Efficacy of Topical 5% Imiquimod Cream for the Treatment of Nodular Basal Cell Carcinoma

Comparison of Dosing Regimens

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Objective: To establish a safe and efficacious dosing regimen for the treatment of primary nodular basal cell carcinoma (BCC) using 5% imiquimod cream.

Design: Two phase 2 studies were conducted: a 6-week, randomized, open-label, dose-response study evaluating 4 dosing regimens and a 12-week, randomized, vehicle-controlled, double-blind, dose-response study evaluating 4 dosing regimens.

Setting: Twenty-four public and private dermatology clinics in Australia and New Zealand (6-week study) and the United States (12-week study) participated.

Patients: The study populations comprised 99 patients enrolled in the 6-week study and 92 patients in the 12-week study. Patients were at least 18 years old and had a biopsy-confirmed diagnosis of nodular BCC.

Interventions: In the 6-week study, imiquimod was applied once daily for 3 or 7 days per week or twice daily for 3 or 7 days per week. In the 12-week study, imiquimod or placebo cream (vehicle) was applied once daily for 3, 5, or 7 days per week, or twice daily for 7 days per week. The entire tumor area was excised 6 weeks after treatment and examined histologically for evidence of remaining BCC.

Main Outcome Measure: The proportion of patients having no histologic evidence of BCC in the posttreatment excision specimen.

Results: Dosing once daily for 7 days per week resulted in the highest clearance rate, with 25 (71%) of 35 and 16 (76%) of 21 patients showing clearance of their tumor in the 6- and 12-week studies, respectively.

Conclusions: Topical 5% imiquimod cream is well tolerated and most effective in treating nodular BCC when applied once daily for 7 days per week for either 12 or 6 weeks.

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Imiquimod (Aldara; 3M Pharmaceuticals, St Paul, Minn) is an immune response modifier that has been shown to induce a local immune response when applied topically. Imiquimod stimulates the production of interferon and other cytokines important in cell-mediated local immune responses and has been shown to promote antitumor and antiviral effects. Because of these effects on the innate and cell-mediated immune response, topical imiquimod cream is being studied as an alternative to current methods in treating basal cell carcinoma (BCC), which is the most common skin cancer in many countries, including the United States.

The incidence of BCC in Australia has increased by 11% between 1985 and 1990, approaching 1000 cases per 100,000 people in subtropical areas. It is estimated that 1.2 million new cases were diagnosed and treated in the United States in 1995 and that the incidence in Europe is also increasing. Of the 3 main subtypes of BCC (nodular, superficial, and infiltrative), studies have shown that nodular BCC is the most common (approximately 60%) and occurs on the head and neck in 60% to 75% of cases.

Recently, a phase 2 dose-response study examined the use of 5% imiquimod cream for the treatment of superficial BCC. We report herein 2 studies with similar protocols that were undertaken to evaluate the
safety and efficacy in using various dosing regimens of 5% imiquimod cream in the treatment of nodular BCC for a period of 6 and 12 weeks. The recommended dosing frequency for the currently approved indication of genital warts is once daily for 3 days per week. Based on pilot studies on patients with BCC, 5% imiquimod cream has shown efficacy in the treatment of BCC tumors with once-daily applications for 3 and 7 days per week. In the case of the studies reported herein, it was desirable to examine a variety of dosing frequencies to establish optimal efficacy for this application while minimizing adverse effects.

STUDIES

Two multicenter studies were initiated: a 6-week, randomized, open-label, dose-response study conducted in Australia and New Zealand and a 12-week, randomized, double-blind, vehicle-controlled, dose-response study conducted in the United States. Because the protocols for these 2 studies were very similar, the methods that follow will pertain to both studies unless otherwise stated.

ETHICS

All protocols, amendments, and informed consent documents were submitted to and approved by each study site’s ethics committee. Before study procedures were initiated, each patient, or the patient’s legal representative, voluntarily signed dated an informed consent statement.

ELIGIBILITY

Patients were eligible if they were at least 18 years old and had a primary target tumor that was histologically confirmed as nodular BCC. Target tumors suitable for treatment in these 2 studies measured 0.5 to 1.5 cm² in area and were greater than 1 cm from the eyes, nose, mouth, ear, and hairline. Tumor biopsy specimens exhibited histologic characteristics of nodular aggregates or nests of atypical basaloid cells extending into the reticular dermis with peripheral palisading, mitotic figures, and clefting from a surrounding fibromyxoid stroma. Circumscribed nodular aggregates comprised the bulk of the tumor. If a tumor exhibited additional superficial BCC characteristics but also contained nodular components that extended into the reticular dermis, the tumor was classified as a nodular BCC with superficial components and the patient was included in the study. Basal cell carcinomas with morphetic infiltrating and micro-nodular patterns were excluded from these studies.

STUDY DESIGN

The 12-week study enrolled patients at 14 sites. Patients were initially randomized to either imiquimod or placebo cream (vehicle) in 1 of the following 3 dosing regimens: once daily for 3 days per week or once or twice daily for 7 days per week. The 6-week study enrolled patients at 10 sites. Patients were randomized to 1 of the following 4 dosing regimens: once or twice daily for 3 days per week or once or twice daily for 7 days per week. After study initiation, enrollment of patients into the twice-daily, 7-day-per-week (7-day) dosing regimen was discontinued in both studies owing to the severity of local skin reactions experienced by the patients in those dosing groups. This dosing group was replaced in the 12-week study with a once-daily, 5-day-per-week (5-day) regimen. The small number of patients already randomized to the twice-daily, 7-day dosing group continued to dose according to that schedule until they completed the end-of-treatment period or discontinued treatment.

Two to 4 weeks prior to treatment initiation, each patient underwent a confirmatory punch or shave biopsy of the target tumor. Investigators were encouraged to use a 2- to 3-mm punch and to remove no more than approximately 25% of the target tumor area. Biopsies extended through the entire depth of the tumor and into the reticular dermis, which was confirmed during the histologic assessment. Biopsy specimens were sent to a central dermatopathology laboratory where they were paraffin processed, stained with hematoxylin and eosin, and microscopically examined for BCC. The presence of a nodular BCC in each biopsy specimen was verified by an independent dermatopathologist.

Patients applied topical 5% imiquimod cream to 1 target tumor just prior to normal sleeping hours according to the dosing regimen to which they were assigned. The target tumor was washed with mild soap just prior to cream application, and the cream was rubbed into and around (approximately up to 1 cm) the tumor. The cream remained in place for at least 8 hours without occlusion. Patients randomized to the 3 day-per-week (3-day) schedule applied study cream on the same 3 alternating days each week (eg, Monday, Wednesday, and Friday), followed by 2 days without dosing. Patients in the 5-day dosing group applied study cream on the same 5 consecutive days each week (eg, Monday–Friday), followed by 2 days without dosing. Patients required to dose twice per day applied study cream 8 to 16 hours between doses. Investigators could prescribe 2 rest periods from treatment (up to 7 days each for a maximum of 14 days) on account of local skin reactions or treatment site adverse events. Patients requiring more than 14 days of rest from study treatment were discontinued from treatment.

SAFETY AND EFFICACY MEASUREMENTS

Patients returned to the clinic for interval visits at the end of weeks 1, 2, 4, and 6 (6-week study) and at the end of weeks 1, 2, 4, 6, 8, 10, and 12 (12-week study) for safety and efficacy evaluations. Prestudy and posttreatment evaluations included physical, hematologic, and blood chemistry examinations and urinalysis. Pregnancy tests were performed for women of child-bearing potential. Target tumors were measured (size expressed as area in square centimeters) and photographed prior to the prestudy biopsy and rephotographed prior to treatment initiation and at each interval visit. Tumor measurements taken at treatment initiation were used to determine baseline target tumor size. The presence and intensity of specific local skin reactions (ie, erythema, edema, induration, vesicles, erosion, ulceration, excoriations and/or flaking, and scabbing) was assessed by the investigator on a 4-point scale (0, none; 1, mild; 2, moderate; and 3, severe) at initiation, interval visits, and the posttreatment excision visit. Vital signs, concomitant medications, and adverse events were monitored at interval visits and at the 6-week posttreatment visit.

Six weeks following the treatment period, patients returned to the clinic to undergo clinical evaluation and surgical excision of the target tumor area. The tumors were excised with a margin of 3 to 4 mm surrounding the tumor. Each specimen was put into blocks not greater than 3 mm in thickness, and serial sections were obtained in at least 1.0-mm increments. The tissue was examined histologically for evidence of residual BCC and to ensure that the tissue margins were free of tumor. In addition, prestudy and poststudy excisions were evaluated in regard to histologic variables such as tumor depth, degree of lymphocytic inflammation, and evidence of regression.

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in residual tumors. Patients returned for follow-up visits after the posttreatment excision, every 2 weeks as necessary, to ensure proper healing of the excision site.

ANALYSES

The statistical analysis was based on the intent-to-treat data set, which consisted of all randomized patients. The primary variable was the complete response (histologic cure) rate, defined as the proportion of patients who had no histologic evidence of BCC in the 6-week posttreatment excision specimen. Patients who did not return for the posttreatment excision were considered to be nonresponders for analysis purposes.

In the 12-week study, vehicle data from all dosing groups were pooled to determine the combined vehicle response rate. Fisher exact tests were used to compare the complete response rates of the once-daily 3-, 5-, and 7-day dosing groups to the combined vehicle group in a pairwise manner. Each test was carried out at an alpha level of .05 divided by 3 to preserve the overall alpha level of .05. The response rate of the twice-daily, 7-day imiquimod dosing group was not compared with vehicle owing to the small sample size for this group. Investigator assessments of whether the target tumors were clinically evident at the 6-week posttreatment excision visit were compared with histologic examination results, and positive and negative predictive values were calculated.

RESULTS

12-WEEK VEHICLE CONTROL STUDY

A total of 200 patients were screened, and 92 white patients (63 men and 29 women) were enrolled. Twenty-four patients were randomized to vehicle and 68 patients were randomized to imiquimod according to the following scheme: twice daily for 7 days per week (4 active and 0 vehicle), once daily for 7 days per week (21 active and 10 vehicle), once daily for 5 days per week (23 active and 6 vehicle), and once daily for 3 days per week (20 active and 8 vehicle). Target tumors ranged in size from 0.30 to 3.0 cm² (Table 1). Eight patients had tumors outside the range specified in the inclusion criteria but were allowed to remain in the study. Of the 92 patients enrolled, 15 were discontinued from the study (8 because of local skin reactions, 2 because of adverse events, 3 because of personal reasons, and 2 because inclusion criteria were not met). Posttreatment excision results were obtained for 11 of those 15 patients.

Efficacy

Eighty-eight patients underwent posttreatment excisions. The highest complete response rate (Figure 1) for the intent-to-treat data set was seen in the once-daily, 7-day dosing group. An increase in the complete response rate was seen with increasing dosing frequency. This increase was statistically significant (P<.001) based on the Cochran-Armitage test for trend (2-sided). All 3 imiquimod dosing groups that were compared with vehicle had statistically significantly higher response rates.

A statistically significant correlation between most intense erosion, as assessed by the investigator, and complete response rate was noted in the imiquimod once-daily, 5-day treatment group (P=.003, Cochran-Armitage

Table 1. Patient Characteristics (12-Week Study)*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Combined Vehicle (n = 24)</th>
<th>Once Daily for 3 d/wk (n = 20)</th>
<th>Once Daily for 5 d/wk (n = 23)</th>
<th>Once Daily for 7 d/wk (n = 21)</th>
<th>Twice Daily for 7 d/wk (n = 4)</th>
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<td>8 (35)</td>
<td>2 (10)</td>
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<td>Mean ± SD age, y</td>
<td>62 ± 11.5</td>
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<td>65 ± 14.1</td>
<td>53 ± 25.9</td>
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<td>Median target tumor size, cm²</td>
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<td>0.7</td>
<td>0.7</td>
<td>0.8</td>
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<td></td>
<td></td>
<td></td>
</tr>
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<td>Face</td>
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<td>8 (40)</td>
<td>11 (48)</td>
<td>6 (29)</td>
<td>1 (25)</td>
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<tr>
<td>Neck</td>
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<tr>
<td>Trunk</td>
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<tr>
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<td>2 (9)</td>
<td>2 (10)</td>
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*Data are number (percentage) of patients unless otherwise specified.

Figure 1. Comparison of dosing regimens. In the twice-daily, 7-day-dosing group, the 1 patient in the 6-week study was not a complete responder, and 3 of 4 patients in the 12-week study were complete responders.
test for trend, 2-sided). In this group of 23 patients, 9 had moderate to severe erosion and all 9 (100%) were complete responders. Of 7 patients with mild erosion and 7 patients with no erosion, 5 (71%) and 2 (29%), respectively, were complete responders. No statistically significant correlation was found for the other treatment groups.

For the intent-to-treat data set, the negative predictive value for posttreatment investigator tumor assessment (all imiquimod groups combined) was 91% (32/35), which indicated that 91% of the patients assessed as negative (target tumor clinically evident) by the investigator were confirmed to be negative histologically. For 2 patients, the investigator was unable to clinically determine whether the target tumor was present. Both of these patients were negative for BCC on histologic analysis of the posttreatment excision specimen. Additionally, 3 imiquimod-treated patients did not have clinical assessments by the investigator (Figure 2).

**Safety**

Local skin reactions occurred in all dosing groups, and most were mild to moderate in intensity, with erythema occurring most frequently in all dosing groups followed by scabbing. Though the local skin reactions were well tolerated by most patients, 8 patients discontinued treatment owing to local skin reactions: 2 patients in the once-daily, 5-day group; 4 patients in the once-daily, 7-day group; and 2 patients in the twice-daily, 7-day group.

Adverse events occurred in all dosing groups. Seventy-eight patients (85%) reported at least 1 adverse event with the most frequently reported adverse event being application site reactions (51%). The 3 most frequently reported symptomatic application site reactions were itching, tenderness, and burning at the target site. Most of these reactions were mild to moderate in intensity. Two patients from the imiquimod twice-daily, 7-day dosing group reported severe application site reactions, 1 with pain at the target site and 1 with tenderness, stinging, and pain at the target site. One patient from the once-daily, 7-day group reported severe tenderness at the target site. At least 1 adverse event, considered possibly or probably related to study drug, was reported by 50 patients (54%). Five patients reported flu-like symptoms that were considered by the investigator to be possibly or probably related to treatment (1 with fever, 3 with headache, 1 with nausea, and 2 myalgia). Two patients discontinued treatment owing to adverse events (1 for irritated spider bites adjacent to the target tumor and 1 for pain, drainage, and tenderness at the target tumor site).

**6-WEEK STUDY**

A total of 163 patients were screened, and 99 white patients (81 men and 18 women) were enrolled in this open-label study. Patients were randomized as follows: twice daily for 7 days per week (1 patient), once daily for 7 days per week (35 patients), twice daily for 3 days per week (31 patients), and once daily for 3 days per week (32 patients). Tumors ranged in size from 0.4 to 2.6 cm² (Table 2). Five patients had tumors outside the range specified in the inclusion criteria but were allowed to remain in the study. One patient, who was enrolled into the study with a diagnosis of superficial BCC, was allowed to complete the study. Of the 99 enrolled patients, 9 patients were discontinued from study treatment (3 owing to adverse events, 1 owing to a local skin reaction, 1 owing to an intercurrent disease, and 4 patients who were lost to follow-up). Posttreatment excisions were performed for 5 of the 9 patients who discontinued treatment.
Efficacy

Ninety-five patients underwent the posttreatment excision, and 57 patients (58%) were complete responders to therapy. Four patients did not return for the posttreatment excision. The highest complete response rate (Figure 1) was seen in the once-daily dosing group. No statistically significant dose-response trend was detected.

A statistically significant correlation between most intense erosion, as assessed by the investigator, and complete response rate was noted in the once-daily, 7-day dosing group ($P = .046$, Cochran-Armitage test for trend, 2-sided). In this group of 35 patients, 4 had severe erosion and all 4 were complete responders. Of 9 patients with moderate erosion, 6 (67%) were complete responders. Of 15 patients with mild erosion and 7 patients with no erosion, 6 (87%) and 2 (29%), respectively, were complete responders. No statistically significant correlation was found for the other dosing groups.

Safety

Local skin reactions were common, and most of the investigator assessments of local skin reactions were mild to moderate in intensity, with erythema occurring most frequently, followed by scabbing. Patient reports of local skin reactions were similar in frequency and intensity to assessments made by the investigators. Though the frequency of severe local skin reactions was lower than that seen in the 12-week study, the number of patients taking rest periods increased as dosing frequency increased. One patient in the once-daily, 7-day dosing group discontinued treatment owing to moderate erythema, edema, and ulceration at the target site.

Adverse events occurred in all dosing groups, with 63 patients (64%) reporting at least 1 adverse event during the study. Application site reactions were the most frequently reported adverse events in all dosing groups, the 3 most frequent symptomatic adverse events being itching, pain, and bleeding at the tumor site.

Fifty-two patients (42%) reported adverse events that were considered by the investigator to be possibly or probably related to study treatment, most of which were application site reactions. Patients reported 10 incidences of flulike symptoms (including headache, nausea, diarrhea, fever, myalgia, fatigue, and malaise), but only 1 report of fatigue in the once-daily, 7-day group was considered by the investigator to be possibly or probably related to study drug.

Two patients discontinued treatment owing to application site reactions that were considered possibly or probably related to study drug: 1 (twice daily for 7 days per week) owing to moderate pain at the target site (chin) in addition to severe swelling and blisters on the lower lip. This patient discontinued treatment with no other treatment required. Another patient (once daily for 7 days per week) discontinued treatment owing to mild tenderness at the treatment site, which subsequently resolved. A third patient discontinued treatment owing to a cerebral vascular accident, though this was not considered by the investigator to be related to study treatment.

The 12-week vehicle-control study demonstrated a statistically significant dose-response, with complete response rates increasing with dosing frequency up to a maximum of 76% with once-daily, 7-day dosing. The complete response rate for once-daily, 5-day dosing was similar to once-daily, 7-day dosing, and the complete response rates of all the treatment groups in the 12-week study were statistically superior to vehicle. The maximum clearance rate (76%) in the 12-week study does not represent a clinically meaningful increase in complete response rate over the 71% found for the once-daily, 7-day group in the 6-week study. However, the 6-week treatment appears to be better tolerated by patients and has a lower incidence of severe local skin reactions, total adverse events, and need for rest periods. Dosing twice daily for 3 days per week did not offer higher efficacy over once-daily, 3-day dosing in the 6-week study, and twice-daily, 7-day dosing was discontinued from the studies because of the possibility of unacceptable local skin reactions.

There was strong agreement between investigators’ clinical assessments of tumor clearance and histologic examination results (negative predictive value of 91.4%). However, there was less agreement when investigators

### Table 2. Patient Characteristics (6-Week Study)*

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<th>Characteristic</th>
<th>Once Daily for 3 d/wk (n = 32)</th>
<th>Twice Daily for 3 d/wk (n = 31)</th>
<th>Once Daily for 7 d/wk (n = 35)</th>
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<td>Female</td>
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<td>4 (13)</td>
<td>10 (29)</td>
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<tr>
<td>Mean ± SD age, y</td>
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<tr>
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<td>0.8</td>
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<td>Target tumor location</td>
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</table>

*Data are number (percentage) of patients unless otherwise specified.
assessed that residual tumor may have been present when in fact the results from histologic examination proved that the tumor had cleared (positive predictive value of 53.6%). Tumor presence may have been overstated by investigators as a result of mild residual erythema or hypopigmentation occurring in some patients 6 weeks following treatment, indicating that a longer follow-up period may be appropriate for future studies.

The complete response rates in these 2 studies were not as high as the complete response rate (88%) seen in the earlier 6-week study treating superficial BCC. The reasons for this difference may be attributable to the physiologic mechanisms of the tumor, since nodular tumors tend to be more dense and extend deeper into the dermis than superficial tumors. These qualities may affect the ease with which topical imiquimod, lymphocytes, or local cytokines penetrate central areas of the tumor. The influence of tumor thickness at prestudy biopsy and presence of lymphocytic inflammation, pattern of any residual tumor, and location relative to the skin surface in poststudy excisions are currently being analyzed in specimens obtained from the 6-week trial.

In these dose-finding studies, the nodular tumors selected for treatment were considered relatively low risk in terms of histologic appearance, location, size, and ease of the mandatory excision at the end of the study. For nodular BCC, these studies demonstrated that once-daily, 7-day application of 5% imiquimod cream is effective, well tolerated, and appropriate for further study. At present, larger or high-risk lesions have not been studied. Local skin reactions of erythema and scabbing are most common and, in some cases, extend beyond the edges of the original tumor, but are usually mild to moderate in intensity. These reactions subside with a temporary interruption of therapy, and few patients discontinue treatment.

These studies have defined a clinically useful dosing regimen for self-applied topical imiquimod cream that is effective for small nodular BCC. Although efficacy levels in these studies have not matched those of excision, there are circumstances in which these levels may be acceptable when there is longer follow-up. These might include cases when patients refuse surgery or when surgery is contraindicated for medical or cosmetic reasons. Topical application of 5% imiquimod cream nevertheless has an acceptable safety profile when applied once daily for 7 days per week up to 12 weeks and, with response rates of 71% and 76% for 6- and 12-week treatment durations, respectively, represents another treatment option for nodular BCC.

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From the St George Hospital, Kogarah, Australia (Dr Shumack); Loyola University Medical Center, Maywood, Ill (Dr Robinson); the Skin and Cancer Foundation Australia, Darlinghurst (Dr Kossard); Dermatopathology Services, LLC, Denver, Colo (Dr Golitz); the Scripps Clinic, La Jolla, Calif (Dr Greenway); the Mayo Clinic, Rochester, Minn (Dr Schroeter); 3M Pharmaceuticals, St Paul, Minn (Ms Andres and Dr Owens); and 3M Health Care, Thornleigh, (Dr Amies). Study group members are listed in a box on page 000.

This study was funded by 3M Pharmaceuticals, St Paul, Minn.

Posters for the 6- and 12-week studies reported here have been presented at the Eighth World Congress of Cancers of the Skin, Zurich, Switzerland, July 18, 2001; the 60th Annual Meeting of the American Academy of Dermatology, New Orleans, La, February 22-27, 2002; and the 20th World Congress of Dermatology, Paris, France, July 1, 2002.

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REFERENCES


Correction

Error in Byline. In the Observation by Gaspar et al titled “Antibiotic Prophylaxis for Full-Face Laser Resurfacing: Is It Necessary?” published in the March 2001 issue of the ARCHIVES (2001;137:313-315), the name of the second author was misspelled in the byline on page 313 and in the Table of Contents on page 259. The bylines in both places should have appeared as follows: “Zoran Gaspar, MB,BS, FACP; Carl Vinciullo, MB,BS, FACP; Timothy Elliott, MB,BS, FACP.”