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Clinical Report

Clinical Usefulness of “Isolite™ Plus” for Oral Environment of Japanese People

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Abstract

The recent demand for dental devices which are easier to handle and offer higher levels of reliability and safety has led to the development in the US of Isolite™ Plus, a new oral support device. When placed in the oral cavity, Isolite™ Plus enables marking of the surgical field, secures the treatment space, ensures a vacuum, protects the cheek and tongue, assists in opening the mouth, prevents accidental ingestion/aspiration, ensures treatment without contamination and enhances comfort and safety during dental treatment. The present study was carried out to verify whether Isolite™ Plus can fit well in the mouth of Japanese people and to determine whether it performs adequately. Thirty resident dentists were required to wear Isolite™ Plus in their mouth and perform mutual simulation training using an air turbine handpiece. After the training, both subjects playing the role of surgeon and those playing the role of patient were asked to complete questionnaires. On the basis of the results, we discuss the clinical usefulness of Isolite™ Plus in Japanese people. In the present investigation, Isolite™ Plus was rated slightly better by surgeons than by patients. The supportive functions of the device were judged inadequate due to the poor fit of the mouthpiece portion of the device to subjects' mouth. For the distribution of Isolite™ Plus in the Japanese market, the mouthpiece portion of the device should be improved so that it can fit the mouth of Japanese people.

Key words: Oral support device—Isolite™ Plus—Dry-field illuminator—Isolation system—Rubber dam

Introduction

In providing dental treatment, dentists have to perform meticulous techniques under adverse conditions which are characteristically dark, narrow and wet. An illuminator can not provide sufficient light to the treat-

ment site in the oral cavity and tends to create a shadow, possibly resulting in serious oversight. Even if a clear field of view has been obtained, treatment can only be performed in a limited space, and the direction and improper manipulation of instruments may cause damage to the surrounding mucosa or

accidental ingestion or aspiration. Since the humidity and temperature in the oral cavity are higher than those in the dental treatment room, it is difficult to completely exclude moisture from the oral cavity. It is therefore impossible to reproduce the performance of restorative materials^{1,3-5,7)} demonstrated in basic experiments in the oral cavity during procedures such as adhesion and polymerization of restorative materials. Thus, it is currently difficult to perform dental treatment aseptically.

For endodontic treatment and some kinds of restorative treatment, the active use of a rubber dam for moisture exclusion has been recommended. The rubber dam-based moisture exclusion method prevents contamination of saliva, blood from the surrounding mucosa and discharge from the gingival sulcus, facilitates the adhesion and polymerization of restorative materials, and clarifies the surgical field while excluding surrounding mucosal tissue, thereby preventing accidents due to the improper manipulation of instruments. In actual clinical practice, however, we encounter many cases in which the rubber dam-based moisture exclusion method can not be used. The rubber dam method excludes surrounding teeth from the dentist's field of view, making the direction of the dental axis unclear and it difficult to approach the root canal. It can also complicate the matching of the shape and color of tooth crowns.

Isolite™ Plus²⁾, a multi-purpose oral support device (Figs. 1, 2 and 3), has recently been developed in the US and has become available at regular dental clinics. This device, when placed in the region surrounding the treatment site in a patient's oral cavity (Fig. 4) enables marking of the surgical field, secures the treatment space, ensures a vacuum, protects the cheek and tongue, assists in opening the mouth, prevents accidental ingestion/aspiration, and ensures treatment without contamination. These functions ensure patient comfort and safety during dental treatment. No educational or research institute, including dental schools, has yet conducted an adequate clinical evaluation of the ease-of-use, comfort

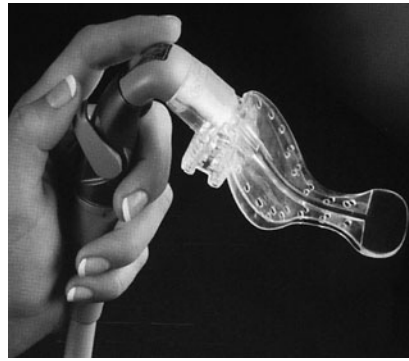


Fig. 1 Oral support device "Isolite™ Plus" control head

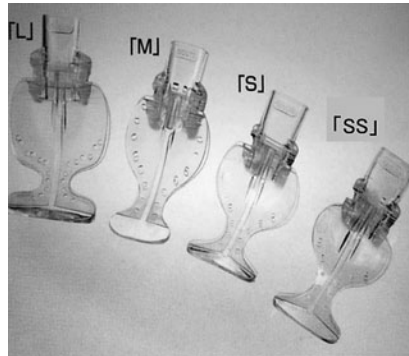


Fig. 2 Oral support device "Isolite™ Plus" mouthpiece size L, M, S, SS 4 types



Fig. 3 Oral support device "Isolite™ Plus" placed in mouth
This device is a Dry-field intra-oral illuminator.

or safety of Isolite™ Plus.

In the present study, we applied Isolite™ Plus for dental treatment in Japanese people

1. Enables marking of surgical field
2. Secures treatment space
3. Ensures vacuum
4. Protects cheek and tongue
5. Assists in opening mouth
6. Prevents accidental ingestion/aspiration
7. Ensures treatment without contamination
8. Ensures comfort and safety during dental treatment

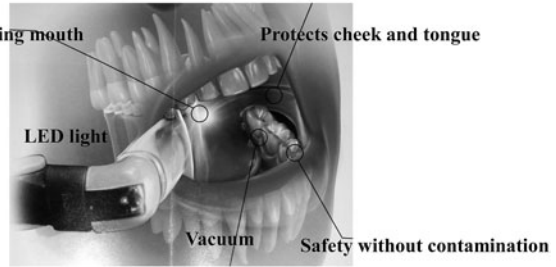


Fig. 4 Functions and structure of oral support device “Isolite™ Plus”

and investigated the veracity of the reputed supportive functions of this device from both the dentists’ (surgeons’) and patients’ viewpoints while identifying problems, with the aim of developing a dental treatment system with higher levels of ease-of-use, comfort and safety.

Methods

The present study was carried out with the approval of the Ethics Committee of Tokyo Dental College (Approval No.184). Thirty volunteer resident dentists in the Department of General Dentistry at Tokyo Dental College Chiba Hospital participated in the study. Informed consent was obtained from all participants who were randomly divided into 15 pairs. Each pair performed mutual practical training in which each took turns playing the role of surgeon and patient. The resident dentists in this study consisted of 18 men and 12 women aged 24–29 years.

Each subject playing the role of surgeon placed the Isolite™ Plus properly into the oral cavity of each subject playing the role of patient. With the intraoral space divided into four blocks, an air turbine handpiece equipped with a dummy bur was placed close to teeth No. 16, 26, 36 and 46 to simulate tooth preparation for a full cast crown. After performing the simulation training, all volunteer subjects were asked to complete two questionnaire forms intended for surgeons and patients

(Tables 1 and 2). Each of the two questionnaires for surgeons and patients had nine questions, and subjects were asked to rate each item in three grades (*i.e.*, acceptable, moderate and unacceptable). For each question, subjects were also asked to specify any particular items or problems they noticed. Overall ratings from the surgeons’ and patients’ viewpoints were made according to a 5-point scoring system with 5 as the highest value and 1 as the lowest.

Results

With regard to ratings from the surgeons’ viewpoint, more than 70% of the subjects gave a rating of acceptable for “securing field of view” and “brightness at treatment site”; 50% gave acceptable and less than 3% gave unacceptable for “exclusion of soft tissue”, “assistance in opening mouth”, “easy to perform treatment with” and “design of device”; and 10% gave unacceptable for “achievement of vacuum”, “ease-of-use of device” and “ease-of-use of turbine” (Fig. 5).

With regard to ratings from the patients’ viewpoint, most subjects gave a rating of acceptable or moderate for “design of device” and “degree of peace of mind during dental treatment” and more than 20% gave unacceptable for “feeling in wearing device”, “condition of breathing”, “performance of aspiration”, “condition of cheek and floor of mouth”, “condition of jaws while opening mouth”, “condition

Table 1 Questionnaire items for surgeons and ratings for items

1. Securing field of view	acceptable • moderate • unacceptable
2. Brightness at treatment site	acceptable • moderate • unacceptable
3. Achievement of vacuum	acceptable • moderate • unacceptable
4. Exclusion of soft tissue	acceptable • moderate • unacceptable
5. Assistance in opening mouth	acceptable • moderate • unacceptable
6. Easy to perform treatment with	acceptable • moderate • unacceptable
7. Ease-of-use of device	acceptable • moderate • unacceptable
8. Design of device	acceptable • moderate • unacceptable
9. Ease-of-use of turbine	acceptable • moderate • unacceptable
10. Overall ratings	5 • 4 • 3 • 2 • 1

Table 2 Questionnaire items for patients and ratings for items

1. Feeling in wearing device	acceptable • moderate • unacceptable
2. Condition of breathing	acceptable • moderate • unacceptable
3. Performance of aspiration	acceptable • moderate • unacceptable
4. Conditions of cheek and floor of mouth	acceptable • moderate • unacceptable
5. Condition of jaws while opening mouth	acceptable • moderate • unacceptable
6. Condition during treatment	acceptable • moderate • unacceptable
7. Feeling of pressure in tongue	acceptable • moderate • unacceptable
8. Design of device	acceptable • moderate • unacceptable
9. Degree of peace of mind during dental treatment	acceptable • moderate • unacceptable
10. Overall ratings	5 • 4 • 3 • 2 • 1

during treatment” and “feeling of pressure in tongue”, showing variations in the rating for the device (Fig. 6).

Overall ratings by surgeons and patients are summarized in Fig. 7. The mean overall rating (degree of satisfaction) of Isolite™ Plus by surgeons was 3.87 points and that by patients was 3.43 points according to the five-grade rating (5 points at maximum). No sex or age-related differences in rating were found in this study.

Discussion

Based on the mean overall ratings by surgeons and patients, Isolite™ Plus was rated slightly better by surgeons than by patients. This was probably because Isolite™ Plus was helpful for surgeons in treating patients, leading to good ratings, while patients were not satisfied with its fit to the mouth, leading to poorer ratings.

In particular, “securing field of view” and

“brightness at treatment site” were rated as acceptable by many subjects. With the recent wide distribution of microscopes and magnifying glasses, surgeons are required to perform meticulous procedures under a clear field of view. Isolite™ Plus uses LED as the source of light and thus provides sufficient brightness and does not affect treatment procedures by increasing temperature. It also uses a flexible, soft silicone mouthpiece for transmitting light, thereby enabling shadowless illumination. These functions provide “expansion of the field of view” at the treatment area, “improvement in the accuracy of meticulous procedures” and “relief of fatigue of surgeons”. On the other hand, “ease-of-use of device” and “ease-of-use of turbine” were poorly rated. The mouthpiece portion of Isolite™ Plus is fixed by biting a bite block. Therefore, when the device is placed in the mouth, the device itself becomes an obstacle, restricting handling of instruments and making it difficult to hold and fix a handpiece. This may explain the low ratings for these items.

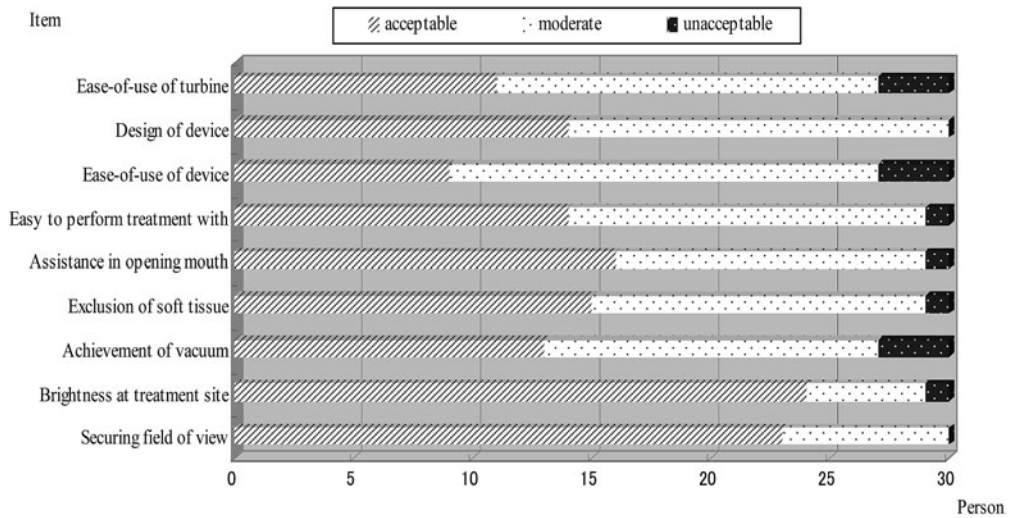


Fig. 5 Ratings for each item from surgeons' viewpoint

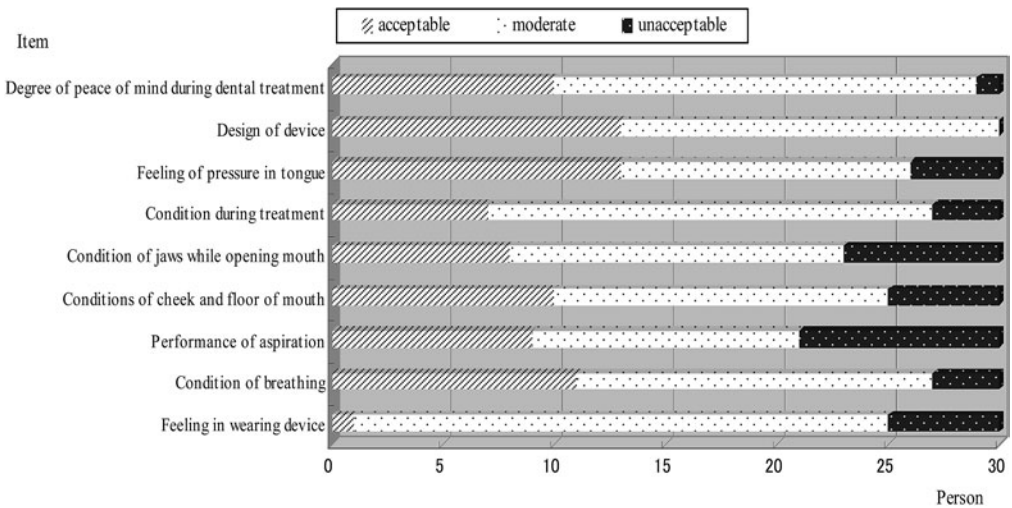


Fig. 6 Ratings for each item from patients' viewpoint

With regard to ratings from the patients' viewpoint, only one patient gave a rating of acceptable for “feeling in wearing device”. This was probably because the mouthpiece portion of the device is not suited to the anatomical structure of the mouth of Japanese people. This is also supported by the fact that a large proportion of the subjects gave a rating of unacceptable for “conditions of cheek and floor of mouth”. The tooth root of Japa-

nese people⁶⁾ is shorter than that of Western people and therefore the tooth socket of Japanese people is considered to be shallower than that of Western people. Therefore, both the floor and anterior floor of the mouth of Japanese people appear to be shallower than those of Western people. The curve on the mouthpiece portion of the device should be improved so that it is more suitable to the anatomical structure of the mouth

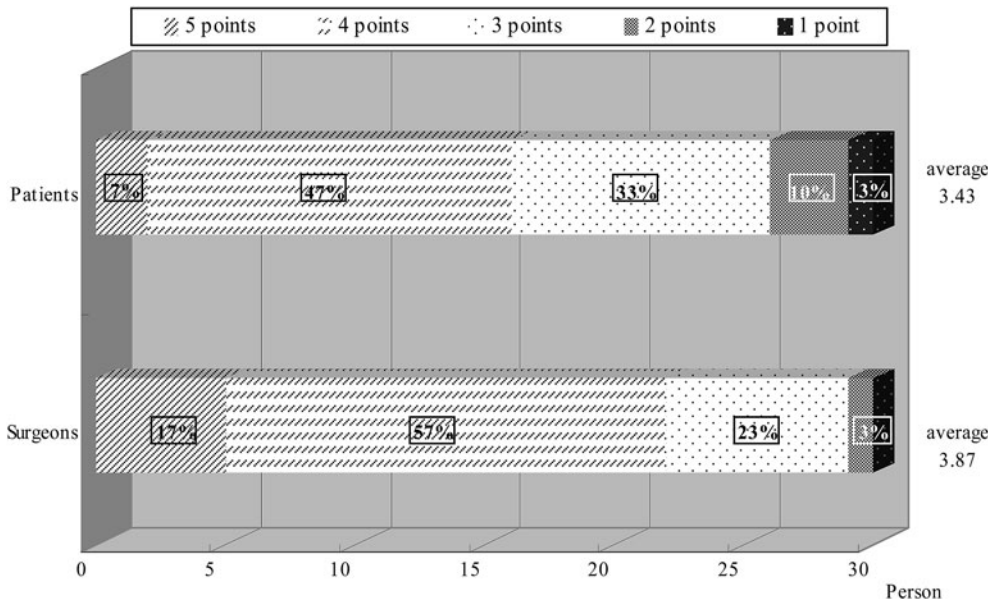


Fig. 7 Overall ratings from surgeons' and patients' viewpoints

of Japanese people. The ratings for “performance of vacuum” by surgeons and that for “performance of aspiration” by patients were low. Isolite™ Plus can control intraoral humidity by continuously aspirating water spray and oral fluids. However, it is impossible to aspirate these fluids completely at the mouthpiece portion. Although accidental ingestion or aspiration of large foreign objects and materials can be prevented by the protective function of the mouthpiece portion, small foreign objects or liquid drugs accidentally falling into the pharynx may pass through the interstice of the protection. It would be therefore preferable to add another vacuum system to the dental unit. For “condition of jaws while opening mouth”, 24% of the subjects playing the role of patients gave a rating of acceptable while 21% gave unacceptable. Biting a bite block on the mouthpiece portion can make it easy to keep the mouth open for a long time, but in some patients with tooth crowding the device did not fit well and even worsened the feeling of discomfort. The deep configuration of the bite block on the mouthpiece portion appears to worsen

the fitness of the device.

Isolite™ Plus may free dentists from the difficulty of having to perform treatment in a dark, narrow and wet environment by creating an environment which is bright, wide and dry. However, the current investigation revealed several aspects requiring improvement, including “feeling in wearing device” and restriction on the handling of instruments. We also found that the device provided an inadequate level of patient comfort during treatment. The device needs to be improved by moderating the entire curve on the mouthpiece portion so that it can fit to the shallow floor of the mouth, reducing the height and width of the base while increasing the length of the nose portion, changing the position of the vacuum hole on the mouthpiece portion appropriately and reducing the weight and size of the device to improve feeling in wearing. These improvements should resolve many of the complaints presented in the present investigation and increase levels of ease-of-use, comfort and safety. For the wide distribution of Isolite™ Plus in the Japanese market, the mouthpiece portion of the device should be

improved so that it can more adequately fit the mouth of Japanese people.

Conclusion

The results of the present investigation evaluating the clinical convenience, comfort and safety of Isolite™ Plus, an oral support device, revealed that the device was effective in improving "securing field of view" and "brightness at treatment site" from the surgeons' viewpoint, but that its ease-of-use and level of comfort were relatively low.

Ratings of the device from the patients' viewpoint varied widely because the mouthpiece portion of the device was not well suited to patients' mouth and therefore the supportive functions of the device were not adequately achieved. The mouthpiece portion of the device should be improved to provide a better fit to the mouth of Japanese people.

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