

Allergic Contact Dermatitis of Styrenic Thermoplastic Elastomers and Latex Sheets in Humans

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Objective: to compare the incidence of allergic contact dermatitis between styrenic thermoplastic elastomers (S-TPEs) and latex sheets in patients scheduled for endodontic treatment by patch testing.

Material and method: A total of 100 subjects were tested with the substances in S-TPEs group (S-TPEs sheet, Styrene isoprene styrene-SIS, Styrene butylene styrene-SBS, dye powder) and latex group (latex sheet, thiuram-mix, mercapto-mix, mercaptobenzothiazole, zinc diethyldithiocarbamate-ZDEC, zinc dibutyldithiocarbamate-ZDBC). The reactions were evaluated at 48 and 96 hours after application of the test materials to the skin of the upper arm.

Results: For the S-TPEs group, none of the subjects showed positive allergic reactions to S-TPEs sheet and its compositions at 48 and 96 hours. For the latex group, seven subjects (7%) had positive allergic reactions to latex sheet at 48 hours, and one (1%) at 96 hours. One subject (1%) showed reactions to thiuram-mix, mercapto-mix, and mercaptobenzothiazole at 48 and 96 hours, one subject (1%) reacted to thiuram-mix, and one subject (1%) reacted to ZDEC at 96 hours. Upon comparison between positive allergic reactions of S-TPEs and latex sheets, a significant difference was demonstrated at 48 hours ($p < 0.05$), but not at 96 hours.

Conclusion: S-TPEs sheet did not cause allergic contact dermatitis, while latex sheet did in a number of subjects.

Keywords: S-TPEs, SIS, SBS, latex, patch test, allergic contact dermatitis

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Introduction

A rubber dam has been widely used and accepted to facilitate and increase efficiency of dental treatment, especially for infection control in endodontic therapy. Moreover, the use of rubber dam is recognized as an effective method to prevent aspiration of instruments or chemical irritants during the treatment [1-3]. Rubber dam is

most commonly made from natural rubber latex [4]. Latex has become a ubiquitous part of life and is the main constituent of over 40,000 medical and dental products [5]. The prevalence of latex allergic reaction has rapidly increased, followed by the increase of rubber latex use [5,6-7]. The prevalence of latex allergy has been reported at 2-17% in the premeditated communities and up to 69% in high risk groups [5,7-13]. The prevalence

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of allergic contact dermatitis from latex is reported to be between 1-6.6% [14-18]. Reactions to latex can be classified by the types of immune reaction: type I (immediate hypersensitivity) and type IV (delayed hypersensitivity or allergic contact dermatitis). Type IV reaction is mostly caused by accelerators (such as thiurams, carbamates, and benzothiazoles) or antioxidants (such as monobenzylether of hydroquinone and phenyl-B-methylamine), which are added in order to cure natural rubber [5,7,19-22]. In recent years, allergic reactions to latex rubber dams have been increasing in dental practice [23-26].

For these reasons, synthetic rubber materials have been proposed as an alternative choice for individuals who have a history of latex allergy. There are many kinds of these materials available, such as nitril, polyethelene, polyvinylchloride, silicone, and elastomer. However, some of these have been reported to cause a delayed type of hypersensitivity (type IV), primarily those which do contain accelerators. Therefore, dental patients still have certain allergic risk to these materials [27-29].

Styrenic thermoplastic elastomer (S-TPE) is a class of thermoplastic elastomers consisting of styrenic block copolymers. Recently, a new formula of S-TPEs has been proposed. The physical properties of S-TPE sheet are suitable for dental rubber dam because they have elastic attributes like those of rubber, and S-TPEs are easy to shape, similar to thermoplastic, without vulcanization process [30,31]. In a previous study, evaluating the mechanical properties of rubber dam sheets showed that S-TPEs sheets have greater tensile strength and tear resistance than those of a non-latex rubber dam sheets (Flexi Dam[®]), but less than those of natural rubber latex sheets (Hygenic[®]) [32]. These results indicated that S-TPEs sheet may be suitable to use as dental dam. In addition, S-TPEs are composed of pure monomers that can be controlled and precisely selected for a specific formula and polymerization

form without accelerators [33]. S-TPEs are new material, possibly never have been reported or studied about allergic reaction. Therefore, allergic contact dermatitis testing needs to be performed before it is used in humans.

The aim of this study was to compare the incidence of allergic contact dermatitis of S-TPEs and latex sheets in patients scheduled for endodontic treatment by patch testing.

Materials and methods

1. Participants

A total of 100 subjects who were referred for an endodontic treatment signed informed consent form prior to participation in the study. Exclusion criteria comprised of children (age below 15 years old), pregnant women, those who are taking drugs such as immunosuppressive, systemic corticosteroid > 20 mg/day within one month or mast cell stabilizers, those with acute dermatitis at the test site, and those with a history of latex allergy or severe drug allergy such as Steven Johnson's syndrome.

2. Procedures

All subjects were patch tested with two groups of allergens. The first group was the S-TPEs group: S-TPEs sheet and its compositions i.e. styrene isoprene styrene-SIS, styrene butylene styrene-SBS, and dye powder). The second group was the latex group: latex rubber dam sheet (Hygenic[®] Coltene/Whaledent Inc., Ohio, USA.), and standard accelerators i.e. thiuram mix, mercaptomix, mercaptobenzothiazole, zinc dithyldithiocarbamate-ZDEC, zinc dibutyldithiocarbamate-ZDBC. Five-millimeter square sheets of S-TPEs, SIS, SBS, and latex were eluted in 0.9% sterile physiological saline solution for 30 minutes. Dye powder and ZDEC were dispersed in white petrolatum to 3% and 1% concentration respectively. The accelerators were

from the standard and additional series of patch test allergens (Chemotechnique Diagnostics Inc., Modemgatan 9, 23539 Vellinge, Sweden). Each was placed in a chamber of the Finn Chamber[®] (Alpharma Inc., Vennasla, Norway) (Figure 1a). The Finn Chamber[®] was applied to the skin of an upper arm (Figure 1b). The patch tests were evaluated at 48 hours and 96 hours.

In this experiment, interpreting the results was performed by 2 dermatologists who were blinded about the test materials. Interpreting criteria was based on the scoring system of the International Contact Dermatitis Research Group (ICDRG).

The scoring system of ICDRG (Figure 2):

- Negative reaction
- + Positive reaction
 - +1 representing erythema, infiltration, possibly papules
 - +2 representing erythema, infiltration, papules and vesicles
 - +3 representing a very severe reaction, intense erythema, infiltration and coalescing vesicles

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The results were evaluated by descriptive analysis and McNemar test at 95% confidence interval at $P < 0.05$.

Results

Among the 100 subjects, 72 were females and 28 were males. For the S-TPEs group, none of the subjects (0%) showed positive allergic reaction to S-TPEs sheet and its compositions (SIS, SBS, dyed powder) at 48 hours and 96 hours. However, three subjects (3%) showed erythematous reaction to SIS, one subject (1%) to SBS, and two subjects (2%) to both SBS and SIS at 48 hours.

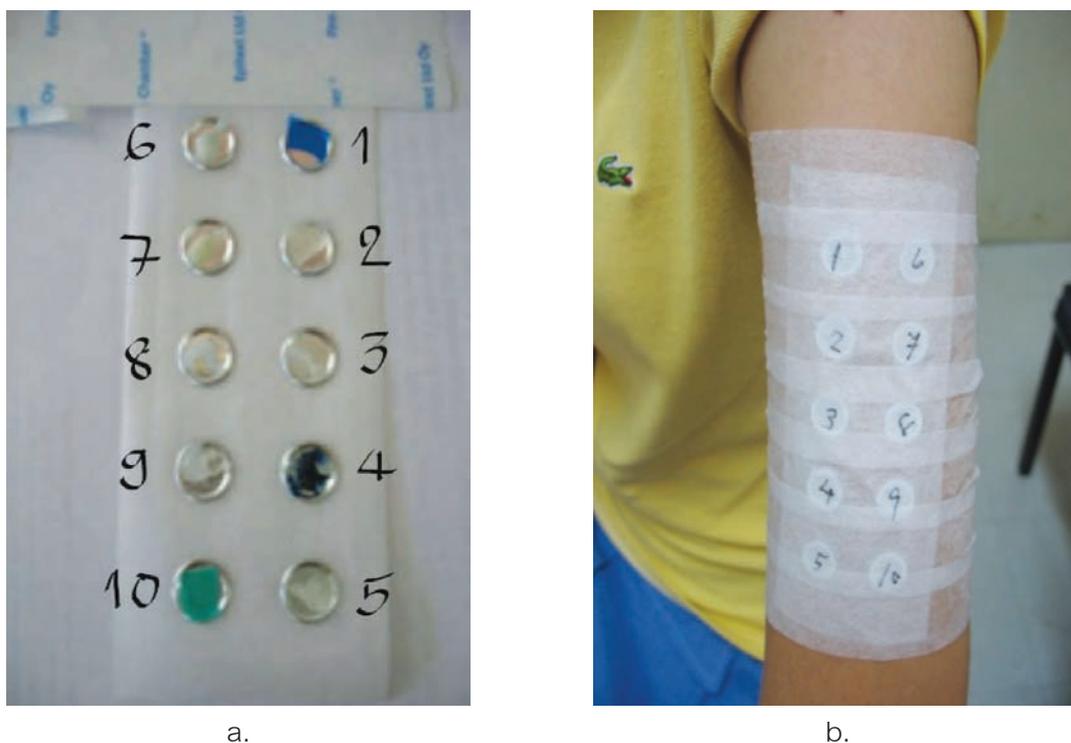


Figure 1. Each allergen was applied to each chamber of Finn chamber[®] tape and then it was applied to the skin of an upper arm (1-4 represent the S-TPE group and 5-10 represent the latex group).

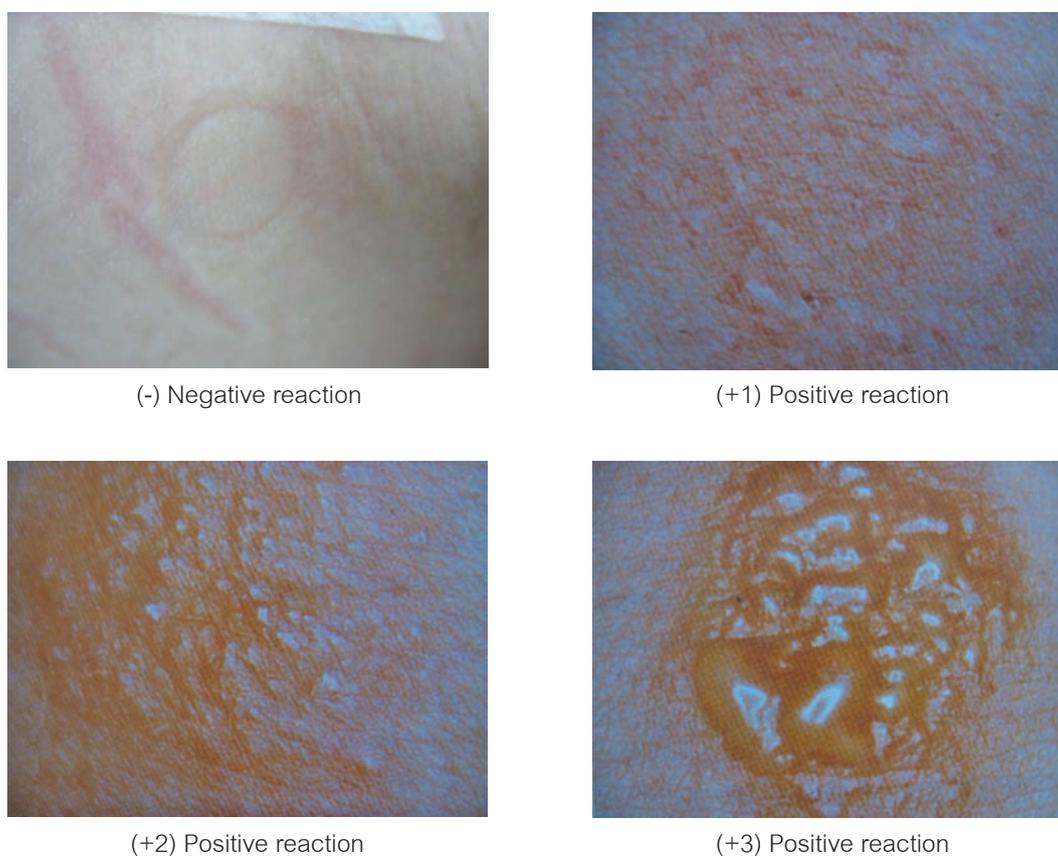


Figure 2. The scoring system of IDCRG

For the latex group, there were seven subjects (7%) that had positive allergic reaction (+1) to latex sheet at 48 hours, but only one of seven subjects (1%) had positive allergic reaction (+1) at 96 hours. There were three subjects who had positive allergic reaction (+1) to accelerators. One subject (1%) showed positive allergic reactions to thiuram mix, mercapto mix, and mercaptobenzothiazole at 48 hours and 96 hours. One subject (1%) showed positive allergic reaction to thiuram mix, and one subject (1%) showed positive allergic reaction to ZDEC at 96 hours.

Notably none of subjects had positive reaction to both allergen groups of S-TPEs and latex.

McNemar test showed a significant difference between the positive allergic reaction of S-TPEs and latex sheet at 48 hours ($P=0.016$), but not at 96 hours ($P=1$).

Discussion

Not a single one of the 100 subjects had allergic contact dermatitis to S-TPE sheet and its compositions. Only 3% of subjects showed erythematous reaction, which is not a true allergy to SIS and SBS, whereas seven subjects had allergic contact dermatitis to latex sheet (Hygenic[®]). The reasons for no positive reaction found in the S-TPE group were possibly due to the pure monomer composition of S-TPEs and the absence of accelerators used in the manufacturing process.

The S-TPE sheet is composed of SIS and SBS. Both are tri-block copolymer of which polystyrene sequences are at the ends of the chain with either a polybutadiene or a polyisoprene sequence at the center. Such structure can help classify SBS and SIS into genre of thermoplastic

elastomers; the thermoplastic part or hard segment is from polystyrene sequence while the sequence of polybutadiene or polyisoprene expressed the elastic part or soft segment. In the hard segment, the polystyrene domain acts as a multifunctional junction point crossing to the elastic phase [30,34,35]. S-TPEs were synthesized from two types of monomer in the inert and purified system [30]. However, there is no report of allergy concerns from these two components of S-TPEs.

S-TPE products can be produced by thermoplastic processing technologies, such as film casting, extrusion, and mold injection. Moreover, they do not need any further curing agent or accelerators in order to produce final products [30,31]. This is different from latex and some synthetic rubber which requires several chemical substances in the manufacturing process, such as ammonia, accelerator, and antioxidant [5,7,27,36], recently reported to cause allergic reaction. The advantages of S-TPEs are that it is not complex to process, has high elongation, and low percentage of tension set. Moreover, its structure consists of aromatic rings, which make it stronger and more resistant to deteriorate than natural latex [30,34,35].

Regarding allergic contact dermatitis from rubber accelerators, our study found that three subjects (3%) were allergic to accelerators of which one of these subjects had a history of rash and itching when he wore rubber shoes. This group of subjects will be a good candidate for S-TPEs use. Many studies have reported that thiuram mix, mercapto mix, and mercaptobenzothiazole are the accelerators most often used in latex processing [5,7,19-22]. These three subjects, who had positive reactions to rubber accelerators, did not have positive reactions to latex sheets. The reasons may be due either to these accelerators were not used in the production of Hygenic[®] rubber dam, or they were used but in small amounts so that the accelerators release was not enough to cause allergic reaction. Furthermore, the vulcanization procedure possibly was changed enough of the

accelerator's properties, such that they lost their potential to cause allergic contact dermatitis [19,21].

Considering the allergic contact dermatitis of the latex group, the subjects who had positive allergic reaction to latex sheet, but not to any accelerators, may be due to the accelerators used for Hygenic[®] rubber dam were different from those in this study. For proprietary reasons, detailed information of the composition of Hygenic[®] has not been disclosed by the manufacturers.

The percentages of positive allergic reaction to latex from this study (7%) indicate that latex can cause allergic contact dermatitis. These results are relevant to other reported prevalence of allergic contact dermatitis to latex in the general population [5,9-11,16]. For instance, Summer et al., in a multicenter study, reported that 1% of the 2,738 volunteers had positive patch tests [17]. Miris et al., found a higher incidence that 16.7% of the 512 volunteers had allergic contact dermatitis to NRL gloves and rubber additives [37]. The higher proportion of the latter study was possibly due to the fact that subjects were health care workers with glove-related symptoms which constitute a high risk group [37].

The results in this study showed that the S-TPEs did not cause allergic contact dermatitis. However is important though to note that this study has a limited sample size which may not entirely represent overall population. Additionally, the subjects in this study were most likely exposed to S-TPEs materials for the first time in their lives, and this might skew result because of inactiveness of symptoms. A further study should be designed with the second exposure and the longer period follow-up to collect the data of dental patients with the use of the S-TPEs rubber dams.

In conclusion, Within the limitation of this study, S-TPE sheet did not cause allergic contact dermatitis while latex sheet did. S-TPE is a promising alternative to latex, especially for persons with history of latex allergy.

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