher than 1.5 by compared to baseline; +1, the relative value of 1.2~1.5

0, no signification change, the relative value of 1.0; -1, the relative value of lower than 0.9~0.5; -2, the relative value of lower than 0.5

b) Skin sebum:

+2, the relative value of higher than 2.0 ; +1, the relative value of 1.2~1.9

0, no signification change ; -1, the relative value of lower than 0.9 ~0.5

-2, the relative value of lower than 0.5

c) Skin surface pH :

one scale grade for $\Delta \text{pH} = \pm 0.2$

※ Skin color:

Skin brightness, one scale grade for $\Delta L = \pm 1.5$; Skin yellow tone, one scale grade for $\Delta b = \pm 0.5$

※ Skin elasticity & firmness

Skin elasticity, one scale grade for $\Delta R5 = \pm 0.05$; Skin firmness, one scale grade for $\Delta R6 = \pm 0.03$

Figure 2. TEWL comparison of ENB mask, Bio-Cellulose mask and Reused ENB mask after 14 days of use by subjects

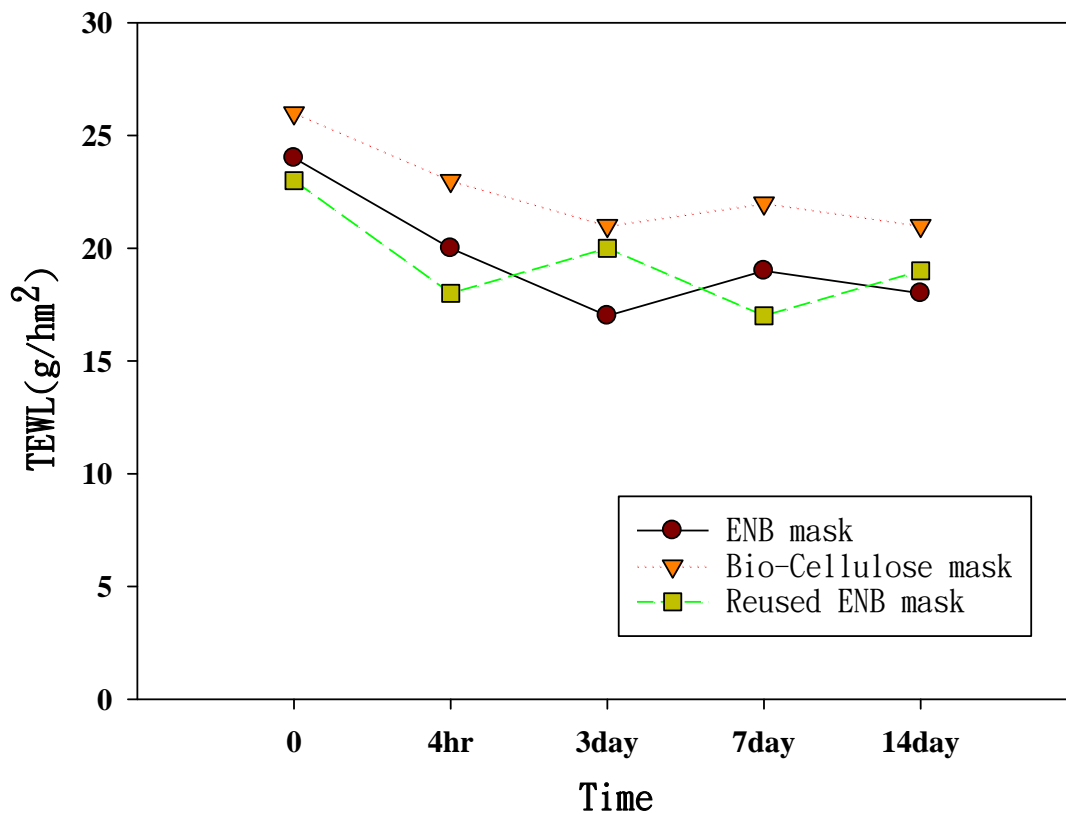


Figure 3. Before and after comparison of skin sebum for ENB mask

$$F(1, 8) = 10.579, p = .014, \text{partial } \eta^2 = 0.602$$

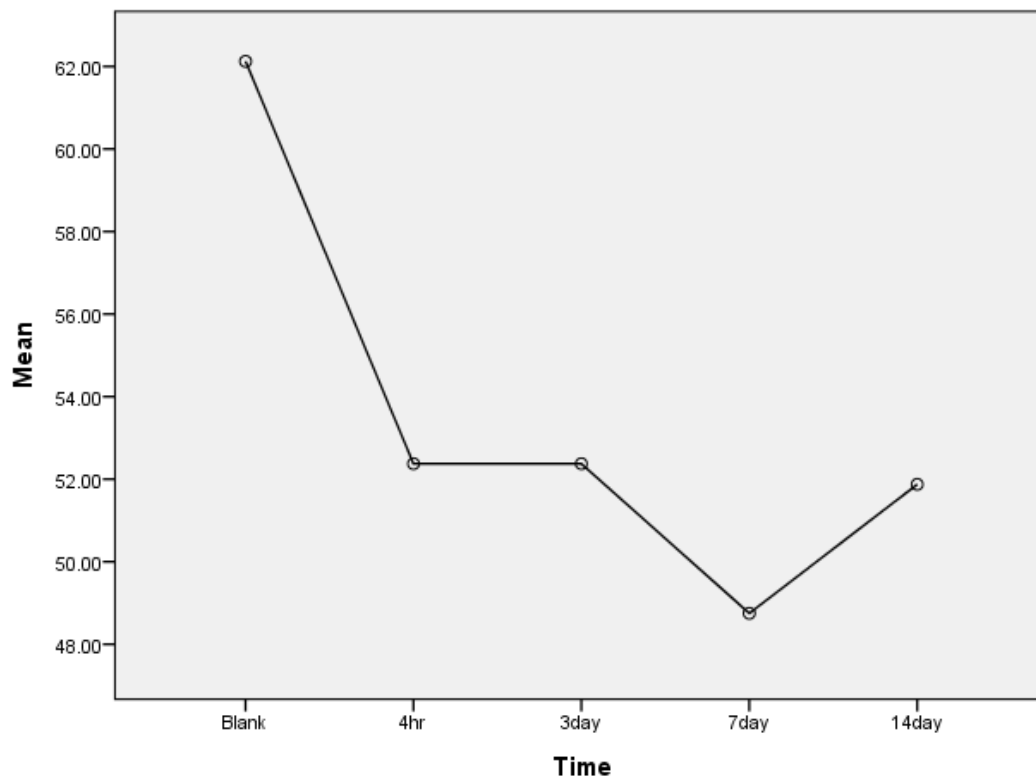


Figure 4. Before and after comparison of skin moisture for ENB mask

$$F(1, 8) = 3.330, p = .111, \text{partial } \eta^2 = 0.322$$

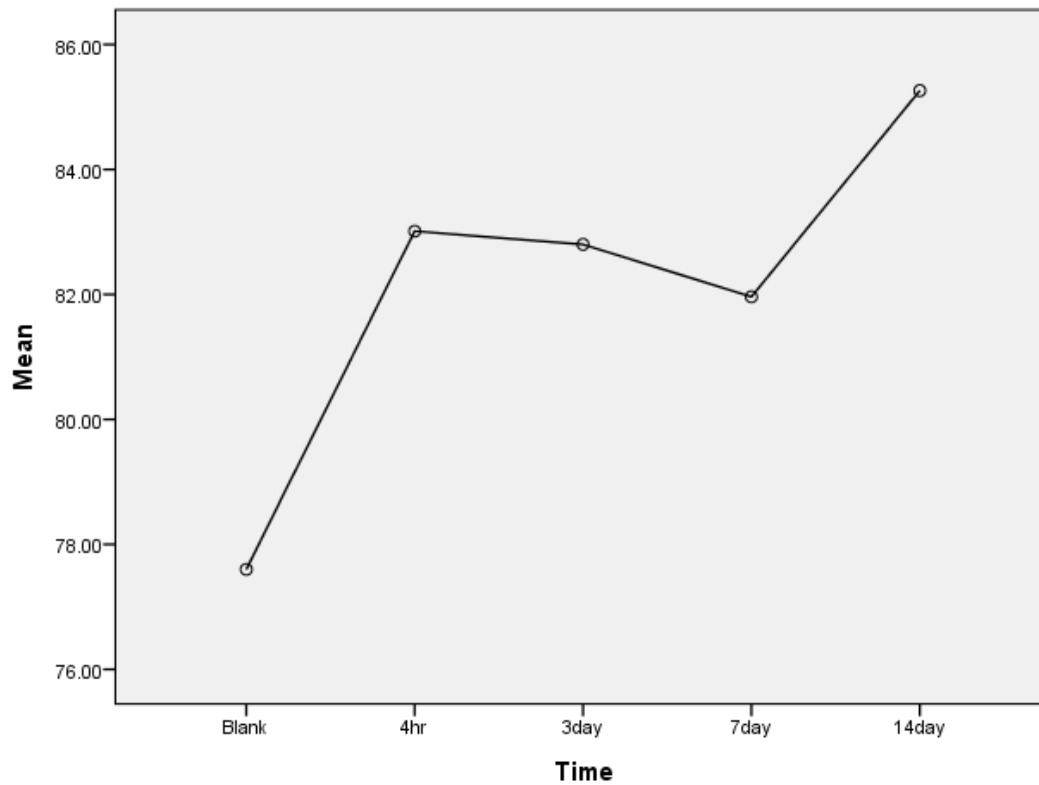


Figure 5. Before and after comparison of skin whiten for ENB mask

$F(1, 8) = 3.214, p = .116, \text{partial } \eta^2 = 0.315$

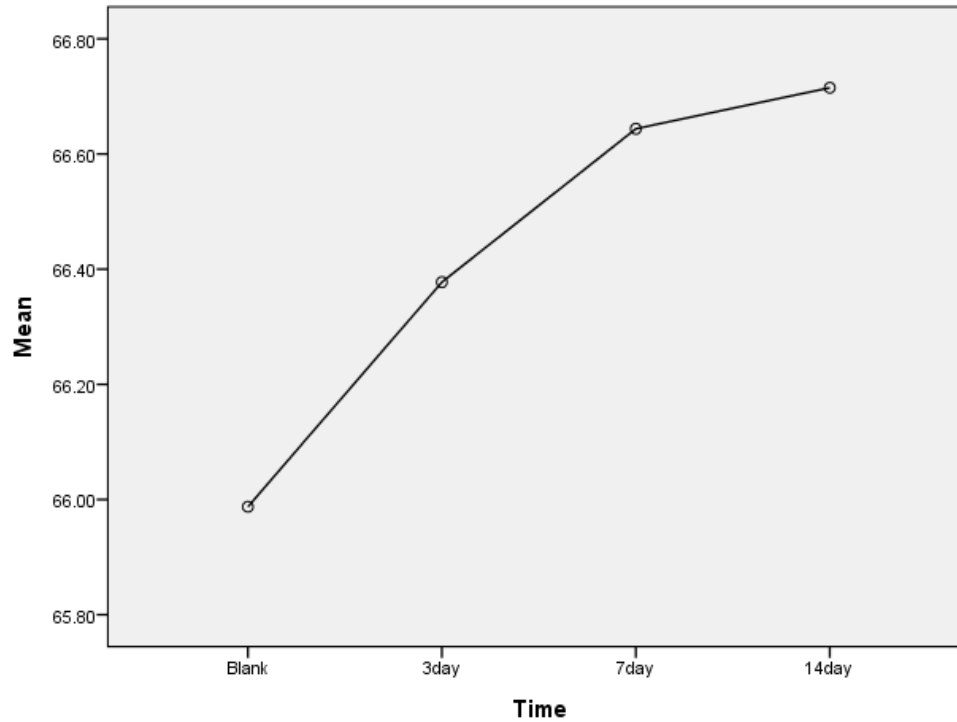


Figure 6. Before and after comparison of skin elasticity for ENB mask

$F(1, 8) = 12.214, p = .010, \text{partial } \eta^2 = 0.636$

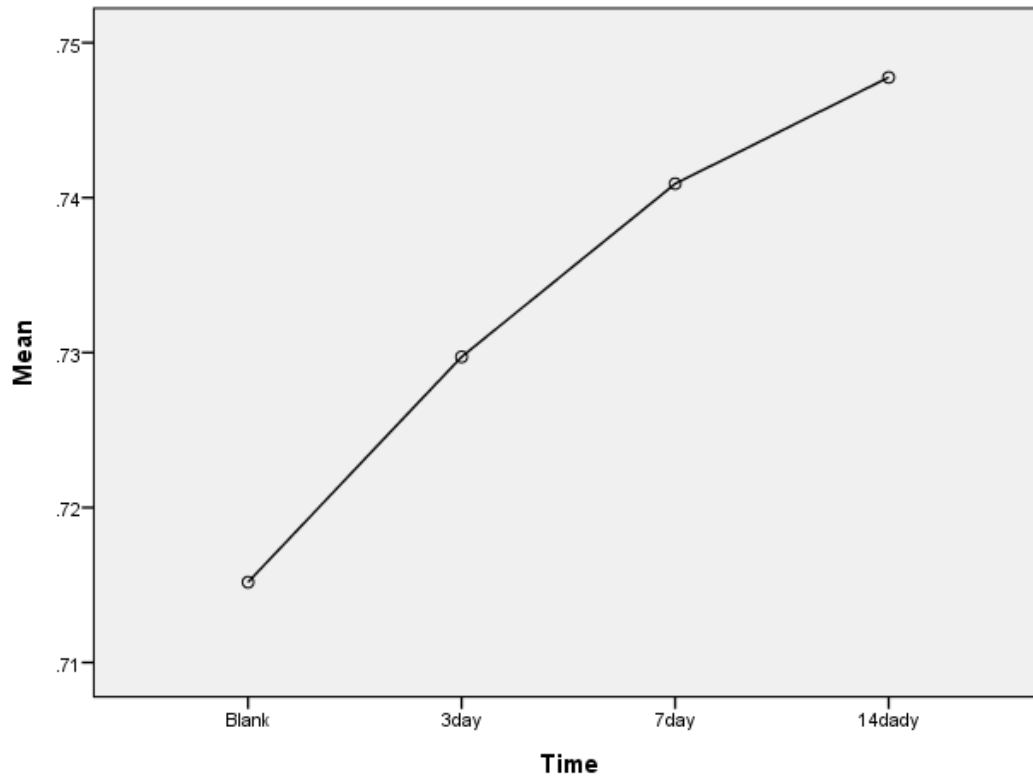


Figure 7. Before and after comparison of skin firmness for ENB mask

$F(1, 8) = 15.638, p = .005, \text{partial } \eta^2 = 0.691$

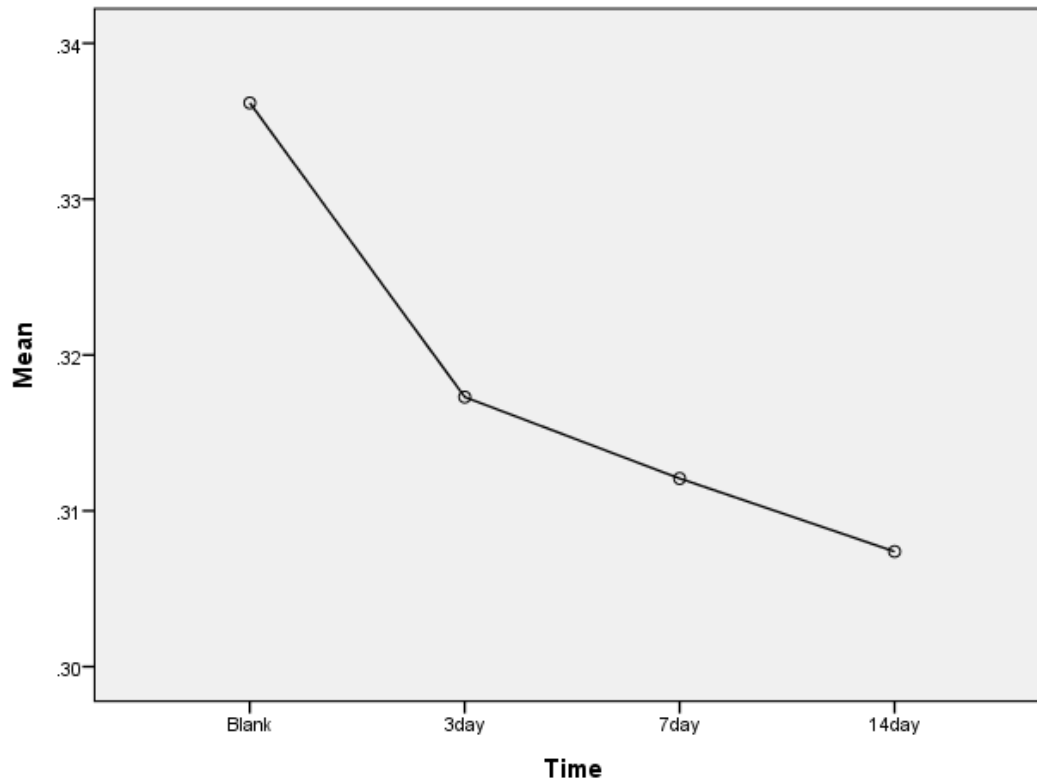


Figure 8. Before and after comparison of skin dark spots and uv spots

in cheek area for ENB mask (14 days)

a) the skin dark spots in cheek area



Before the study (Baseline) (79)



Same subject after treatment (76)

b) the skin uv spots in cheek area



Before the study (Baseline) (220)



Same subject after treatment (213)

Figure 9. Before and after comparison of skin pores and texture in cheek area for ENB mask

a) the pores in cheek area



Before the study (Baseline) (753)



Same subject after treatment (755)

b) the texture in cheek area



Before the study (Baseline) (319)



Same subject after treatment (255)

Figure 10. Before and after comparison of porphyrins and wrinkles in cheek area for ENB mask

a) the porphyrins in cheek area



Before the study (Baseline)(561)



Same subject after treatment (418)

b) the wrinkles in cheek area



Before the study (Baseline)(6)



Same subject after treatment (11)

Figure 11. Before and after comparison of skin dark spots and uv spots in cheek area for Bio-Cellulose mask

a) the skin dark spots in cheek area



Before the study (Baseline)(107)



Same subject after treatment(97)

b) the skin uv spots in cheek area



Before the study (Baseline)(172)



Same subject after treatment(155)

Figure 12. Before and after comparison of skin pores and texture in cheek area for Bio-Cellulose mask

a) the pores in cheek area



Before the study (Baseline)(1196)



Same subject after treatment(949)

b) the texture in cheek area



Before the study (Baseline)(1064)



Same subject after treatm (756)

Figure 13. Before and after comparison of porphyrins and wrinkles in cheek area for Bio-Cellulose mask

a) the porphyrins in cheek area

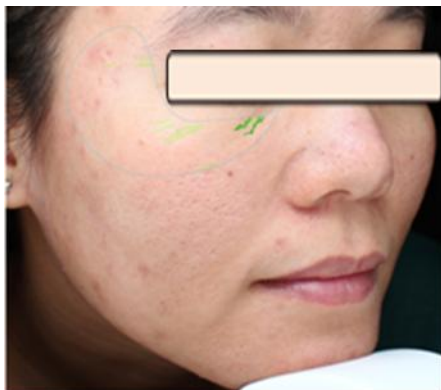


Before the study (Baseline)(1668)

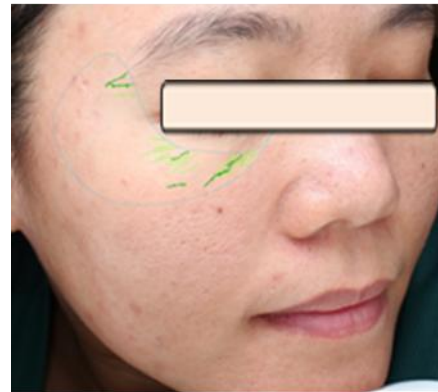


Same subject after treatment (1625)

b) the wrinkles in cheek area



Before the study (Baseline)(9)



Same subject after treatment(11)

Figure 14. Before and after comparison of skin dark spots and uv spots in cheek area for ENB mask (28 days)

a) the skin dark spots in cheek area

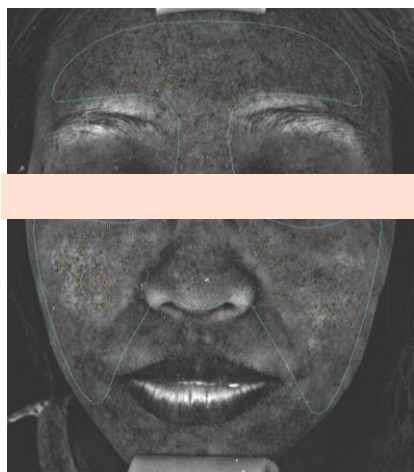


Before the study (Baseline) (80)

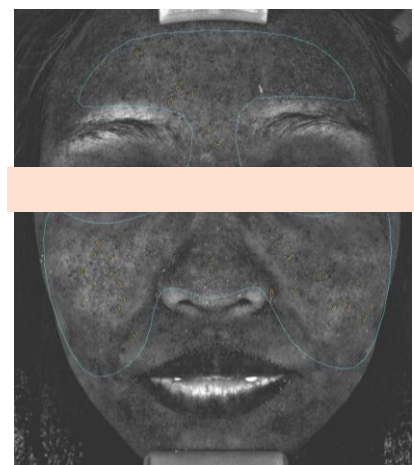


Same subject after treatment (76)

b) the skin uv spots in cheek area



Before the study (Baseline) (49)



Same subject after treatment(34)

Figure 15. Before and after comparison of skin pores and texture in cheek area for ENB mask (28 days)

a) the pores in cheek area



Before the study (Baseline) (543)



Same subject after treatment(531)

b) the texture in cheek area



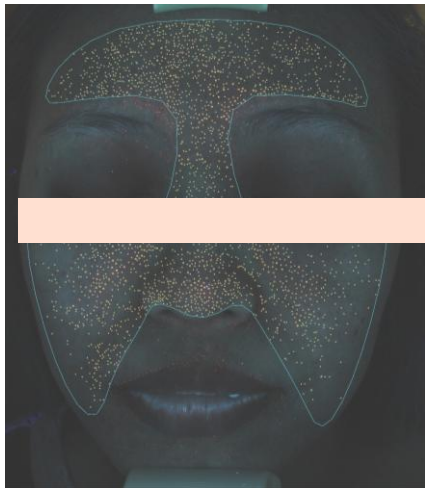
Before the study (Baseline) (470)



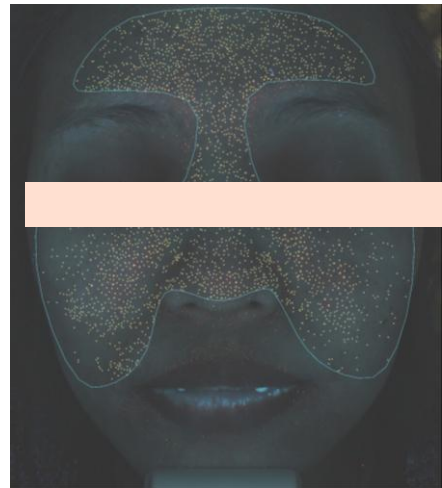
Same subject after treatment(318)

Figure 16. Before and after comparison of porphyrins and wrinkles in cheek area for ENB mask (28 days)

a) the porphyrins in cheek area



Before the study (Baseline) (2239)



Same subject after treatment (2186)

b) the wrinkles in cheek area

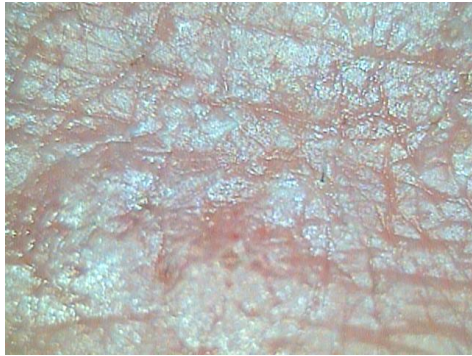


Before the study (Baseline) (19)

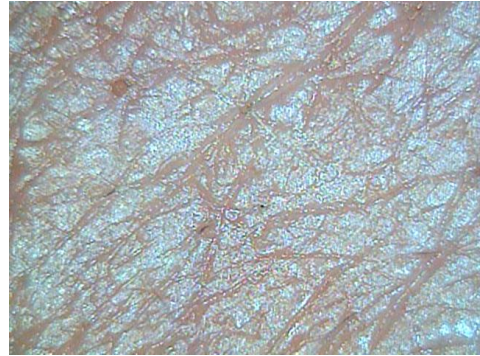


Same subject after treatment(14)

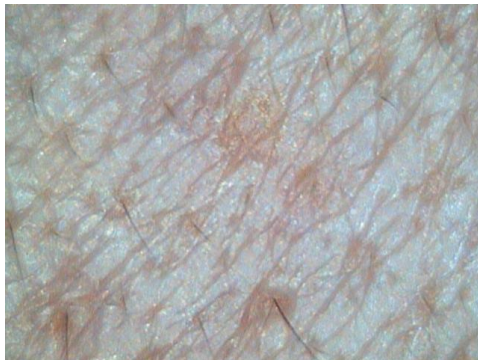
**Figure 17. Before and after comparison of sensitive skin for
ENB mask(3days)**



Before the study (Baseline)



Same subject after treatment

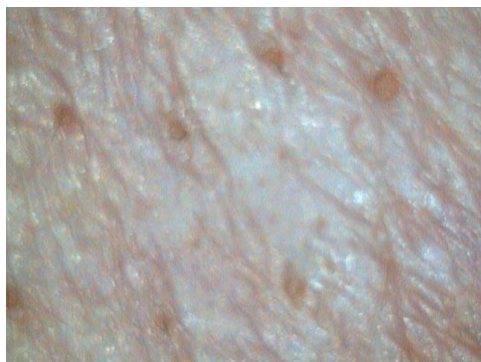


Before the study(Baseline)



Same subject after treatment

**Figure 18. Before and after comparison of sensitive skin for
Bio-Cellulose mask(3days)**

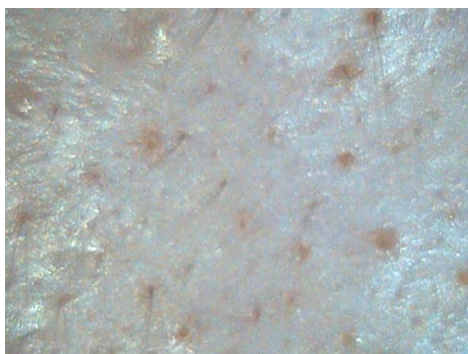


Before the study(Baseline)



Same subject after treatment

**Figure 19. Before and after comparison of sensitive skin for
Reused ENB mask(7days)**



Before the study(Baseline)



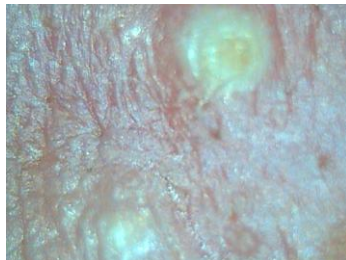
Same subject after treatment

Figure 20. Before and after the changes of acne for ENB mask

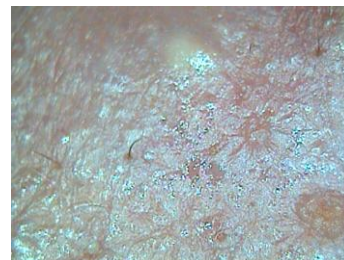
a) Acne in cheek area



Before the study(Baseline)

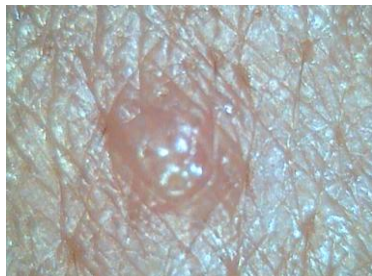


after treatment(1hr)

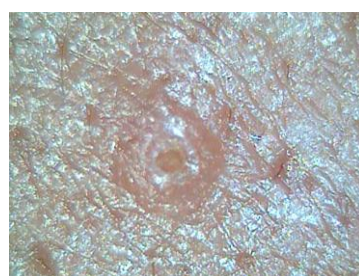


after treatment (3days)

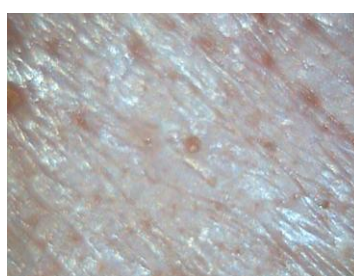
b) Acne in cheek area



Before the study(Baseline)



after treatment(1hr)



after treatment (3days)

c) Acne in cheek area



Before the study(Baseline)



after treatment(1hr)



after treatment (3days)

d) Acne in cheek area



Before the study(Baseline)



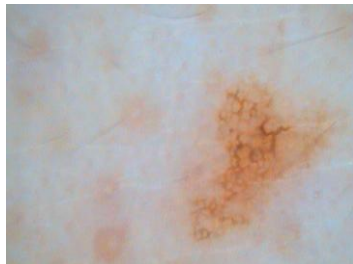
after treatment(1hr)



after treatment (3days)

Figure 21. Before and after the changes of color spots for ENB mask

a)Color spots in cheek area



Before the study(Baseline)



Same subject after treatment(28days)

b) Color spots in cheek area



Before the study(Baseline)



Same subject after treatment(28days)