

FRAME

Fund for the Replacement of Animals in Medical Experiments



Press Release

FRAME announces Dorothy Hegarty Award winners

The Dorothy Hegarty Award is presented each year by FRAME (Fund for the Replacement of animals in Medical Experiments) to the authors of the most significant paper published in its scientific journal.

The journal, ATLA (Alternatives to Laboratory Animals) is published six times a year and carries details of the latest research relating to the development, validation, introduction and use of alternatives to laboratory animals. The ATLA editorial board chooses the paper which, in their opinion, is likely to make the most significant contribution to the Three Rs.

The 2008 award has been won by a team of researchers from Germany who collaborated on a validation study of the use of commercially available human skin models in absorption testing.

Three types of skin model were tested and compared with pig skin and the data showed that all the commercial models were appropriate alternatives to the animal sample when testing penetration of substances in solution.

The award carries a cash prize, which the winners plan to use to continue their work. Since the paper was published in early 2008 the team has already taken the study forward. Lead author Monika Schäfer-Korting said: "We are going on with this research in three ways. For several years now we have investigated the influence of nanosized carrier systems, both lipidic and non-lipidic in nature, for skin penetration enhancement. We have just launched BMBF-funded consortium investigating skin metabolism, which is of relevance for skin absorption too. And we are running preliminary studies on disease models."

Ends

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Registered Charity: No 259464

Dorothy Hegarty Award 2008

The Dorothy Hegarty Award 2008 has been won by a team of researchers from Germany who collaborated on a validation study of the use of commercially available human skin models in absorption testing.

Three types of skin model were tested and compared with pig skin and the data showed that all the commercial models were appropriate alternatives to the animal sample when testing penetration of substances in aqueous solution.

The Award is presented each year to the authors of a paper published in FRAME's scientific journal, ATLA. The editorial board chooses the paper which, in their opinion, is likely to make the most significant contribution to the Three Rs. The award carries a cash prize, which the winners plan to use to pay for assistance in data submission to the ESAC.

Since the paper was published in early 2008 the team has taken the study forward. Lead author Monika Schäfer-Korting said: "In fact, we are going on with this research in three ways. For several years now we have investigated the influence of nanosized carrier systems, both lipidic and non-lipidic in nature, for skin penetration enhancement. We have just launched BMBF-funded consortium investigating skin metabolism, which is of relevance for skin absorption too. And we are running preliminary studies on disease models."



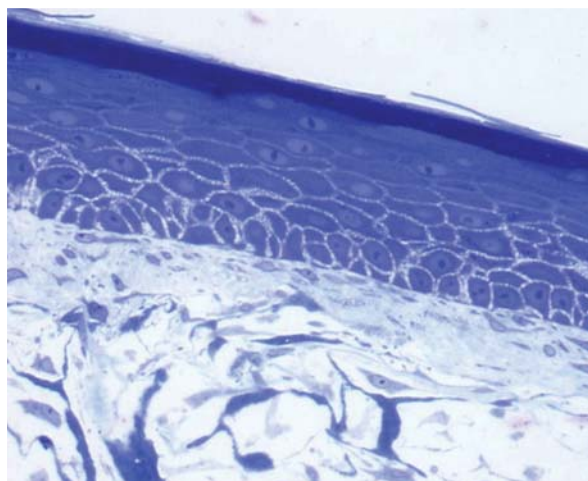
Lead author Monika Schäfer-Korting

Abstract:

A formal validation study was performed, in order to investigate whether the commercially available reconstructed human epidermis (RHE) models, EPISKIN®, EpiDerm™ and SkinEthic®, are suitable for *in vitro* skin absorption testing. The skin types currently recommended in the OECD Test Guideline 428, namely, *ex vivo* human epidermis and pig skin, were used as references. Based on the promising outcome of the prevalidation study, the panel of test substances was

enlarged to nine substances, covering a wider spectrum of physicochemical properties. The substances were tested under both infinite-dose and finite dose conditions, in ten laboratories, under strictly controlled conditions. The data were subjected to independent statistical analyses. Intra-laboratory and inter-laboratory variability contributed almost equally to the total variability, which was in the same range as that in preceding studies. In general, permeation of the RHE models exceeded that of human epidermis and pig skin (the SkinEthic

tendency toward lower variability of the data. Importantly, however, the permeation data showed a sufficient correlation between all the preparations examined. Thus, the RHE models, EPISKIN, EpiDerm and SkinEthic, are appropriate alternatives to human and pig skin, for the *in vitro* assessment of the permeation and penetration of substances when applied as aqueous solutions.



Skin model

RHE was found to be the most permeable), yet the ranking of substance permeation through the three tested RHE models and the pig skin reflected the permeation through human epidermis. In addition, both infinite-dose and finite-dose experiments are feasible with RHE models. The RHE models did not show the expected significantly better reproducibility, as compared to excised skin, despite a

The full list of authors is: Monika Schäfer-Korting, Udo Bock, Walter Diembeck, Hans-Jürgen Düsing, Armin Gamer, Eleonore Haltner-Ukomadu, Christine Hoffmann, Monika Kaca, Hennie Kamp, Silke Kersen, Manfred Kietzmann, Hans Christian Korting, Hans-Udo Krächter, Claus-Michael Lehr, Manfred Liebsch, Annette Mehling, Christel Müller-Goymann, Frank Netzlaff, Frank Niedorf, Maria K. Rübhelke, Ulrich Schäfer, Elisabeth Schmidt, Sylvia Schreiber, Horst Spielmann, Alexander Vuia and Michaela Weimer.

Notes:

- FRAME (Fund for the Replacement of Animals in Medical Experiments) is a scientific charity established in 1969. Its ultimate aim is the total replacement of animal testing with non-animal alternatives.
- FRAME considers that the current scale of live animal experimentation is unacceptable and should not be allowed to continue.
- FRAME advocates the use of alternative methods, referred to as the Three Rs approach – Replacement, Reduction, Refinement.
- The Three Rs concept embraces the *replacement* of animal procedures with alternative methods, the *reduction* of the number of animals used to an unavoidable minimum, and *refinement* of procedures so that the suffering of any animals necessarily used is minimised.
- FRAME promotes a moderate, but determined, approach by encouraging a realistic consideration of the ethical and scientific issues involved in the use of laboratory animals, and the adoption of the Three Rs strategy.
- ATLA publishes peer-reviewed scientific articles on the latest research relating to the development, validation, introduction and use of alternatives to laboratory animals. It is read in more than 50 countries.
- ATLA has been a leading journal in the field for more than 25 years. It encourages informed debate through its editorials and comment section, and regularly publishes conference proceedings and workshop reports.

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