

## CLINICAL REPORT

# *In vivo* Testing of the Protection Provided by Non-latex Gloves against a 2-Hydroxyethyl Methacrylate-containing Acetone-based Dentin-bonding Product

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**In dentistry, allergic contact dermatitis to acrylates and allergic contact urticaria to latex are important occupational hazards. There is a need to identify non-latex gloves which are suitable for dental work but at the same time provide adequate protection against acrylate monomers. In a previous study, a new open-chamber system was used for testing the *in vivo* protection of 6 different gloves against an acrylate-containing ethanol-based dental adhesive. A nitrile glove gave the best protection among the gloves suitable for dental work. In the present study, the test model was used to investigate the *in vivo* protection of 7 non-latex gloves against a dental bonding product containing 2-hydroxyethyl methacrylate (2-HEMA) in an acetone/water vehicle. Eight 2-HEMA-allergic patients participated. Two neoprene gloves gave the best protection. The protection of the poorest glove was comparable to that of the positive control (no glove). The study produced *in vivo* data useful in the implementation of individual preventative measures against contact allergy to acrylates. Key words: protective gloves; occupational; contact allergy; dental; acrylates; 2-hydroxyethyl methacrylate; prevention.**

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Dentin-bonding systems contain high concentrations of acrylates. Many of the acrylate monomers are potent sensitizers (1, 2). Dental personnel work daily with uncured acrylates, with a risk of contamination of gloves as well as of unprotected skin. The sensitized patient may develop long-standing eczema, especially on the fingertips, with symptoms including hyperkeratotic, scaling skin with painful fissures, poor sensibility and, in some cases, paresthesias (1). The clinical picture is not always suggestive of allergic contact dermatitis. The condition may result in long periods of sick leave, and some patients have to leave their occupation permanently. Among healthcare personnel, e.g. in dentistry, allergic contact urticaria to latex is another important occupational skin disease. In addition, latex allergy is frequently associated with allergic hand eczema (3).

Commonly used latex and vinyl gloves have been shown to give poor protection against acrylates in clinical practice and in *in vitro* permeation studies (4–8). One *in vivo* study, using 48 h occlusive patch testing with a diluted acrylate-containing product, gave similar results (9). These results were confirmed

in an *in vivo* study, using a new open-chamber system (10), testing the protection provided by 6 different gloves against a commonly used ethanol-based dental adhesive containing the potent sensitizers 2-hydroxyethyl methacrylate (2-HEMA) and triethylene glycol dimethacrylate (TREGDMA) (11). The study also confirmed the better protective capacity of nitrile gloves (6, 8, 9); however, there are still insufficient clinical data concerning the use of thin nitrile gloves in dentistry. An additional and important drawback of latex gloves is the risk of developing allergic contact urticaria from latex proteins (3).

The aim of the present study was to use the standardized open-chamber system (10) for testing the protective efficacy *in vivo* of 7 latex-free synthetic gloves against a commonly used acetone/water-based dental-bonding product containing 2-HEMA on 8 patients with known contact allergy to 2-HEMA. For each glove, the adhesive was applied for periods of 7.5, 15 and 30 min. For comparison, and as a positive control, unprotected skin (no glove) was provoked with the acrylate product for 7.5 min. In the validation analysis, the obtained *in vivo* data were compared with data from previous studies (4–9, 11).

## MATERIAL AND METHODS

A total of 11 patients with previous patch test-verified contact allergy to 2-HEMA were tested. Three of these patients were excluded because of negative reactions to the positive control (no glove) and in the glove testing. Thus, 8 patients (7 women and 1 man; age 44–65 years; median 54 years) were included in the study. All patients had additional acrylate allergies (Table I). Seven of the patients worked, or had worked, in dentistry. In one patient (H) the source of sensitization was acrylate-containing artificial nails. The study was approved by the Regional Ethics Committees for Human Research, Linköping University Hospital and Medical Faculty, Malmö University Hospital, Sweden.

### Test product and gloves

A common dentin-bonding system available on the Swedish market was used as the test product. The bonding product contains 39.1% (w/w) 2-HEMA in a vehicle consisting of equal amounts of acetone and water (data from the manufacturer). The protective efficacy of 7 different gloves (Table II) against the undiluted product, as used in dental practice, was tested on each of the 8 patients. The gloves were chosen to represent different non-latex gloves currently in use (or potentially of use) in dentistry.

### Testing procedure

Samples taken from the palms of each of the 7 gloves were placed in triplicate on the skin of the back of the trunk, using an open-chamber system for glove testing (10). A 50 µl sample of the undiluted liquid bonding system, as used commercially, was applied in the chambers. Three exposure times (7.5, 15 and 30 min) for each glove were chosen

Table I. Data on the 2-HEMA-allergic patients ( $n=8$ ) participating in the study. Patients A, B, D, E, F and G were tested with the acrylates in the dental screening series (Chemotechnique Diagnostics AB, Malmö, Sweden). Patients C and H were tested with a number of additional acrylates, the Table showing those giving positive reactions

Patient	Age (years)	Sex	Occupation when tested	Acrylates giving patch test-verified allergies
A	53	F	Dentist	MMA, TREGDMA, UDMA, EGDMA, BUDMA, DMAEMA, THFMA
B	44	F	Dental nurse	EGDMA
C	63	M	Dental technician	MMA, TREGDMA, EGDMA, 2-HPMA
D	60	F	Dental nurse	MMA, TREGDMA, EGDMA, DMAEMA, THFMA
E	65	F	Dental nurse	EGDMA
F	49	F	Dental nurse	MMA, TREGDMA, EGDMA, BUDMA
G	49	F	Dental nurse	EGDMA
H	55	F	Hairdresser	MMA, TREGDMA, EGDMA, BUDMA, DMAEMA, HDDA, THFMA, BMA

MMA = methyl methacrylate; TREGDMA = triethylene glycol dimethacrylate; UDMA = urethane dimethacrylate; EGDMA = ethylene glycol dimethacrylate; BUDMA = 1,4-butanediol dimethacrylate; 2-HEMA = 2-hydroxyethyl methacrylate; DMAEMA = N, N-dimethylaminoethyl methacrylate; HDDA = 1,6-hexanediol diacrylate; THFMA = tetrahydrofurfuryl methacrylate; BMA = N-butyl methacrylate; 2-HPMA = 2-hydroxypropyl methacrylate.

based on field studies in dental practice showing that 30 min is a maximal time period, i.e. one that is rarely exceeded without changing gloves. The skin test surfaces were left unwashed immediately after the testing but the patients were allowed to take a shower later the same day according to their own habits. One test position was left uncovered (chamber without glove), as a positive control. The exposure time of the control was 7.5 min, i.e. the same time as the shortest application time for glove testing. The control area was wiped immediately after testing. In the test series of 8 patients, the test plates were shifted to ensure that each glove and control were tested in each of the 8 test positions.

To establish the patients' present reactivity, a serial dilution patch test with the bonding (in acetone/water 1/3 w/w) corresponding to 2%, 0.63%, 0.2%, 0.063%, 0.02%, 0.0063%, 0.002%, 0.00063%, 0.0002% and 0.000063% w/v 2-HEMA concentrations was performed. Thus, the strongest concentration of 2-HEMA in the dilution series was the same as in the (Meth) Acrylate series (MA-1000; Chemotechnique Diagnostics, Malmö, Sweden). Dilution samples (20  $\mu$ l) were applied in van der Bend chambers on the lateral aspect of the upper right arm for 48 h. Visual readings of all test reactions according to the International Contact Dermatitis Research Group guidelines (12) were performed on days 3 and 7.

#### Statistics

Fisher's exact test was used in the statistical evaluation. The program StatXact (Cytel Software Corporation, Cambridge, MA) was used in the calculations, which were based on the number of positive reactions for each glove. Overall statistical analyses of test results were performed separately for each application time (7.5, 15 and 30 min), testing the hypothesis that the numbers of positive reactions for each glove were equal.

## RESULTS

Serial dilution testing with the bonding showed positive reactions to concentrations as low as 0.63% (w/v) 2-HEMA in all 8 patients. Seven of the patients reacted to 0.2% 2-HEMA, 2 reacted to 0.063% 2-HEMA and 1 to 0.02% 2-HEMA.

Glove testing took approximately 1 h for each patient, and was well tolerated. The results are presented in Fig. 1. The best protection was obtained for the 2 neoprene gloves: DermaPrene<sup>®</sup> DermaShield and Biogel Neotech<sup>®</sup>. The Tactylon<sup>®</sup>, N-dex<sup>®</sup>, Elastyren<sup>®</sup> and Medett<sup>®</sup> Super Strong gloves gave poorer protection, all showing similar results. The Medett<sup>®</sup> Super Sensi Touch glove gave very poor protection against the bonding product, the results being comparable with those of the positive control (no glove). The overall statistical analysis indicated differences between the gloves:  $p=0.03$  for 30 min application,  $p=0.003$  for 15 min application and  $p=0.004$  for 7.5 min application. Owing to the small sample size and the problem of multiple comparison according to Bonferroni no paired comparisons between gloves were performed (13). The differences between the gloves were more pronounced if the degree of reactions (scoring) was considered, although this was not suitable for statistical analysis. A dose-response relationship was observed between different application times of the acrylate product and the number of reactions. All patients showed a positive reaction on unprotected skin provoked with the adhesive for 7.5 min and followed by dry wiping.

Table II. Manufacturers' data for the gloves tested in this study

Glove	Manufacturer	Material	Single-wall thickness (mm)
Elastyren <sup>®</sup>	ECI Medical Technologies Inc., Canada	Styrene-ethylene-butadiene triblock copolymer (patented)	0.25 (fingertip); 0.23 (palm)
Tactylon <sup>™</sup>	Tactyl Technologies, Inc., USA	Styrene-butadiene copolymer	0.1
N-dex <sup>®</sup>	Best Manufacturing Company, USA	Nitrile (acrylic nitrile/butadiene)	0.1
DermaPrene <sup>®</sup> DermaShield	Ansell Medical, Malaysia	Neoprene (polychloprene)	0.18 (palm); 0.20 (fingertip)
Biogel <sup>®</sup> Neotech	Regent, UK	Synthetic elastomer (polychloprene) (DuPont)	0.19 (palm); 0.19 (fingertip)
Medett <sup>®</sup> Super Strong	Medisp, Portugal	Polyethylene, copolymer plastic	0.05
Medett <sup>®</sup> Super Sensi Touch	Medisp, Portugal	Polythene, copolymer plastic	0.03

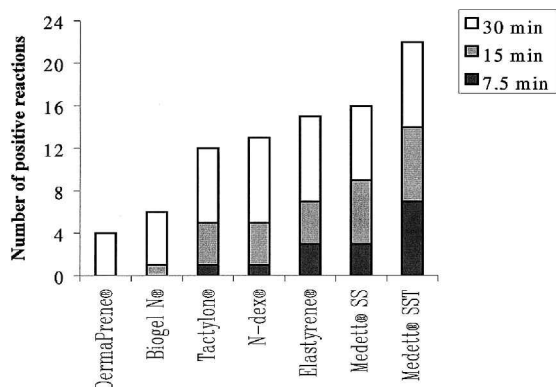


Fig. 1. Results of glove testing. The strongest reaction for the two readings is shown. The maximum possible number of positive reactions for each glove is 24 (3 application times  $\times$  8 patients).

## DISCUSSION

Among dental personnel, allergic contact dermatitis to acrylates and allergic contact urticaria to latex are two major occupational hazards. There is thus a need to identify *in vivo* gloves, preferably non-latex, which are suitable for dental work and at the same time adequately protective against acrylate monomers. In the present study, an open-chamber system was used for *in vivo* testing of the protection provided by 7 different non-latex gloves against a commonly used dental-bonding product containing the strong sensitizer 2-HEMA. Eight patients with known contact allergy to 2-HEMA were tested in an identical way, based on preparatory field studies in dental practice.

Differences in the protective efficacy of the various gloves could be demonstrated. The best protection was obtained by the 2 neoprene gloves: DermaPrene<sup>®</sup> DermaShield and Biogel Neotech<sup>®</sup>. These are both sterilized surgeon's gloves in the higher price range. Among the other gloves in the middle range, giving less protection, the N-dex<sup>®</sup> glove is frequently used in dental work. It is commercially available in non-sterile big packages at a comparably low price. Tactylon<sup>®</sup> and Elastyren<sup>®</sup> are sterilized surgeon's gloves in the same price range as the neoprene gloves. The Medett<sup>®</sup> gloves are made of thin, non-elastic materials and are intended for use as inner gloves, e.g. for latex-allergic users. As the purpose of the Medett<sup>®</sup> gloves is different from that of the other gloves tested, a direct comparison of protective results should be made with care. A thin inner glove made of polythene may be of protective value as a complement to a more resilient outer glove of, for example, neoprene or nitrile. This was shown in a recent *in vitro* study by Mäkelä et al. (8). That study also confirmed the better protective capacity of Biogel Neotech<sup>®</sup> vs. N-dex<sup>®</sup> against a mixture of 2-HEMA (50%) and TREGDMA (50%).

A dose-response relationship was observed for different application times of the acrylate product; as expected, longer application times of the adhesive gave both a greater number of reactions and stronger reactions.

All patients showed a positive reaction on unprotected skin provoked with the adhesive for 7.5 min followed by dry wiping. The Medett<sup>®</sup> Super Sensi Touch glove gave results comparable with those of no glove at all. Based on this finding and on a previous study (11), a glove giving poor

protection might be as bad or even worse than no glove at all. The occlusive effect of the glove probably contributes to this. It is recommended that contaminated skin should be washed with soap and water as soon as possible after use (11, 14).

The study produced *in vivo* data useful in the implementation of individual preventative measures against contact allergy to acrylates in dentistry. At present, a test series using other adhesives and gloves is being carried out, the results of which will be presented at a later date.

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