The usefulness of the test procedure for measuring retentive force of dental magnetic attachment as stipulated in ISO 13017 standard

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Introduction

The international organization for standardization of dental magnetic attachments, ISO 13017, was published in 2012[1]. However, measurement of retentive force of dental magnetic attachments which is one of the items specified by the standard was difficult because a standard set of procedure instructions had not been developed. Problems pertaining to repeatability, accuracy, and ease of measurements were common. Therefore, Japanese Society of Magnetic Applications in Dentistry designed a specific device for measuring retentive force and developed the method for carrying out the measurements. Afterwards, the proposal was evaluated[2] and the detailed test procedure method for measuring retentive force was published as ISO 13017 Amendment 1 in 2015[3]. However, effectiveness of the Amended standard procedure has not been established with regard to those conducting the experiment, guided by the standard, for the first time.

Objective

The aim of the study was to evaluate usefulness of the amended test procedure instructions for a first time user. The specific steps to be improved would be investigated also as part of the process.

Materials and Methods

1. Participants, samples and measuring device

Five participants (A, B, C, D, and E) who were Dental students were selected randomly. Inclusion criteria involved those who English is not their native language, and had never conducted the experiment before. Three different samples of dental magnetic attachments were used; two kinds of flat type (Gigauss D600, GC and Hyper Slim 3513, Morita) and one of post type (Hicorex Post keeper 3513, Morita). The measuring device used (Fig. 1) matched ISO 13017:2012/Amd.1:2015 description. The device was connected to a digital force gauge (ZPS, Imada). A cross-head speed was controlled by a hydraulic check unit (Kinecheck 3022-19-1-1/4, Meiyu Airmatic).

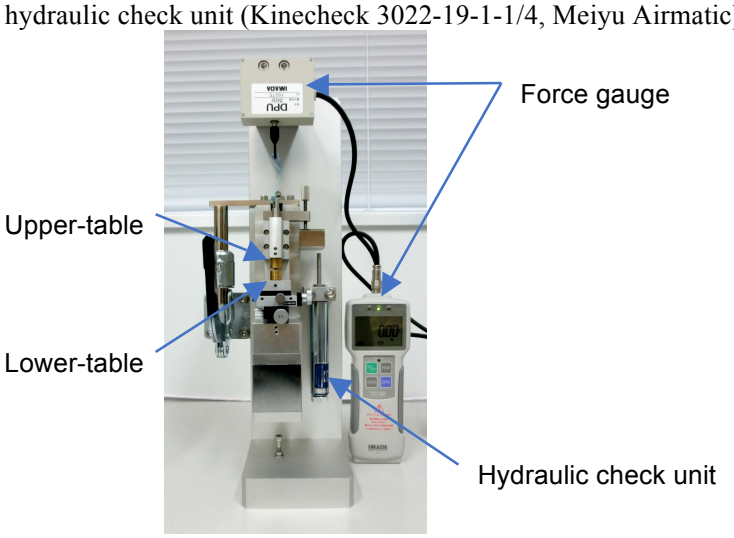


Fig. 1 Device for measuring retentive force

2. Prerequisite conditions for the various stages of experiment

The experiment was conducted in phases. Each participant repeated the experiment and a set of measurements was recorded after fulfilling the conditions of the particular stage.

First: Each participant was required to read the ISO standard test procedure instructions alone then carry out the experiment. No discussions were allowed among participants at this level.

Second: Discussion of the procedure instructions only, was allowed between the participants and an expert who is well versed with the technique. The experiment was repeated and second set of data generated.

Third: Detailed practical demonstration of the experiment by an expert to the group of participants. Afterwards, a third set of measurements was generated.

3. Test procedure instructions for measuring retentive force

The experiment was conducted as detailed by ISO Manual. The outline of test procedure instructions for measurement of retentive force applied in in this study was as follows;

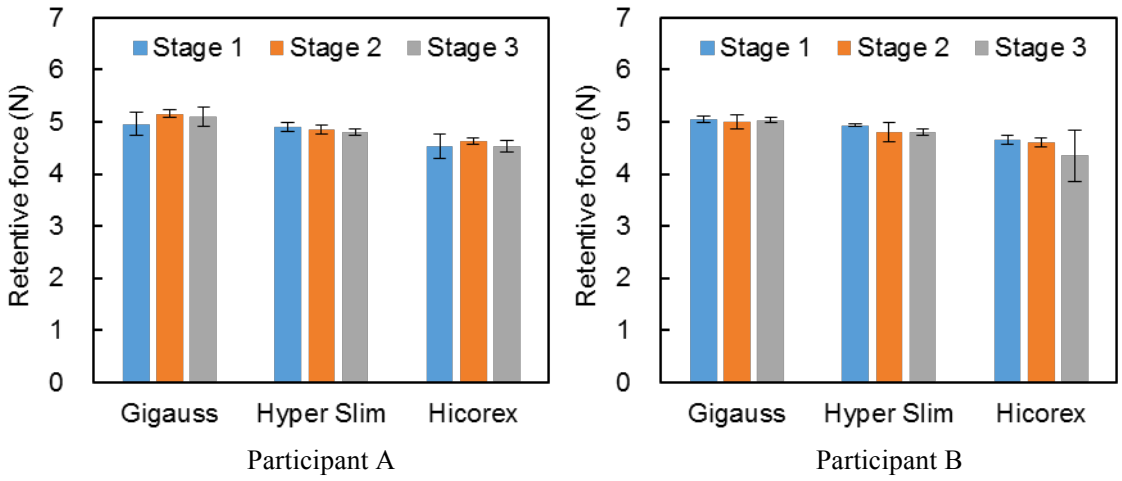
a) The dental magnetic attachments are fixed on the upper and lower tables by use of a cyanoacrylate adhesive only or reinforced with self-curing acrylic resin.
b) The specimens are loaded in tension on the device at a cross-head speed of 4.5 mm/min.
c) Readings are recorded from the digital force gauge as detailed in the manual and calculations done to establish the retentive force value
d) The lower table is raised to establish contact between the keeper and magnetic assembly and step b and c repeated five times to yield five readings.
e) The median value from the data set is determined.
f) A different sample of magnetic attachment is fixed and steps b to e followed. The procedure is done three times corresponding to the three samples at every stage.

4. Statistical analysis

The data generated was statistically analyzed using ANOVA and Tukey HSD test ($\alpha = 0.05$).

Results

Retentive force measurements (median values) by each participant is shown in Fig. 2. All the values generated corresponded with more than 85% of the figure quoted in the manufacturer's literature accompanying the package. The retentive force of each sample of magnetic attachment at second and third stages tended to be higher than that of first stage, although there was no significant difference ($p>0.05$) except in the case of Gigauss by participant E. The standard deviation of Hicorex was relatively large compared to that of the other magnetic attachments among participants B, D, and E.



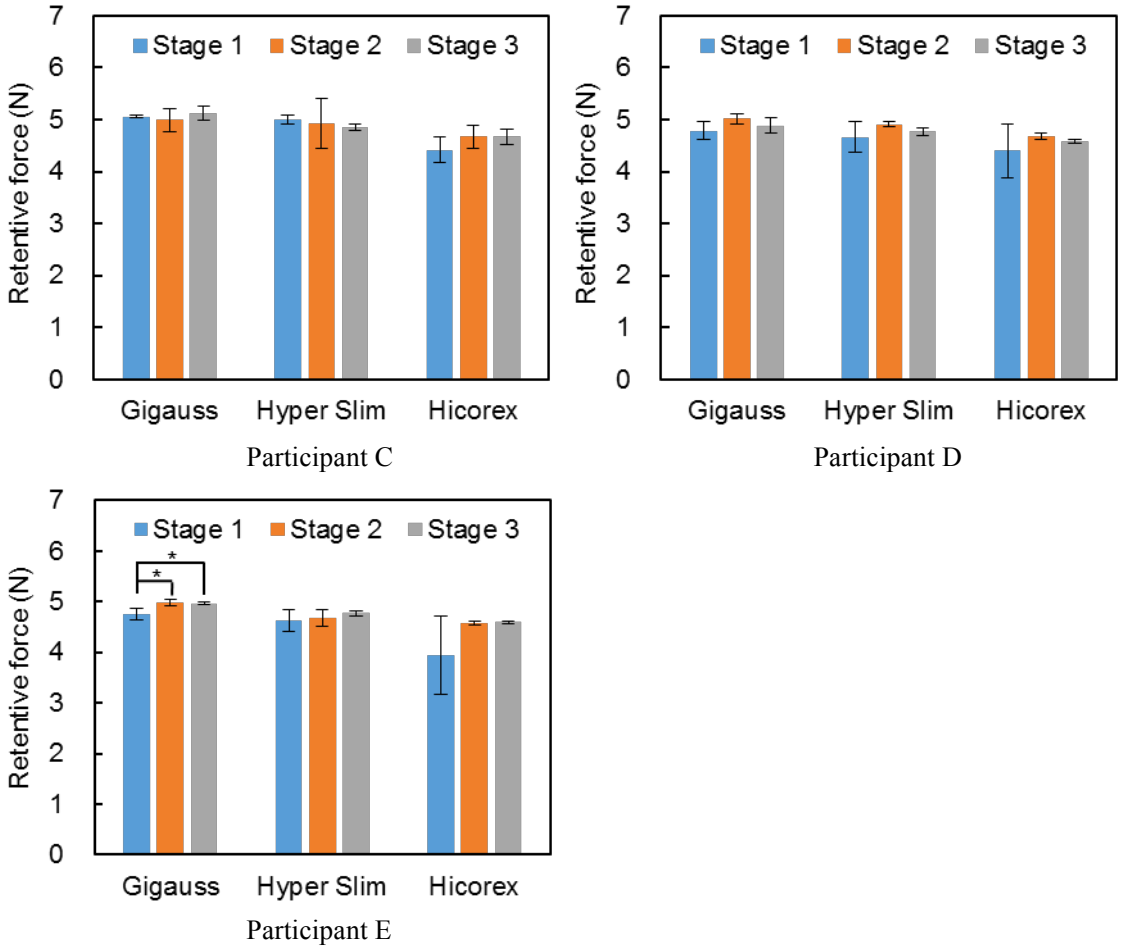


Fig. 2 Retentive force measured by each participant (*p<0.05)

The retentive force during the first stage as indicated in Fig. 3, shows comparison of values among the participants. Participant D and E generated lower values during first stage in all the sample magnetic attachments compared to the other participants, although there was no significant difference (p>0.05). However, at the second and third stage, the values were almost similar among all the participants for each particular sample of magnetic attachment. The force values for Hicorex tended to be lower than that of Hyper Slim and Gigauss at all stages.

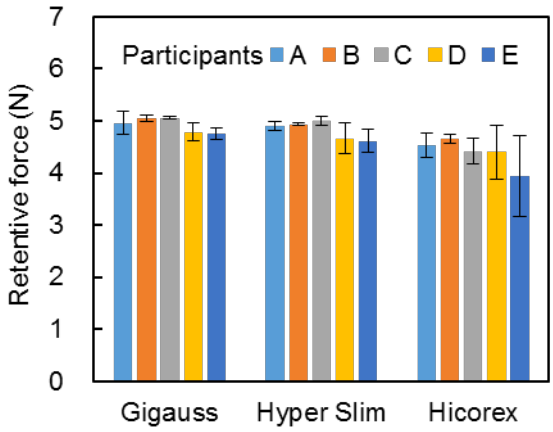


Fig. 3 Retentive force at the first stage

Discussion

An error in execution of the test procedure instructions is indicated by low readings. Similarly, high values or measurements indicate that the set up was done correctly as a result of proper interpretation of the instructions and understanding of technique. The values attained at second stage were higher than those of first stage. This suggests that discussion of the procedure instructions with an expert improves the technique of carrying out the measurements thereby leading to higher and more accurate values. This pattern concurs with Evaluation of testing procedure accuracy proposal[2]. Errors emanating from first stage were observed by an expert as the participants carried out the experiment and noted to be as follows:

(i) The word "magnetic assembly" was confused with "a set of a magnetic assembly and keeper" (participant D).
(ii) A table was moved before the adhesive set completely (participant E) thereby increasing possibility of movement during the experiment.
(iii) After the removal of the adhesive double sided tape, the mating face which was initially adherent was not cleaned (all participants).
(iv) The X-Y stage for adjusting the alignment of upper and lower tables was not used (except participant B).

The above errors may cause a warp alignment of the magnetic attachment and result in reduced retentive force values. The error mentioned as (iii) above was occasioned by lack of a specific clause in the manual stipulating that cleaning should be done. The test procedure manual should be amended to include: "the adherent surface is cleaned after the removal of the tape". More so "use of double sided tape only when needed" should be added as it is not always necessary to temporarily secure magnetic assembly with tape before final fixation with adhesive.

The other errors may have been corrected by careful reading of the manual. Since the values at third stage did not differ significantly from those of second stage, the influence of a practical demonstration by an expert is minimal. The results revealed that many participants could gain satisfactory retentive force values for the first time by reading of the ISO standard test procedure manual alone. Moreover, participants got more accurate figures after second stage discussion in comparison with first stage.

Hyper Slim and Hicorex use the same magnetic assembly. In addition, the keepers are made of the same material although the shapes are different. Therefore, the retentive force values should ideally be the same. However, Hicorex values of retentive force were generally lower and with a higher standard variation than that of Hyper Slim. This is because the alignment of Hicorex easily warps, due to difficulty in fixing its keeper which is of post type on a lower-table. If the keeper is fixed correctly, accurate values can be obtained regardless of the keeper's shape[4]. More precise values can be attained by gaining more experience on the procedure or by making use of a dedicated jig.

Conclusions

These results indicate that the amended test procedure standard as stipulated in ISO 13017 is a useful guide in measurement of retentive force.

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