HISTOPATHOLOGICAL EXAMINATION OF NEWLY-DEVELOPED ADHESIVE SILICONE DENTURE RELINING MATERIAL

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Abstract
We aimed to evaluate the subcutaneous tissue reaction to a newly developed adhesive silicone denture relining material, SG, (Neo Dental Chemical Products Co., Ltd. Tokyo, Japan). We embedded the experimental material SG and another existing control material, Roeko Seal (RS), in the dorsal area of 22 male ddY mice. One week and 12 weeks after the embedding, the tissues surrounding the embedded materials were removed and a histopathological examination was performed. The results demonstrate that the basic histopathological aspects are the formation of granulation tissue and the change of the tissue to fibrous capsule over time. The results suggest that the newly-developed SG is safe as compared with the control RS, whose composition is similar.

Key words: Tissue reaction; Histopathological evaluation; Silicone-containing material

INTRODUCTION
Silicone bio-materials are inert, synthetic chemical compounds having a wide variety of forms, as well as various medical and dental uses. Chemically, silicones are polymers that include silicon together with carbon, hydrogen, oxygen, and sometimes other chemical elements. Some common forms include silicone oil, silicone grease, silicone rubber, and silicone resin. Heat-resistant and rubber-like silicone materials are commonly used in breast implants, cookware, medical applications, sealants, adhesives, lubricants and insulation.

We have developed a adhesive silicone denture relining material SG and conducted a histopathological evaluation. Because some endodontic materials, such as the root canal filling materials Vitapex [1, 2, 3, 4] and Roeko Seal [5, 6, 7, 8, 9] have similar properties, we used Roeko Seal for use as a control material.

Table 1. Main Components of Experimental and Control Materials.

| Materials  | Main Components                                      |
|------------|------------------------------------------------------|
| Experimental SG | Vinylpolysiloxane, Hydrogenpolysiloxane, Platinum catalyst |
| Control RS | Polydimethylsiloxane, Silicone oil, Paraffin-base oil, Hexachloroplatinic acid, Zirconium dioxide |
At 1 week and 12 weeks after injection, 3 mice from each group were anesthetized with isoflurane and gas-air mixture, and the tissue surrounding the injection sites were excised. The excised tissues were immediately fixed in 4% paraformaldehyde/0.5M phosphate buffered solution, embedded in paraffin, and sections were prepared.

Table 2. Experimental Periods and Number of Animals.

| Periods     | 1 Week | 12 Weeks | Total |
|-------------|--------|----------|-------|
| Experimental SG | 6      | 5        | 11    |
| Control RS   | 5      | 6        | 11    |
| Total        | 11     | 11       | 22    |

Fig. 1. Experimental (SG) specimen. a: 1-week-specimen, x 50; b: 1-week-specimen, x 100; c: 12-week-specimen, x 50; d: 12-week-specimen, x 100.

Fig. 2. Control (RS) specimen. a: 1-week-specimen, x 100; b: 12-week-specimen, x 100.
The tissue sections were stained with hematoxylin and eosin and examined by light microscopy for examination of histopathological changes. We followed the International Organization for Standardization (ISO) guidelines for evaluating the local effects of injection materials [10, 11].

RESULTS

EXPERIMENTAL GROUP: SG

The embedded area was composed of quietly-scattered fibrous tissues. In 1-week specimens, there were thin-layered tissues, which consisted of granulation tissues (Fig. 1-a). This granulation tissue consisted of fibroblasts (Fig. 1-b) that had received some damage and thus had degenerated, resulting in necrosis. The surrounding rose, colored connective tissue showed almost no inflammatory cell infiltration and some scattering of red blood cells. In the 12-week specimens, the encapsulation membrane began reduction of the depth (Fig. 1-c). There was inflammatory cell infiltration, with some enlarged vessels (Fig. 1-d).

CONTROL GROUP: RS

Histopathologically, as observed in 1-week specimens, granulation tissue proliferation was evident in the embedded region of RS. The proliferating granulation tissue consisted of numerous palisading collagen bundles, with almost no inflammatory cell infiltration. Slight infiltration was observed at the surface layer of the proliferating granulation tissues, the region in contact with the embedded material RS (Fig. 2-a). After 12 weeks, the thickness of the proliferated granulation tissues was reduced to thin fibrous tissues. However, there was some inflammatory cell infiltration which appeared in the middle-layered portion, especially evident in the determination edge of the material (Fig. 2-b).

DISCUSSION

There has been considerable literature devoted to examining tissue reactions to biomaterials, especially at the time of development. Our evaluation was made using a comparative histopathological method, with existing materials as controls. We selected the control material RS because the composition and clinical field were nearly the same as for the new-developed SG. We performed our histopathological examinations following the ISO guidelines for evaluating the local effects of injection materials [10, 11].

The results were reported in terms of tissue reactions to the biomaterials. The silicone-containing biomaterials and their biocompatibilities were also investigated. In clinical dentistry, commercially-available silicone-containing materials include Vitapex [1,2,3,4] and Roeko Seal [5, 6, 7, 8, 9]. During present examination, the observation of 1-week specimens showed that a thin layer of necrotic area was formed. However, under the necrotic tissue, there were also numerous fibroblastic tissues. In RS control specimens, tissue reactions to RS included the formation of granulation tissue and a gradual change into fibrous capsules. There were also some inflammatory cells reactions remaining in the 12-week specimens. On the other hand, in the experimental SG-group specimens, there were almost no inflammatory cell infiltrations observed in 12-week specimens. Thus, this histopathological result means the injury irritation of SG is thought to be comparatively weak. Accordingly, we think there are no problems for use inside the human body.

In conclusion, we examined local effects through the subcutaneous tissue reaction to the newly-developed material SG. We used the existing material “Roeko Seal” as a control, and the results demonstrate that the basic histopathological reaction is the formation of fibrous capsule consisting of granulation tissue around the experimental and control embedded materials. Based on the present results, we conclude that the newly-developed SG provides an adequate additional relining material.