A Study on Performance Evaluation of Magnetic Dental Attachments

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This study measures retentive force as function of the diameter, the cross-head speed, and the number of detachments of dental magnetic attachments in a clinical environment, and analyzes the validity of the international standard method for testing them. In this study, tests 1, 2, and 3 were used to measure the retentive force as a function of the contact area of the magnetic attachment, and tests 2 and 4 as a function of the cross-head speed. Test 2 and 5 compared function of the retentive force as a function of repeated detachments Results showed that the retentive force increases as the sample surface increases, and decreases as the cross head speed increases. Additionally, after 1500 detachment cycles, the retentive force increased. Finally, the international standard test method was validated, because an objective method for testing magnetic attachments in clinical environment could not be found.

Keywords: magnetic dental attachment, ISO 13017, retentive force, clinical environment

1. Introduction

Because the life expectancy of humans increases with the development of medical technology, dental treatment for elderly has become an important issue. In particular, some countries, including the United States and Canada, have a high percentage of full denture patients among those aged 65 and above [1, 2]. However, in some patients, such as those with severe progression of oral residual algae, it is quite difficult to produce a full denture with a retaining force that allows chewing comfortably [3].

In these patients, restoring the prosthesis using an osteoadhesive implant is essential. Such implants can be divided into implant forms using implant-supported fixed prosthesis and dental attachment assemblies [4, 5]. In aged patients, using implant-supported fixed prosthesis is often difficult because of long treatment and manufacturing times, patient physiological, anatomical and economic conditions, and the large numbers of implants to be placed [6, 7]. However, implant overlay using dental attachment has the advantage of being a simple and short procedure because of the small number of implants required. Denture strength, load-bearing and chewing abilities can be improved with respect to conventional dentures in patients with severe periodontal bone resorption or poor dental status [8, 9].

Dental attachments are Food and Drug Association (FDA) class I dental materials used to accurately restore or stabilize a denture. In the case of a locator or O-ring attachment, the initial stability and retentive force of the denture are improved, though the latter may be reduced because of the wear caused by repeated detachments [2, 10]. Among dental attachments, magnetic dental attachments are a kind of implant and prosthesis-holding devices made of a semi-permanent magnetic material. They are composed of a magnetic assembly and a keeper. Commonly, the magnetic assembly is introduced into the denture, fixing the keeper on top of the implant and securing the denture by applying a suction force to both its sides. Magnetic attachment has been widely used because it provides a proper retentive force, reducing harmful lateral pressure in the oral cavity and ensuring easy removal and cleaning of dentures [11].

Currently, the only international standard that defines the method for measuring the retentive force of magnetic dental attachments is the one by the International Organization for Standardization (ISO 13017) [12]. This international standard method should be followed when testing magnetic attachments. However, according to the current standard, only the retentive force is measured, and

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a measurement method that considers different actual situations of the clinical environment is not present.

The cross-head speed for desorption, as specified in the international standard, is below 5 mm/min [12], though in the actual clinical environment the cross-head speed is higher (50 mm/min) [2, 13, 14]. Additionally, magnetic dental attachments, which are worn in the oral cavity for months or years, can have different sizes, and may be weakened by repeated detachments.

At present, though a retentive force test probing the repeated detachment of locators or other types of attachments is available [13-15], there are few basic studies for the clinical use of dental magnetic attachments. Methods for measuring the retentive force dental attachments in clinical environment are missing. The purpose of this study is to use the ISO 13017 method of Ref. [12] to measure the retentive force for different detachment rates, number of repeated detachments, and size of dental magnetic attachments, considering the clinical environment. The null hypothesis used in this study is the same as that of the international standard. An additional objective is to verify whether a scientific test method in clinical environment can be established.

2. Materials and Methods

2.1. Classification of tests
In this study, tests 1, 2, and 3 were used to measure the retentive force as a function of the contact area of the magnetic attachment, and tests 2 and 4 as a function of the cross-head speed. Test 2 and 5 compared function of the retentive force as a function of repeated detachments (Fig. 1).

2.2. Selection and preparation of specimens
The magnet assemblies of tests 1, 2, and 3 had diameters of 4.5, 4.9, and 5.1 mm, respectively, and a height of 1.3 mm. Samples having a keeper diameter of 4.2 mm were selected (Magden, Shinwon Dental, Seoul, Korea). The samples of tests 4 and 5 had a magnet assembly diameter and height of 4.9 mm and 1.3 mm, respectively, and a keeper diameter of 4.2 mm (Magden, Shinwon Dental, Seoul, Korea). A total of 25 samples were prepared. Commonly, magnet assemblies were embedded in acrylic resin in rectangular molds of width 3 cm, length 2 cm, and height 1 mm (Fig. 2).

2.3. Preparation of artificial saliva
Artificial saliva was prepared according to ISO 10271 for testing repeated detachments of magnetic dental assemblies. The saliva was obtained by dissolving 0.40 g NaCl, 0.4 g KCl, 0.69 g NaH$_2$PO$_4$H$_2$O, 0.005-48 g Na$_2$S$_9$H$_2$O, 0.005 g urea, and 0.795 g CaCl$_2$H$_2$O in approximately 950 ml of water. The pH was adjusted to 7.2±0.1 using either 1 % C$_3$H$_6$O$_3$ or 4 % NaOH. The total volume of the solution prepared was 1000 ml. The prepared artificial saliva was used in the test to simulate the oral environment.
saliva was stored at a temperature of 37 ± 2 °C.

2.4. Measurement of retentive force as a function of the magnetic dental attachment

Tests 1, 2, and 3 were carried out using a universal tester (Instron 5900, Canton, Massachusetts, USA). The magnet assembly was fixed to a clamp, and another clamp was connected to a lab analogue compatible with the keeper (Fig. 3). Then, the magnet assembly and the keeper are positioned on the same axis, the former above the latter, and a tensile force is applied at a cross-head speed of 5 mm/min until their surfaces are completely separated. The same test method was applied to test 4. In this case, the retentive force was measured at a cross-head speed of 50 mm/min.

Test 5 was carried out using a universal tester (Instron 5940, Canton, Massachusetts, USA), with the magnetic assembly fixed to the upper clamp. The keeper was kept in a test-only bath of artificial saliva at 37 ± 2 °C reproducing the oral cavity. Then, the retentive force was measured by probing 1500 repetitive detachments at a constant cross-head speed of 3 mm/min (Fig. 4). The resulting retentive force was averaged over five measurements.

2.5. Statistical analysis

Statistical analysis of the measurements was performed using a statistical software (IBM SPSS Statistics v24.0, IBM Corp., Armonk, NY, USA). For the retentive force measured as a function of the diameter of the magnetic dental attachment, the Kolmogorov-Smirnov and the Shapiro-Wilk tests were used as the normality test. Because this was not satisfied, a nonparametric test such as the Kruskal-Wallis one was used to compare the average values and analyze their differences. The type I error level was set to 0.05. Additionally, the Mann-Whitney U test was performed as a post hoc analysis to identify the differences between the tests, applying a significance
level as adjusted by the Bonferroni method.

The Kolmogorov-Smirnov and Shapiro-Wilk tests were used also for the normality test of the retentive force measured as function of the cross-head speed and of repeated detachments of the magnetic dental attachment. The differences were analyzed using the nonparametric Mann-Whitney U test, setting the type I error level to 0.05.

3. Results

Table 1 shows the results of the retentive force and retentive force per area as functions of the size of the magnetic dental attachment. The average retentive force was 2.5 ± 0.7 N, 2.9 ± 0.9 N, and 3.4 ± 0.9 N, and the average retentive force per area was 0.19 ± 0.05 N, 0.19 ± 0.06 N, and 0.20 ± 0.05 N for test 1, 2, and 3, respectively. The value of the retentive force was statistically significant (P < 0.05), whereas that of the retentive force per area was not (P > 0.05).

Table 2 shows the results of the retentive force and retentive force per area as functions of the cross-head speed of the dental attachment. The average retentive force was 2.9 ± 0.9 N and 1.9 ± 0.3 N, and the average retentive force per area was 0.19 ± 0.06 N and 0.12 ± 0.02 N for test 2 and 4, respectively. In this case, both the retentive force and the retentive force per area were statistically significant (P < 0.05).

Table 3 shows the results of the retentive force and the retentive force per area as functions of the number of detachments of the magnetic dental attachment. The retentive force was 2.9 ± 0.9 N and 3.5 ± 0.7 N, and the retentive force per area was 0.19 ± 0.06 N and 0.2 ± 0.5 N for test 2 and 4, respectively. For repeated removal of the magnetic dental attachment, the retentive force and retentive force per area were statistically significant (P < 0.05).

4. Discussion

The effectiveness of the magnetic attachment introduced into the dental prosthesis strongly depends on the size and direction of the magnetic field and the force of the magnetic material. However, in this study, it is meaningful to analyze the variables of the magnetic attachment in the experimentally reproduced oral environment by comparing the retention capacity measured both through the inter-

Table 1. Retentive force and retentive force per area as functions of the size of dental magnetic attachments.

<table>
<thead>
<tr>
<th>Retentive force</th>
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<tbody>
<tr>
<td>Mean ± SD</td>
<td>Median</td>
</tr>
<tr>
<td>Test 1</td>
<td>2.5 ± 0.7 \textsuperscript{a}</td>
</tr>
<tr>
<td>Test 2</td>
<td>2.9 ± 0.9 \textsuperscript{ab}</td>
</tr>
<tr>
<td>Test 3</td>
<td>3.4 ± 0.9 \textsuperscript{b}</td>
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</tbody>
</table>

Unit: N
SD: standard deviation, CI: confidence interval
Values marked \textsuperscript{a} and \textsuperscript{b} are statistically significant (P < 0.05).

Table 2. Retentive force and retentive force per area as functions of the cross-head speed of dental magnetic attachments.

<table>
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<tbody>
<tr>
<td>Mean ± SD</td>
<td>Median</td>
</tr>
<tr>
<td>Test 2</td>
<td>2.9 ± 0.9 \textsuperscript{a}</td>
</tr>
<tr>
<td>Test 4</td>
<td>1.9 ± 0.3 \textsuperscript{b}</td>
</tr>
</tbody>
</table>

Unit: N
SD: standard deviation, CI: confidence interval
Values marked \textsuperscript{a} and \textsuperscript{b} are statistically significant (P < 0.05).

Table 3. Retentive force and retentive force per area as functions of the detachment counts of dental magnetic attachments.

<table>
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<tr>
<td>Mean ± SD</td>
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</tr>
<tr>
<td>Test 2</td>
<td>2.9 ± 0.9 \textsuperscript{a}</td>
</tr>
<tr>
<td>Test 5</td>
<td>3.5 ± 0.7 \textsuperscript{b}</td>
</tr>
</tbody>
</table>

Unit: N
SD: standard deviation, CI: confidence interval
Values marked \textsuperscript{a} and \textsuperscript{b} are statistically significant (P < 0.05).
The existing methods for testing the retentive force of magnetic dental attachments are mainly finite element analysis and the magnetic retentive force test [11, 16-18]. In finite element analysis, the sum of the magnetic forces in the center of the object inspected is calculated by considering the magnetic field in three-dimensional disk-shaped structures approximating the object. In this way, both qualitative and quantitative results can be extracted. However, finite element analysis can hardly be applied to complex objects, such as the one of our experiments. In contrast, the retentive force test is a method of measuring the retentive force by using a magnetic connector after fixing the magnetic assembly and the keeper. This is the standard ISO method used for testing magnetic attachments [12]. In this study, a test in accordance with the international standard method was used, additionally reproducing the clinical environment.

In particular, tests 1, 2, and 3 entirely reproduced the standard method, and tests 4 and 5 measured the retentive force in the reproduced clinical environment. To obtain accurate data, the measurements were repeated five times per sample and the average and median values were calculated. Additionally, to analyze the international standard method and the one including the clinical environment accurately, the desorption rate in the oral cavity was adjusted to the most accurate one, after preparing the artificial saliva, reproducing the oral humidity and temperature, and before the test was carried out. Then, the retentive force per area was compared in the two cases.

The measurements for different diameter, detachment speed, and repeated detachments of the magnetic dental attachment were statistically significant (P < 0.05); however, there was no significant difference (P > 0.05). As seen from Table 1, the retentive force increased as the diameter of the magnetic dental attachment orderly increased from test 3 to 1, with a statistical significance below the threshold (P < 0.05). Because the diameter increasing at constant magnetic flux density results in the total magnetic flux acting on a larger area, the retentive force is accordingly higher.

However, there was no statistical significance (P > 0.05) when comparing the magnetic retentive force per area. This proves that the strength of the magnet in the actual contact area has not changed, and because the area widens, the magnetic flux rises, increasing only the average retentive force. Therefore, the size of the magnetic assembly is an important parameter when selecting the magnetic attachment, because it is related to the retentive force in the oral cavity. However, a previous study reported that the similarity of the diameters of magnetic assembly and keeper was the most important factor [18]. In the current study, the optimal retentive force may not have been obtained, because the sizes of magnetic assembly and keeper are different.

Table 2 compares the retentive force for different cross-head speeds of the magnetic dental attachment. As seen, test 4 showed a lower average retentive force and retentive force per area than test 2, and both showed statistical significance (P < 0.05). Thus, the retentive force appears to be proportional to the cross-head speed of the magnetic dental attachment. This is because the retentive force is characterized by thixotropy, a physico-mechanical property that depends on the pulling speed.

The cross-head speed is 50 mm/min in the reproduced clinical environment, and 5 mm/min in the ISO standard [12]. The reason for setting the cross-head speed to 50 mm/min is that previous studies reported a similar detachment speed in edentulous oral cavities [2, 13, 14]. Consequently, it may be necessary to revise the cross-head speed in the next international standard.

As seen from Table 3 for the retentive force as function of the number of detachments of the magnetic dental attachment, test 5 showed higher retentive force and retentive force per area than test 2, and both showed statistical significance (P < 0.05). Previous studies have shown that the retentive force decreases and that, when using a locator, its contact part is worn out when repeatedly detaching the magnetic dental attachment [19-21]. In the current study, however, larger values were obtained as the attachments were repeatedly attached and detached, presumably because of artificial saliva [22]. Artificial saliva is viscous, and it is believed that the retentive force increases when the viscosity increases. Additionally, because the retentive force per area did not decrease in the magnetic dental attachment, differently from the same force in the plastic material of the locator, the retentive force did not decrease either, rather increasing because of the viscosity of artificial saliva.

In this study, the attachment and detachment test was repeated for 1500 cycles. We first note that, according to a previous study, assuming 4 detachments per day, 750 cycles correspond to 6 months; then, 1500 cycles correspond to 1 year [14].

According to this study, different factors, each with its weight, may play a role in the final retentive force. However, when measuring the retentive force in clinical environment, these factors cannot be applied directly, because of the different variables in play. In particular, it is difficult to measure the cross-head speed exceeding the international standard one and to provide objective indicators that ex-
plain the increased retentive force of the magnetic dental attachment in an oral-like environment. Therefore, the international standard method is the only one available to evaluate dental attachments and allow or deny permits. However, in this study, the issues of testing dental attachments in a clinical environment were identified.

There were some limitations in this study. First, the testing device lacked a low-friction ball bearing slide, whereas in the ISO standard [12], the retentive force is measured using a device equipped with such bearing. Secondly, the number of samples was limited. However, to increase the significance of the test, the retentive force measurement was repeated five times for each sample.

In future studies, it will be necessary to carry out standard retentive force tests of magnetic dental attachments using a device having a low-friction ball bearing slide.

5. Conclusion

In this study, despite its limitations, statistically significant values were found for the retentive force as function of the diameter, cross-head speed, and number of detachments of the magnetic dental attachment. However, no significance was found for the measured retention force per area as function of the diameter. As a conclusion, it is difficult to apply the international standard method to clinical environment, because it is difficult to make find objective variables to evaluate the performance of magnetic dental attachments.

Acknowledgments

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References