



SDI FINAL EVALUATION FORM 1.1

PART 1:

Journal Name:	Journal of Advances in Medical and Pharmaceutical Sciences
Manuscript Number:	Ms_JAMPS_19036
Title of the Manuscript:	Pilot study of photoallergic reactions to UV filters among dental professionals
Type of the Article	Original Research Article

PART 2:

FINAL EVALUATOR'S comments on revised paper (if any)	Authors' response to final evaluator's comments
While the conclusions were modified (and I agree with the content), all throughout the remaining of the paper the authors suggest that there is a photosensitizing effect from the chemicals in the dental materials. While this effect may have been demonstrated in skin products, this study <u>fails</u> to demonstrate any cause and effect relationship. This should be clearly stated throughout the paper, in the results as well as in the discussion. To suggest that there is a "slight effect" is misleading. Before writing these things the authors should discuss with the statistician. I doubt he/she will agree with authors' comments. For example: First result, it says: "Higher was the incidence of positive reactions to Benzophenone-3 after UV-irradiation among women (13.8% before vs 24.1% after UV-irradiation; $P=.23$) and the group of dental patients (8.8% vs 20.6%; $P=.75$). No statistical significances were established." It should say something like: Results for reactions to Benzophenone-3 showed no significant differences between the groups. There is a non-significant increase in the number of the reactions in 2 subgroups: a) Women, that showed a 24.1% incidence after exposure to UV-irradiation vs 13.8% before, b) Dental patients, that showed a 20.6% incidence after exposure to UV-irradiation vs 8.8% before" <u>The most important thing is that there are no significant results.</u> Second result: it says	Thank you for the valuable conclusion remarks. After a detailed discussion with the statistician we achieved an agreement that really our study failed to demonstrate any cause and effect relationship between the occupational exposure in dentistry to UV-filters – containing dental materials and photosensitization and decided to follow strictly the recommendations of the respected Reviewer. The text concerning the results listed below by the Reviewer is corrected according to the recommendations. Corrected.



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“Concerning the incidence of positive reactions to Benzophenone-4 after UV-irradiation, data were similar – it increased among women (6.9% vs 13.8%; $P=.63$) and dental patients (11.8% vs 14.7; $P=.54\%$), without statistical significant differences”.

There are absolutely no differences. You cannot conclude there are differences with so small numbers. Discuss with your statistician and see what he/she says. Incidentally you are missing “%” in 14.7

Third result:

Again there is no statistical difference. That should be the only conclusion and that should be clearly stated. A change of 4 to 3 does not imply a decrease in incidence.

When you address the Bis-GMA, again there is absolutely no difference between the groups and that one is the only result: there are no statistical differences between the groups.

In discussion is written:

“According to the results from the present study, the groups of women and of dental patients without occupational exposure in dentistry are with highest incidence of positive skin patch test reactions to Benzophenone-3 and Benzophenone-4 after UV-irradiation, without statistical significance. Generally, the use of dental material containing benzophenons do not elicit photosensitization.”

According to the results of this study there are no differences between the groups. You cannot continue to say that there is a difference. I think you should say that perhaps dental materials are not as sensitizing as dermatological products, or you could suggest that the study needs to be repeated with a larger (probably much larger) sample if in your experience these dental materials are photosensitizing.

It says:

“In our study, most intriguing skin patch testing results were achieved after UV-irradiation of avobenzone. This substance seemed to play as a typical photosensitizer, since positive reactions were observed only after the application of UV-irradiation, in the group of women and the one of dental professionals. Since this is a pilot study, further investigations are needed before a categorical statement about the role of exposure to avobenzone for onset of photosensitization in dental practice could be given.”

Again, and this is always the same criticism:

3 cases appeared in women and 1 in dental professionals. We cannot conclude anything from this. Is there are a relationship? May be, but then we need another study to prove it. May 100 subjects?, may be more? You need to discuss this with your statistician and know which one is your target number of subjects for your next study.

My common sense tells me that if this was really a problem then dental professionals would have the highest incidence of reactions. You try to suggest that rather it is the patients-group the one that is more affected. (Again I think these numbers are not meaningful).

Corrected.

Corrected.

Corrected.

Corrected to “According to the results from the present study, dental material containing benzophenons do not elicit photosensitization. We could conclude that dental materials are not as sensitizing as dermatological products, but the study needs to be repeated with a larger (probably much larger) sample before a final statement to be given.”

Corrected to “The results from the present study don’t confirm the role of exposure to avobenzone for onset of photosensitization in dental practice. Since this is a pilot study, further investigations, with much more subject tested are needed before a categorical statement could be given. This substance seemed to play as a typical photosensitizer, since positive reactions were observed only after the application of UV-irradiation, in the group of women and the one of dental professionals.”



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It says: “According to the results achieved in our pilot investigation, PABA doesn't seem to be a significant photosensitizer among dental professionals, as well as among the control group. We didn't observe increase in positive reactions after UV-irradiation; furthermore, decrease of the incidence of positive skin patch test reactions among the groups of men and dental patients was found.” Here it is the same comment but in the “opposite direction”: the fact that there is a decrease in the number (that by the way is from 5 to 4 and from 4 to 3) still prevents from concluding anything. Besides the above commentaries that I think are major impairments to publish something serious and believable, let me please suggest that when in past review I suggested that: 1) Table 3 should have a column for the probability information Due to the lack of statistical significance we don't think such information should be presented in the table. Then you should add “N/S” after each value, or otherwise add under the table a note that says “all values had no statistical significant differences”. 2) Can Benzophenon and Benzophenone be used interchangeably This is not the topic of the present study. What I meant is that according to google: “Benzophenone” is correct but “Benzophenon” is not	Corrected to “We didn't observe statistically significant increase in positive reactions to PABA after UV-irradiation. According to the results achieved in our pilot investigation, doesn't seem to be photosensitizer in dental practice.” <u>The abstract was corrected accordingly.</u> The note “all values had no statistical significant differences” is added under the table. Of course, “Benzophenone” is correct, “Benzophenon” is a typing mistake and was corrected.
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