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Biological evaluation of a polyvinyl siloxane impression material

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Summary *Objectives*. The aim of this study was to determine the irritant properties of a new polyvinyl siloxane impression material (Ghenesil™, Lascod-Italy) after single application to intact skin of the rabbit.

Methods. The material was evaluated for primary skin irritation according to the UNI EN ISO 10993-10:1996 using three healthy male New Zealand White rabbits. The back of the animals was clipped free of fur and divided into four sites with the same area 24 h before application of the sample. The material was applied to only two sites; the other two were used as controls. All the sites were covered by gauze and the back of the rabbit was wrapped with a non-occlusive bandage. After 4 h, the bandage and the test material were removed; 1 h later the sites were examined for skin irritation and the observation was repeated after 24, 48 and 72 h.

The Score of Primary Irritation (SPI) was calculated for each animal and the Primary Irritation Index (PII) was calculated as the arithmetical mean of SPI values.

Results. The PII of the test material resulted 0.06.

Significance. Based on present results, it can be concluded that the primary skin irritation of the polyvinyl siloxane impression material tested can be considered negligible.

Introduction

Polyvinyl siloxane impression materials are widely used in dentistry, due to their high accuracy and high dimensional stability [1]. Biocompatibility testing of a material is an essential step towards the acceptance of the material, besides testing its physical properties [2]. Several investigations have described the important qualities of addition silicones, but the available dental literature reveals a lack of information on the biocompatibility of polyvinyl siloxane impression materials [3].

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Currently, most scientists agree that no material is truly inert in the body [4]. Dental impression compounds have constituents that are biologically active, even in the set stage, and have the potential to elicit adverse biological reactions [5].

Most of dental impression materials are mixed just before use to allow setting in contact with oral tissues. In this condition, the materials are apt to be the most irritant, toxic or able to sensitize tissues.

The probability of irritant, allergic, or toxic reactions from these materials or their components is low, nevertheless studies show that these reactions are possible [6,7]. Moreover, all the rubber impression materials, such as polyether, polysulfide, silicone and reversible hydrocolloids, exhibit some degree of toxicity in cell cultures [5]. Despite extensive use, there are very few reports of adverse reactions caused by dental impression compounds unless pieces of material have been retained in oral tissues over a long time.

Clinical reports have indicated problems of allergic contact stomatitis secondary to polyether rubber for dental impression and of foreign body response to retained polyether and polysulphide rubber impression materials [8–11]. Moreover, jatrogenic foreign body reactions associated with addition-type silicone impression materials have been described in several case reports [12,13].

The purpose of the present investigation was to determine the irritant properties of a polyvinyl siloxane impression material after single application to intact skin of the rabbit [14,15]. The Primary Irritation Index (PII) of addition-type silicone elastomers has never been described before in dental literature.

Materials and methods

The addition-type silicone Ghenesil™ (regular body) was supplied by Lascod S.p.A. (Sesto Fiorentino-Firenze, Italy). The material was evaluated for primary skin irritation according to the guidelines of the UNI EN ISO 10993-10:1996. The impression material is presented in the form of two pastes (a base and an accelerator) autodispensed from a dual cartridge, and mixed in equal quantities before use. The base material contains a polymethyl hydrogen siloxane copolymer, which is a moderately low molecular mass polymer with silane terminal groups. The accelerator material contains the vinyl-terminated polydimethyl siloxane. This too is a moderately low molecular mass polymer, but has vinyl terminal groups. The accelerator material also contains chloroplatinic acid as a homogeneous metal complex catalyst. Non-ionic surfactants of nonylphenoxypolyethanol homologues as wetting agent and palladium as hydrogen absorber are added. The base and the accelerator pastes also contain colouring agents and fillers as silanated amorphous silica.

Three healthy male New Zealand White rabbits were purchased from Harlan (S. Pietro al Natisone-Udine, Italy) and acclimated to the laboratory. The rabbits, identified by tags, were individually housed and received Morini diet G.L.P. MIL feed on a daily basis; tap water was available ad libitum. Animal husbandry was conducted in accordance with the European guidelines.

A preliminary evaluation was conducted using one rabbit, while the final test involved the other two. The back of the animals was clipped free of fur with an electric clipper 24 h before application of the sample. For the experiment, the clipped areas of skin of each rabbit were divided into four sites with the same area (20×20 mm). The silicone compound was mixed according to the manufacturer's directions and immediately applied to two sites with a thickness of 5 mm; the other two sites were used as a control (no material present). Both the treated and the control sites were covered by gauze and the back of the rabbit was wrapped with a non-occlusive bandage, thereafter the animals were returned to their cages. After 4 h, the bandage and the test material were removed and 1 h later the sites were examined for skin irritation. Observation of the sites with material and control was repeated after 24, 48 and 72 h. The reaction, defined as erythema or edema, was evaluated according to the score of the skin reactions reported in Table 1.

Table 1 Classification system for skin reactions.

Reaction	Score
Erythema	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to eschar formation	4
Edema	
No edema	0
Very slight edema (barely perceptible)	1
Well-defined edema (edges of the area well defined by definite raising)	2
Moderate edema (raising approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond the area of exposure)	4
Total possible score for primary irritation	8

Table 2 Response categories of irritation in rabbit.

Category	PII
Negligible	0-0.4
Slight irritation	0.5-1.9
Moderate irritation	2-4.9
Severe irritation	5-8

The Score of Primary Irritation (SPI) was calculated for each rabbit as the difference between the sum of the scores for erythema and edema at 24, 48 and 72 h divided by the number of the observations for the treated sites and the sum of the scores for erythema and edema at 24, 48 and 72 h divided by the number of the observations for the control sites (see formula below). The PII was calculated as the arithmetical mean of the SPI values of the three animals. The evaluation of PII was performed according to the categories showed in Table 2.

Formula used to calculate the SPI

$$SPI = \left[\frac{\sum(Er+Ed)_{24h}+(Er+Ed)_{48h}+(Er+Ed)_{72h}}{No.\,of\,observations}\right]_T - \left[\frac{\sum(Er+Ed)_{24h}+(Er+Ed)_{48h}+(Er+Ed)_{72h}}{No.\,of\,observations}\right]_C$$

T, treated; C, control; Er, erythema; Ed, edema.

Results

In the preliminary experiment performed in one rabbit, a very slight erythema was observed after 24 h in one of two sites treated with the sample. In the other two animals, erythema or edema was not present after 24, 48 and 72 h in both sample and control sites. Individual results of skin irritation scores are reported in Table 3.

The PII of the test material was 0.06.

Discussion

Addition-type silicones are considered as medical devices, and assessment of irritation is a significant step in the evaluation of their biocompatibility. Researchers and regulatory agencies recognize that in vitro and animal tests play an important role in the biologic evaluation of dental materials [4,16-18].

Based on the results of this in vivo investigation, the irritant properties of the polyvinyl siloxane impression material, tested after 4 h of direct contact to rabbit skin, can be considered irrelevant in view of clinical applications. Moreover, the present investigation showed no significant evidence that the addition-type silicone tested can cause diffuse inflammation or local severe skin reaction.

No information was found in the available literature relative to the PII of addition-type silicone impression material using animal tests, for this reason it is not possible to relate this investigation to similar relevant studies.

Previous biological evaluations of polivinyl siloxane for dental impression have been performed only in cell cultures using cytotoxicity tests. These in vitro studies have suggested that the toxicity of silicone compounds used for dental impression varies with the chemical composition or the type of material. It was found that condensation-type silicones are extremely toxic, probably due to the ethyl- or methyl-alcohol released during setting, while addition-type silicones are quite harmless [6]. Sydiskis and Gerhard demonstrated that after 3 days of incubation the mixed addition-type silicone impression material has some degree of toxicity in cell cultures [5]. Of interest, the results also showed that the base components produced a relatively large response index while the catalyst produced no cytotoxic effects. Otherwise, Ciapetti and Coll showed that addition-type silicones are almost

Table 3 Score of erythema and edema after application of test material.

Animal (rabbit)		24 h		48 h		72 h		
		T[a]	C[b]	T	C	T	C	SPI
1	Erythema	0-1	0-0	0-0	0-0	0-0	0-0	1/6-0/6=0.17
	Edema	0-0	0-0	0-0	0-0	0-0	0-0	
2	Erythema	0-0	0-0	0-0	0-0	0-0	0-0	0/6-0/6=0
	Edema	0-0	0-0	0-0	0-0	0-0	0-0	
3	Erythema	0-0	0-0	0-0	0-0	0-0	0-0	0/6-0/6=0
	Edema	0-0	0-0	0-0	0-0	0-0	0-0	

[a] Treated site.
[b] Control site.

always non-toxic even when tested in exaggerated culture conditions (i.e. prolonged exposure of cells to the materials) [7]. In this context, several studies have shown that exaggerated exposure during in vitro tests of toxicity may sometimes be inappropriate as there is the risk of rejecting potentially useful materials that could have successful clinical applications.

Any direct comparison or ranking between different biocompatibility tests on dental impression compounds would be inappropriate, therefore caution is warranted in attempting to correlate cell culture tests with animal experiments. The material tested in this investigation is in clinical use. According to our data, the PII of addition-type silicone impression material tested is negligible, but our results also show that the potential of irritation does exist. We suggest that clinical trials and careful follow-up of patients may be useful to investigate a specific biological response observed during the clinical experience of the impression material.

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