

# A Prospective Evaluation of the Efficacy of Topical Adhesive Pads for the Reduction of Facial Rhytids

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**Objective:** To determine the efficacy of an over-the-counter topical skin adhesive pad for reducing central forehead and glabellar rhytids over a 4-week period.

**Design:** Prospective series involving 30 healthy volunteers with central forehead and glabellar rhytids at a tertiary care academic medical center. The participants used topical skin adhesive pads over the central forehead area and the glabella for 4 weeks in an effort to reduce rhytids. Before and after treatment, the participants had facial photographs taken and completed a questionnaire assessing the severity of their rhytids. Blinded to the timing of the photographs, 2 independent facial plastic surgeons scored the pretreatment and posttreatment rhytid severity using the Glogau scale (1-4) and a wrinkle severity scale (1-10) to evaluate treatment effect.

**Results:** Twenty-six participants (87%) completed follow-up with an average of 7.4 hours of use of the topical adhesive pads per night. The independent evaluators

found minimal improvements in the Glogau scores (mean [SD], 0.12 [0.33] [ $P=.08$ ] and 0.06 [0.22] [ $P=.18$ ] for the central forehead area and the glabella, respectively). The same evaluators also found minimal change in the wrinkle severity scores (mean [SD], 0.21 [1.28] [ $P=.41$ ] and 0.25 [0.75] [ $P=.10$ ] out of 10 for central forehead rhytids and glabellar rhytids, respectively). None of these measures were statistically significant. The study participants' self-evaluations demonstrated changes in the wrinkle severity scores of 0.35 (2.10) ( $P=.41$ ) in the central forehead area and 0.73 (1.7) ( $P=.04$ ) in the glabella.

**Conclusions:** Subjective self-evaluation of topical adhesive pads demonstrates improvement in glabellar rhytids but may be affected by bias. Independent, blinded evaluation by facial plastic surgeons showed no statistical benefit in the reduction of rhytids in the central forehead area or the glabella.

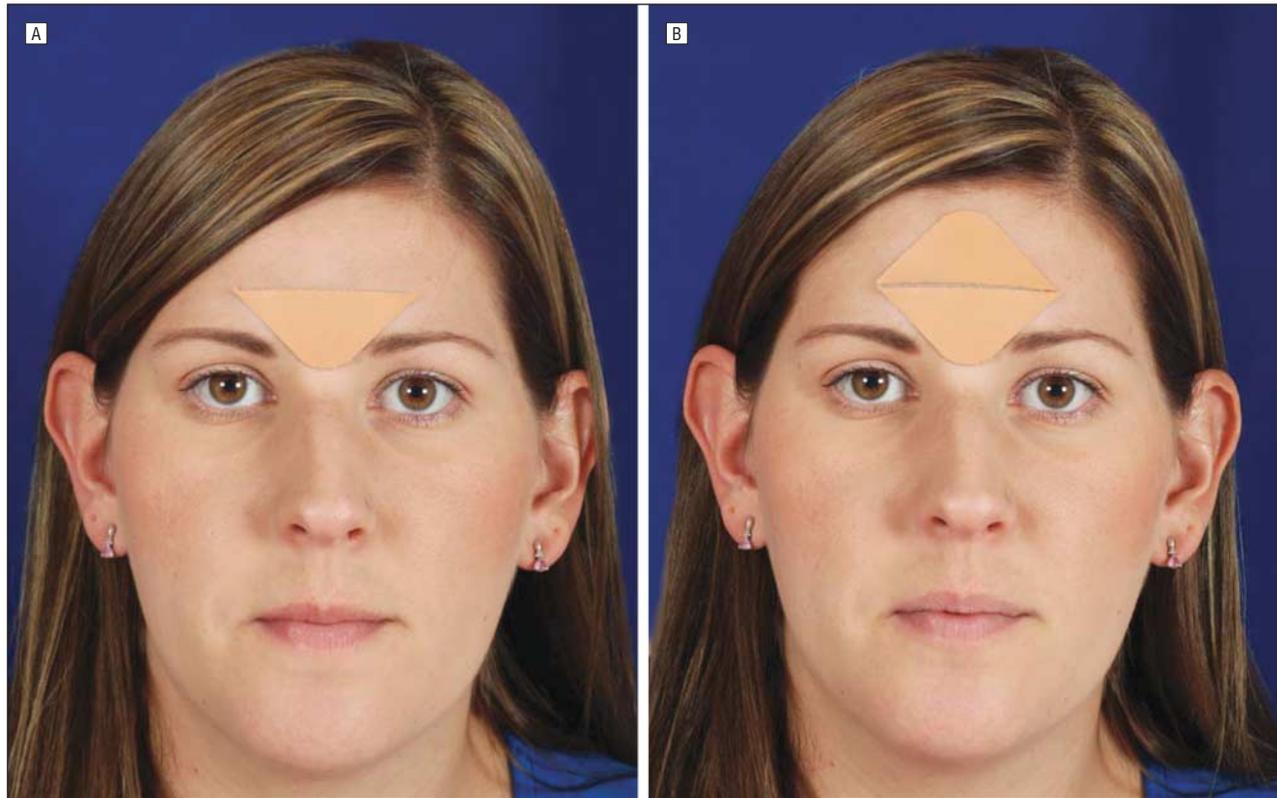
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**R**HYTIDS ARE A COMMON PRESENTING complaint for the patient with an aging face. Skin cleansers, moisturizers, and sun protection (including sun avoidance, clothing, and sunscreen) are important for the prevention of rhytids. Despite widespread use of such preventive measures, public demand for nonsurgical treatments for rhytids is high.<sup>1-3</sup> Treatment for rhytids includes over-the-counter products (moisturizers and topical adhesive pads), prescription creams, injectable fillers, botulinum toxin A injections, chemical peels, dermabrasion, and laser resurfacing. Studies have shown topical preparations of tretinoin,  $\alpha$ -hydroxy acid, and N6-furfuryladenine (Kinerase cream) to be effective in treating photodamaged skin.<sup>4-6</sup> Ultimately, the ideal effective treatment for rhytids would be inexpensive, topical, noninvasive, and readily available (ie, over the counter). Topical adhesive pads do have these 4 attributes; however, their efficacy in reducing rhytids is unclear.

Frownies (B & P Company Inc, Dayton, Ohio) are the most well-known topical adhesive pad product on the market.

They are sets of unbleached, natural craft paper with a water-soluble dry gum adhesive on one side. They are sold in sheets of perforated triangles. After the adhesive side is moistened, each separate triangle can be applied to the skin over the glabella and the central forehead area (**Figure**) as well as to the corners of the eyes and mouth. Theoretically, this application is intended to reduce local muscle contraction and spread out skin lines to reduce both the severity of existing rhytids and the formation of dynamic rhytids. The manufacturer claims that the topical adhesive pads act to retrain the facial musculature to move less and to cause fewer rhytids. The pads are available over the counter in cosmetic stores and pharmacies and online at the price of \$19.95 for 144 pads (as of January 2009). Distribution of the pads began around the turn of the century. Many celebrities have given testimonials to the effectiveness of Frownies. The manufacturer claims to achieve noticeable lasting results by the end of 1 month of every-night use of the topical adhesive pads. However, we are not aware of any published studies that have determined or explored the efficacy of topical

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**Figure.** Model demonstrating the placement of topical adhesive pads (Frownies; B & P Company Inc, Dayton, Ohio) for the treatment of the glabella (A) and the glabella and the central forehead area (B).

adhesive pads in the reduction of facial rhytids (as of January 2009). With this prospective study, we aimed to determine the efficacy and tolerance of use of an over-the-counter topical skin adhesive pad (Frownies) in the reduction of rhytids in the central forehead area and the glabella over a 4-week period.

## METHODS

This study received approval from the institutional review board's Human Subjects Ethics Committee at Stanford University, Stanford, California. We recruited 30 normal healthy volunteers who were older than 18 years and interested in the reduction of central forehead and glabellar rhytids. We advertised in a local newspaper for healthy volunteers. Our exclusion criteria included pregnancy, breast feeding, inability to complete the questionnaire, mental impairment, botulinum toxin A treatment within 6 months, or a prior brow-lift. All study participants signed informed consent forms. We did not pay the participants for their involvement.

We met with each participant twice. At the first clinic visit, the participants had pretreatment facial digital photographs taken (frontal and 45° to the right and left), completed a questionnaire, and received training in the application and use of the topical adhesive pads. Each Frownies box came with written instructions and diagrams on their use. We instructed the participants to wear the pads for at least 5 hours per night for 4 weeks while sleeping. We warned the participants of the possible risk of an allergic skin reaction. Each participant then returned to clinic 4 weeks later, at which time they had post-treatment photographs taken and completed a posttreatment questionnaire.

## PHOTOGRAPHS

Pretreatment and posttreatment photographs were standardized with regard to patient position, facial tone, and lighting. Frontal (anteroposterior) and three-quarter views were taken with the patient in the proper position with regard to the Frankfort plane. Two independent facial plastic surgeons evaluated the 3 pretreatment and the 3 posttreatment photographs of each study participant in a blinded fashion (ie, they were not aware of the timing of the photographs with respect to the use of the topical adhesive pads). The evaluators scored the severity of the rhytids in the central forehead and the glabella separately using 2 scoring scales: the Glogau scale (1-4) and a wrinkle severity scale (1-10). We compared the pretreatment and post-treatment Glogau scale and wrinkle severity scores for possible treatment effect.

## QUESTIONNAIRES

The first questionnaire (pretreatment) determined each participant's age, smoking history, numeric scores of severity of pretreatment central forehead and glabellar rhytids (1-10 scale), satisfaction with rhytids (1-10 scale), and expectation for how well the topical adhesive pads would reduce facial rhytids (1-10 scale). The second questionnaire (posttreatment), which the participants completed after they had used the topical adhesive pads for 1 month, determined the degree of compliance of the use of the pads (number of days missed and average number of hours used per night), satisfaction with the effect of the topical adhesive pads (1-10 scale), degree of discomfort (1-10 scale), reasons for discomfort, whether the pads effected their ability to sleep, the severity of posttreatment central forehead and glabellar rhytids (1-10 scale), the degree of improvement

**Table 1. Mean and Range of Severity Scores of Pretreatment and Posttreatment Rhytids as Determined by Blinded Independent Evaluators Using Glogau (1-4) and Wrinkle Severity (1-10) Scales**

Rhytids	Evaluator No. 1, Mean (Range)	Evaluator No. 2, Mean (Range)	Average Between the 2 Evaluators, Mean (Range)	Change After Treatment, Mean (SD) [Range]	P Value
Central forehead area, Glogau scale					
Pretreatment	3.08 (1 to 4)	3.19 (2 to 4)	3.13 (1.5 to 4.0)	NA	
Posttreatment	2.85 (2 to 4)	3.19 (2 to 4)	3.02 (2.0 to 4.0)	0.12 (0.33) [-0.5 to 0.5]	.08
Central forehead area, wrinkle severity scale					
Pretreatment	4.77 (1 to 9)	4.69 (1 to 8)	4.73 (1.0 to 8.0)	NA	
Posttreatment	4.35 (1 to 9)	4.69 (1 to 9)	4.52 (1.0 to 8.5)	0.21 (1.28) [-3.0 to 3.0]	.41
Glabella, Glogau scale					
Pretreatment	3.04 (1 to 4)	3.19 (2 to 4)	3.12 (1.5 to 4.0)	NA	
Posttreatment	2.92 (1 to 4)	3.19 (2 to 4)	3.06 (1.5 to 4.0)	0.06 (0.22) [-0.5 to 0.5]	.18
Glabella, wrinkle severity scale					
Pretreatment	5.27 (1 to 9)	5.12 (1 to 9)	5.19 (1.0 to 9.0)	NA	
Posttreatment	4.81 (1 to 9)	5.08 (1 to 9)	4.94 (1.0 to 9.0)	0.25 (0.75) [-1.5 to 2.0]	.10

Abbreviation: NA, not applicable.

brought on by the pads in the central forehead area and glabella (1-10 scale), and whether they would continue using the pads on their own. We then compared the pretreatment and posttreatment rhytid severity scores (1-10 scale) for possible treatment effect.

### STATISTICAL ANALYSIS

We compiled the scores from the independent evaluators and the pretreatment and posttreatment questionnaires. We determined the average score and ranges for each of independent evaluator and questionnaire assessments. We performed paired *t* tests to compare the means of the scores, with  $P < .05$  considered statistically significant.

### RESULTS

We enrolled 30 study participants, 26 of whom (87%) completed the study. Three dropped out of the study (1 developed a rash and 2 felt that the pads were not working). We removed 1 participant because of reported non-compliance. Because of a scheduling conflict, 1 participant wore the pads for 5 weeks instead of 4 weeks. The participants reported a mean of 7.4 hours of use per night. Five participants were slightly noncompliant in that they missed a total of 1, 2, 3, 4, and 4 nights of use, respectively, in 1 month.

Twenty-five participants (96%) were women. The average age was 57 years (age range, 37-78 years). Twenty-four participants (92%) reported themselves as being Caucasian, 1 as Asian, and 1 as Hispanic. Twenty-five participants (96%) reported that they were nonsmokers. Two participants had used topical adhesive pads in the past (1 year earlier and 20 years earlier). Three study participants had used botulinum toxin A in the glabellar area before the study (range, 2-10 years before enrollment). One participant had undergone blepharoplasty 2 years before enrollment. The participants reported no other history of facial plastic surgery. Before using the topical adhesive pads, the participants reported a mean score of 6.2 out of 10 in their expectation of how well the topical adhesive pads would reduce the rhytids on their face.

**Table 1** presents the mean and range of severity scores of pretreatment and posttreatment rhytids as determined by the 2 independent blinded evaluators using the Glogau and wrinkle severity scales. The average Glogau scores, as determined by the 2 independent evaluators, showed minimal improvement (mean [SD], 0.12 [0.33] [ $P = .08$ ] and 0.06 [0.22] [ $P = .18$ ] for central forehead and glabellar rhytids, respectively). Wrinkle severity scores also showed minimal change (mean [SD], 0.21 [1.28] [ $P = .41$ ] and 0.25 [0.75] [ $P = .10$ ] for central forehead and glabellar rhytids, respectively). None of these changes were statistically significant.

We further analyzed the data by separating patients into categories of worse, no improvement, or improvement based on increase, no change, or lowering of Glogau or wrinkle severity scores as determined by our independent evaluators. **Table 2** presents the number and percentages of study participants with specific degrees of improvement or worsening in their rhytids and the ranges of improvement or worsening as determined by the 2 independent blinded evaluators using the Glogau and wrinkle severity scales. Evaluation of the central forehead area demonstrated no improvement by either measure. In the glabella, there was a trend toward improvement in the wrinkle severity score (mode, 12), but no such trend was observed in the Glogau scale. However, as noted above, this did not reach statistical significance.

The study participants were asked to rate the severity of their wrinkles, both before and after treatment, on a scale of 1 to 10, with 10 being most severe. They did not know what scores they had given themselves previously. **Table 3** presents the results comparison of the pretreatment and posttreatment questionnaires. After 28 days of use of the topical adhesive pads, the mean improvement in the central forehead rhytids was 0.35 severity points (pretreatment, 5.85 [2.38]; posttreatment, 5.50 [2.25];  $P = .41$ ), and the improvement in the glabellar rhytids was 0.73 severity points (pretreatment, 6.46 [1.92]; posttreatment, 5.73 [1.80];  $P = .04$ ).

At the conclusion of the study, in addition to rating wrinkle severity, we asked participants to rate the de-

**Table 2. Number and Percentages of Study Participants With Specific Degrees of Improvement and the Ranges of Improvement or Worsening as Determined by 2 Independent Blinded Evaluators Using the Glogau (1-4) and Wrinkle Severity (1-10) Scales**

Degree of Improvement of Rhytids	No. (%) of Participants
Central forehead area	
Glogau scale	
Worse	4 (15)
No improvement	21 (81)
Improvement	1 (4)
Wrinkle severity scale	
Worse	3 (12)
No improvement	12 (46)
Improvement	11 (42)
Glabella	
Glogau scale	
Worse	3 (12)
No improvement	14 (54)
Improvement	9 (35)
Wrinkle severity scale	
Worse	7 (27)
No improvement	7 (27)
Improvement	12 (46)

gree of improvement that they thought they had obtained, on a scale of 1 to 10, with 10 representing the most improvement. **Table 4** presents specific scores for the degree of improvement in the participants' central forehead and glabellar rhytids after use of the topical adhesive pads (1-10 scale). For their raw improvement score (1-10), the participants reported a mean of 3.7 for improvement of rhytids in the central forehead area and 4.4 in the glabella.

Fourteen participants (54%) reported some degree of discomfort in wearing the topical adhesive pads. They specifically complained of pruritus, acne, stickiness, the noticeable feeling of the pads' presence on their skin, and a slight pain when removing the pads. Two participants (8%) reported some difficulty sleeping when using the pads. With regard to planned future use of the topical adhesive pads, the participants reported the following: 6 definitely (23%), 13 maybe (50%), and 6 no (23%). Many participants reported that they felt that the topical adhesives had a temporary effect (for an hour to a few hours after removal). Several study participants explained that the temporary effect might have specific uses such as in the hours directly before a social engagement.

#### COMMENT

In this study, we prospectively examined the efficacy and tolerance of the use of topical adhesive pads that are purported to reduce facial rhytids. The public demand is high for wrinkle treatments that are inexpensive, topical, non-invasive, and over the counter, such as topical adhesive pads.<sup>1,3</sup> As facial plastic surgeons, we have a responsibility to determine the efficacy of such products so that we may provide unbiased, evidence-based recommenda-

**Table 3. Pretreatment and Posttreatment Questionnaire Scores**

Variable	Score, Mean (SD) [Range]
Pretreatment expectation of improvement with treatment, 1-10 scale	6.2 (2.91) [1-10]
Severity of central forehead rhytids, 1-10 scale	
Pretreatment	5.85 (2.38) [1-10]
Posttreatment	5.50 (2.25) [1-9]
Difference of means <sup>a</sup>	0.35 (2.12)
Severity of Glabella rhytids, 1-10 scale	
Pretreatment	6.46 (1.92) [3-9]
Posttreatment	5.73 (1.80) [2-9]
Difference of means <sup>b</sup>	0.73 (1.69)
Hours per night of use	7.4 (1.1) [6-10]
Discomfort with use	1.9 (1.35) [1-6]
Satisfaction with use	5.2 (2.59) [1-10]

<sup>a</sup>  $P = .41$ .

<sup>b</sup>  $P = .04$ .

**Table 4. Number and Percentages of Study Participants Reporting Degrees of Subjective Posttreatment Improvement in the Posttreatment Questionnaire**

Degree of Improvement of Rhytids, 1-10 Scale	No (%) of Participants
Central forehead area	
Mean, 3.7	
Range, 1-8	
No improvement, 1	7 (27)
Mild improvement, 2-4	9 (35)
Moderate improvement, 5-7	6 (23)
Major improvement, 8-10	4 (15)
Glabella	
Mean, 4.4	
Range, 1-8	
No improvement, 1	5 (19)
Mild improvement, 2-4	8 (31)
Moderate improvement, 5-7	9 (35)
Major improvement, 8-10	4 (15)

tions to our patients, as several of these products have failed to live up to manufacturer's claims when examined in an unbiased fashion.<sup>1,2,7</sup>

For this study, we achieved adequate follow-up participation (87%) and adequate compliance of use (7.4 hours per night on average, with 5 participants reporting mild intermittent noncompliance). The patient cohort was mostly composed of healthy, middle-aged, non-smoking, white women, few of whom had undergone any previous cosmetic procedures. Our approach to determining the efficacy of topical adhesive pads was 2-fold. First, we attempted to determine, objectively and without bias, what effect, if any, the product had on rhytids in 2 regions of the forehead (central and glabellar). Independent evaluators used both the Glogau scale and our wrinkle severity score to rate each of these regions after the study participants had used the topical adhesive pads for 1 month. By these indices, we found that the product does not significantly improve rhytids in the central forehead area or the glabella. We further analyzed our

data for trends by examining the number of participants whose independently evaluated Glogau or severity scores increased, decreased, or stayed the same. For the central forehead area and the glabella, the evaluators found a range of improvements and worsening, with a non-statistically significant trend toward improvement in the glabella by the wrinkle severity score (but not by Glogau scale). It may be that this variability is a product of normal variance of the facial skin structure, independent of the use of topical adhesive pads.

The second approach was to have the participants self-rate wrinkle severity before and after treatment as well as the perceived degree of improvement after treatment. Our previous work has shown that self-perception of improvement is sometimes incongruous with independent evaluation.<sup>1,2,7</sup> We again found that, according to the study participants, self-perception of benefit does not always agree with independent evaluation. Specifically, a statistically significant decrease in wrinkle severity score was noted by subjects in the glabellar (but not the central forehead) region, while our independent evaluators found no such change.

Overall, the cohort tended to feel that they achieved mild improvement with moderate satisfaction and minimal adverse effects. Based on the posttreatment questionnaire results, the participants also reported a mean of 3.7 (out of 10) in the central forehead area and 4.4 (out of 10) in the glabellar region. Although most of the participants cited a specific discomfort with the use of the topical adhesive pads, the cohort appeared to tolerate the pads with only minor complaints. One participant developed a skin allergy and decided to discontinue involvement in the study. The average satisfaction score was 5.2 out of 10. Most participants were considering the future use of the product on the central forehead area, the glabella, and other areas of the face.

The limitations of this study include the following: it lacks randomization and a placebo group for comparison of the effects of the topical adhesive pads; it operates on the assumption that untreated rhytids (without any intervention such as the topical adhesive pads) would not perceptibly change over the course of a month; and its results are based on subjective reporting by patients and semiquantitative photographic reporting by independent evaluators. Also, the participants' desires for improvement in their rhytids could have influenced scoring, especially when the 6.2 out of 10 level of expectation of efficacy is considered.

Similarly, the evaluators' possible preconceived biases against the effectiveness of topical adhesive pads could have influenced their scoring in a negative way, thereby causing them to find no difference between the rhytids in the pretreatment and posttreatment photographs. We addressed this possibility by randomizing the pretreatment and posttreatment photographs to our evaluators in a blinded fashion. The relatively homogeneous nature of the cohort may compromise the ultimate generalizability of our results, particularly to nonwhites and men. Furthermore, we studied the effect of the topical adhesive pads only on the central forehead area and the glabella and not on the corners of the eyelids and the mouth. Also, we did not directly observe any of the study participants using the topical adhesive pads; therefore, the study participants' reports of use and compliance may vary from reality. However, because this co-

hort comprised motivated individuals who came to us with interest in reducing their own rhytids, we believe that we have good reason to trust their reports.

As stated earlier, many study participants remarked about a temporary reduction in rhytids in the first few hours after use. This study was not designed to determine the presence of any short-term effectiveness of the topical adhesive pads in reducing rhytids. Taking photographs within an hour after a night of use could have helped us analyze this popular yet anecdotal claim.

In conclusion, the present study demonstrates that the use of topical adhesive pads for 1 month does not improve rhytids in the central forehead area or the glabella. However, patient self-evaluation, which may be biased, indicated that the pads may offer subjective mild improvement in glabellar rhytids but that they do not substantially improve central forehead rhytids. Topical adhesive pads are safe to use and tolerable for most users, with the slight risk of a skin reaction. This study could not effectively record the possibility of the topical adhesive pads causing a temporary, short-term (within hours) reduction of rhytids, if it does exist. More studies on the efficacy of such over-the-counter products will be needed in the future as new products come to the market.

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**Author Contributions:** Dr Ryan had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Ryan and Most. *Acquisition of data:* Ryan. *Analysis and interpretation of data:* Ryan and Most. *Drafting of the manuscript:* Ryan and Most. *Critical revision of the manuscript for important intellectual content:* Ryan and Most. *Statistical analysis:* Ryan. *Administrative, technical, and material support:* Ryan and Most. *Study supervision:* Most.

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