Projects of Japanese Dental Science Federation in 2016

Investigation of materials with a high level of evidence and survey research

The Japanese Society of Magnetic Applications in Dentistry

Survey and Research on International Standardization and Clinical Evaluation of Magnetic Dental Attachments

Prepared by:

Masayuki Hideshima (Medical Committee Chair; Tokyo Medical and Dental University), Shuji Okawa (President; Meikai University), Chikahiro Okubo (Vice Chair, Tsurumi University), Shinichi Masumi (Former Chair, Kyushu Dental College), Yukyo Takada (Chairperson of ISO Committee; Tohoku University), Kazuhiro Nagata (Chairperson of Clinical Evaluation Committee; Nippon Dental University at Niigata)

Related Committees:

【Medical Committee】: Masayuki Hideshima[1] (Chair), Yoshitada Umekawa[2] , Shogo Ozawa[3] , Toshihiro Kawano[4] , Mai Kono[5] , Yasunori Suzuki[6] , Joji Tanaka[7] , Kan Nagao[8], Akira Nishiyama[1], Kazumoto Hoshiai[3].

【ISO Working Committee】: Yukyo Takada[9] (Chair), Tomohiko Ishigami[2], Yoshitada Umekawa[2], Ryo Kanbara[3], Yoshinori Nakamura[3], Eri Makihara[4], Shinichi Masumi[4]

【Clinical Evaluation Committee】: Kazuhiro Nagata[10] (Chair), Tetsuo Oyama[2] , Mineyo Sone[11] , Tatsuhiko Masuda[3]

[1]Tokyo Medical and Dental University, [2]Nihon University School of Dentistry, [3]Aichi Gakuin University School of Dentistry, [4]Kyushu Dental College, [5] Health Sciences University of Hokkaido, [6]Tsurumi University School of Dentistry, [7]Chiba Prefecture, [8]Tokushima University, [9]Tohoku University School of Dentistry, [10] Nippon Dental University at Niigata, [11]Meikai University School of Dentistry,

Table of Contents

Survey and Research on International Standardization and Clinical Evaluation of Magnetic Dental Attachments

The Japanese Society of Magnetic Applications in Dentistry

Masayuki Hideshima (Chair, Medical Committee; Tokyo Medical and Dental University), Shuji Okawa (Chair, Meikai University), Chikahiro Okubo (Vice Chair, Tsurumi University), Shinichi Masumi (Former Chair, Kyushu Dental University), Yukyo Takata (Chair, ISO Committee; Tohoku University), ; Kazuhiro Nagata (Chair, Clinical Evaluation Committee; Nippon Dental College at Niigata)

I. Introduction

The Japanese Society of Magnetic Dentistry was founded in 1980 as a research group for new denture attachments, and was promoted to an academic society in 1991.

Since the establishment of the society, each organization affiliated with the society has conducted prognostic studies on the clinical application of magnetic attachments, and after the promotion to the society, a clinical evaluation committee has been established to accumulate data on the long-term progress of magnetic dental attachments (hereinafter referred to as "magnetic attachments") based on a common protocol.

On the other hand, the ISO task force committee was established in 2007 for the international standardization of magnetic attachments, and has undergone examinations by the International Organization for Standardization (ISO). As a result, Japanese magnetic attachments acquired ISO13017 certification on July 15, 2010, achieving international standardization of magnetic attachments.

In recent years, the need for evidence-based medicine and improvement in quality have prompted various academic societies to develop guidelines for medical practice. For CQs with low levels of evidence, a questionnaire survey was conducted among relevant experts, and a Delphi survey was also conducted to converge opinions by feeding back the results. The "Clinical Practice Guideline for Magnetic Attachments 2013" has been completed. It is now included in the Japanese Dental Association's Dental Practice Guideline Library and posted on its website.

The purpose of this study was to summarize the research achievements of our society on magnetic attachments in Japan, which have achieved international standardization, and to collect research with a high level of evidence and reliable clinical data.

We would like to report on the evaluation of the clinical application of magnetic attachments, international standardization, and the formulation of medical practice guidelines, in this order, to assist in the selective treatment or insurance coverage of magnetic attachments currently under consideration by our society.

II. Evaluation of magnetic attachments for clinical application

Since the inception of the study group, prognostic studies have been conducted at various institutions, and the results have been presented at research meetings and academic conferences and published in journals.

In 1990, magnetic attachments were approved as a medical device by the Ministry of Health, Labour and Welfare, and in 1991, after the Society of Magnetic Dentistry was promoted to the Japan Society of Magnetic Dentistry, a clinical evaluation committee was established, a protocol for postoperative follow-up was formulated, and magnetic attachments from various institutions and manufacturers were evaluated.

1. Clinical evaluation of Hicorex (Prognosis after 1 year and 4 months)

In 1997, a survey (Table 1) of 1,123 cases with 1,719 teeth was conducted at 261 institutions from November 1992 to March 1994, in which Hitachi Metals' Hicorex MD was applied, and the results were published by the Tokyo Medical and Dental University in the Japanese Journal of Prosthodontics, with the following findings[1].

1) Distribution of cases: By gender, 459 males (695 teeth), 616 females (945 teeth), and 48 unknown (79 teeth), and by age, the largest number of both males and females were in their 60s, followed by those in their 50s and 70s (Figures 1, 2).
2) Abutment teeth: In the maxilla, canine teeth (44%), first premolars, second premolars, and central incisors were the most common, in that order. In the mandible, canine teeth (44%), first bicuspids, second bicuspids, and lateral incisors were most common, in that order (Fig. 3).
3) Postoperative period: 3-6 months; 917 teeth (53.3%), in the order of 0-3 months, 6-12 months, and 12 months or longer (Figure 4).
4) Postoperative problems: Gingival inflammation, pain of abutment teeth, and discoloration of keepers were observed in 5 of 1123 cases.

調査施設名　　担当医師名

製品名称	一般的名称	義歯アタッチメント用金属（歯科用金属）	販売名	ハイコレックス MD	
患者	（略名）	男 MTS 年 月 日生 女 （ 才）	（職業）	（住所）	外来 入院
疾患		既往歴	合併症 1. 呼吸器疾患　2. 心 疾 患 3. 造血器疾患　4. 腎 疾 患 5. 代謝性疾患　6. 免 疫 疾 患 7. 薬物アレルギー　8. 光線過敏症 （その他 ）		
			合併症の治療薬・併用療法		
	適応症と判断した理由				
上記製品を使用するに至った理由					
使用方法・時期	年 月 日	部位	口腔内適用状況		
	H				
患者の体質等特記事項					
副作用の有無（無・有） → 次頁に詳細に記載して下さい。					
中止	中止理由				

重点調査項目	調 査 内 容
アレルギー反応	・歯肉の発赤，腫脹，かゆみ ・唾液の分泌，喉の渇き ・皮膚の湿疹，発赤，かゆみ
磁界の影響	・歯牙，歯肉の着色 ・歯の動揺増加の有無 ・舌の知覚，味覚の異常

Table 1: Medical Device Adverse Reaction Survey Card and Survey Items

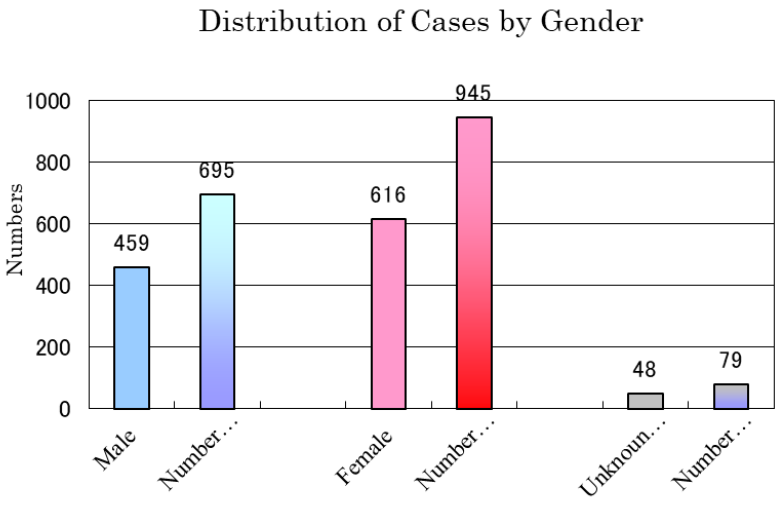


Fig 1: Distribution by gender and number of abutment teeth for magnetic attachments (all 1123 cases, 1719 teeth)

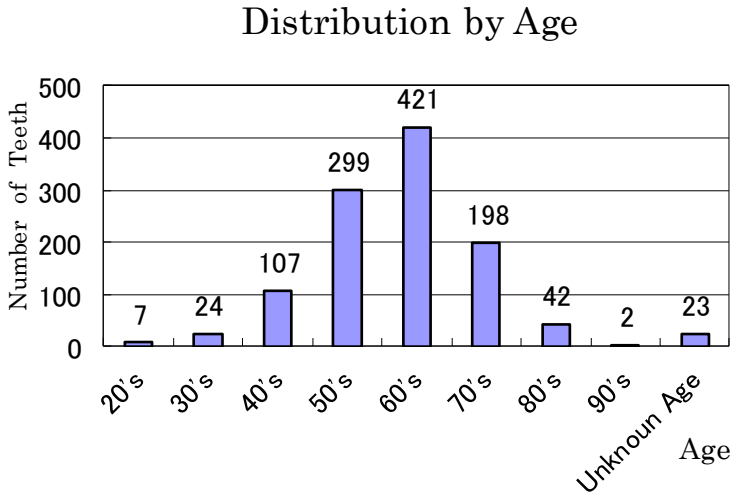


Figure 2: Age distribution of study subjects (all 1123 cases)

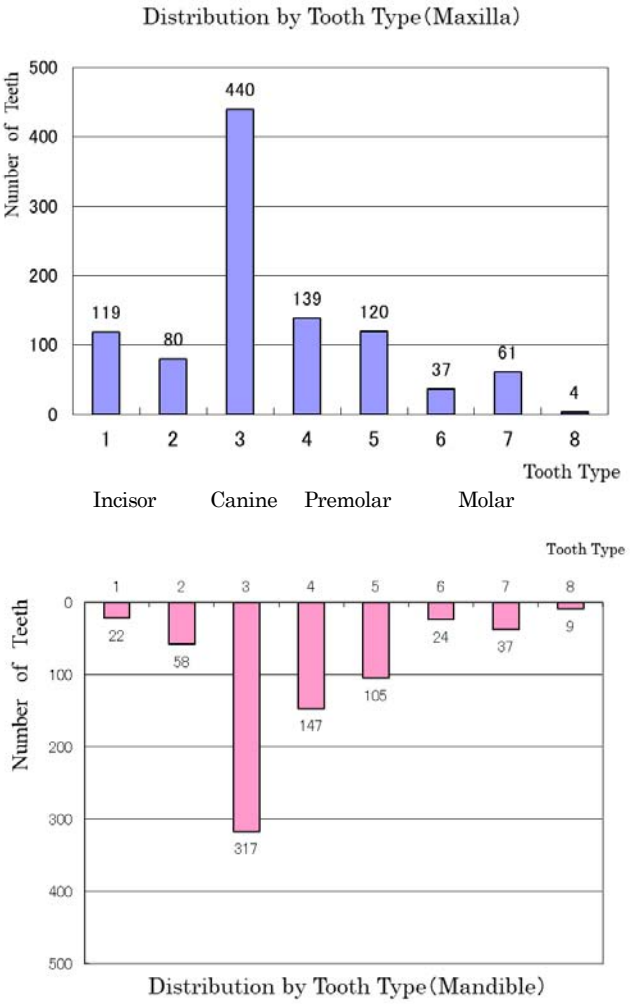


Fig3：Distribution by Tooth Type（Maxilla & Mandible）
（All 1719 abutment teeth）

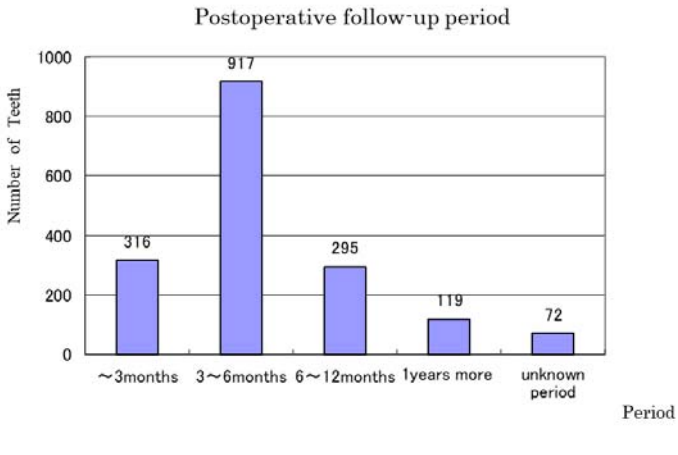


Fig 4: Duration after Delivery of magnetic attachment (all 1719 abutment teeth)

2. Clinical evaluation of Magfit (Prognosis after 10 years)

In 2004, an analysis of the postoperative course of Magfit applied to 105 metal dentures (240 teeth) and 750 resin dentures (1133 teeth) (Table 2) over a 10-year period from May 1993 to May 2003 at Aichi-Gakuin University was published in the Japanese Journal of Magnetic Dentistry, and the following results were obtained[2,3].

1) The average number of magnetic attachments applied per denture: 2.3 teeth for metal dentures and 1.5 teeth for resin dentures (Table 2).

2) Age distribution of metal dentures: The most common age group was 60s, followed by 70s and 50s (Figure 5).

3) Comparison of metal dentures in the upper and lower jaws: The number of abutment teeth in the upper jaw was about 1.5 times greater than that in the lower jaw, and application to the upper

canine was the most common (Fig. 6).

4) Comparison of abutment devices in metal dentures: 42% of the abutment devices were magnetic attachments only, and the remaining 58% were other devices (Table 3).

5) Longevity of abutment teeth in metal dentures: 95% after 5 years and 88% after 10 years (Table 4).

Number of MA abutments	Metal plate	Number of abutment teeth	Resin plate	Number of abutment teeth	Total number of plates	Total number of abutment teeth
1	38	38	492	492	530	530
2	21	42	179	358	200	400
3	28	78	45	135	73	213
4	11	44	26	104	37	148
5	4	20	4	20	8	40
6	3	18	4	24	7	42
Total	105	240	750	1133	855	1373
Average number of abutment teeth per plate		2.3		1.5		1.6

Table2：Number of abutment teeth and distribution by denture plate type for magnetic attachments (MA)

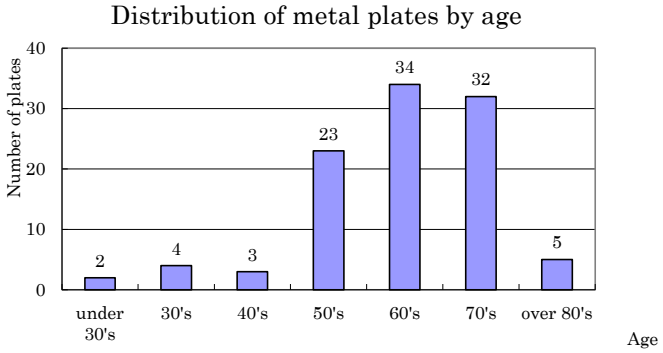


Fig5：Age distribution of subjects (105 total cases)

Number of MA abutments	MA only	Combination with other retainer
1	3	35
2	10	11
3	17	9
4	6	5
5	4	
6	3	
	43	60
	41.7%	58.3%

Table3： Number of abutment teeth of MA's in metal dentures and distribution of retainers by other devices

	After 5 years	After 10 years
Extructed teeth	12	28
Survival rate	95.0%	88.3%

Table 4 ：Survival rate of abutment teeth in metal dentures (All 240 abutment teeth)

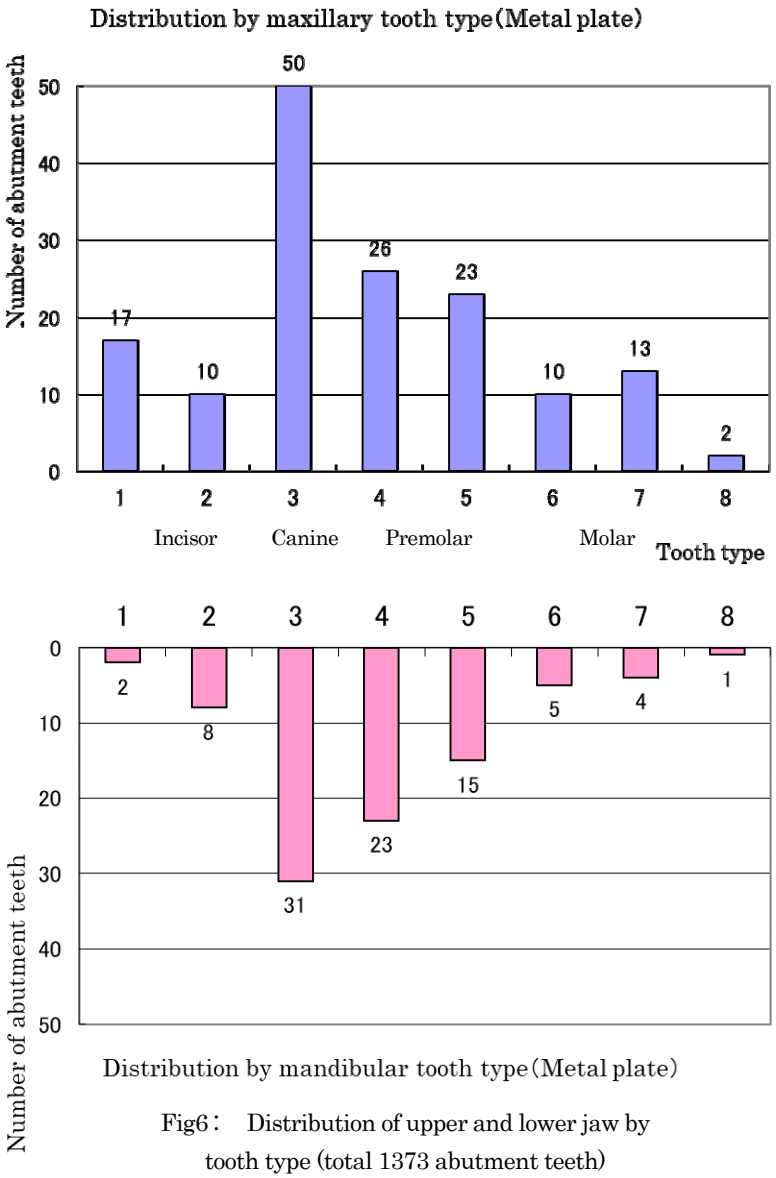


Fig6： Distribution of upper and lower jaw by tooth type (total 1373 abutment teeth)

3. Clinical evaluation of Magfit (Prognosis after 15 years; continuation of 2 (after 10 years).)

In 2009, the progress of 252 teeth was analyzed over a 15-year period from May 1993 to May 2008 for the additional study described in 2. [4].

1) Survival rate of abutment teeth of metal dentures: Of the 252 teeth, 135 (54%) were available for investigation, of which 29 (12%) were lost (extracted) and 106 (42%) remained. Therefore, the survival rate over 15 years was 79% (Table 5, Fig. 7).

2) Survival rate of abutment teeth of resin dentures: Of the 111 dentures examined, 83 (75%) were available, 16 (12%) were lost (extracted), and 67 (60%) remained.)

3) Comparison by tooth type: In the cases with Kennedy Class I and II free end defects, the abutment teeth were frequently extracted. On the other hand, extraction was less common in

cases with all or none of the molar support zone in the A and C types of the Eichner classification (Fig. 8).

4) Comparison of the survival rate of abutment teeth: Metal denture patients aged 75 years or younger had a longer survival rate of abutment teeth than resin denture patients aged 65 years or older (Fig. 9).

	After 15 years
Extructed teeth	29
Survival rate	78.5%

Table5：Survival rate of abutment teeth in metal plate dentures (135 of a total of 252 abutment teeth were eligible for the survey)

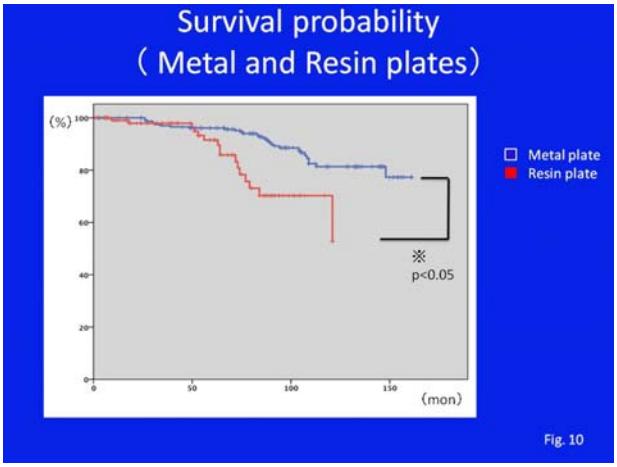
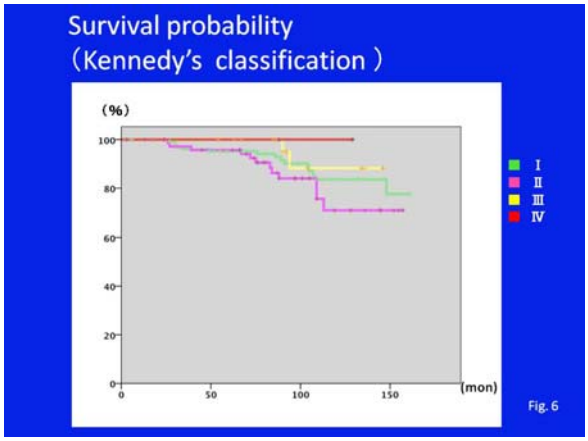


Fig7：Comparison of the life extension rate of abutment teeth between metal and resin dentures (all 83 abutment teeth)



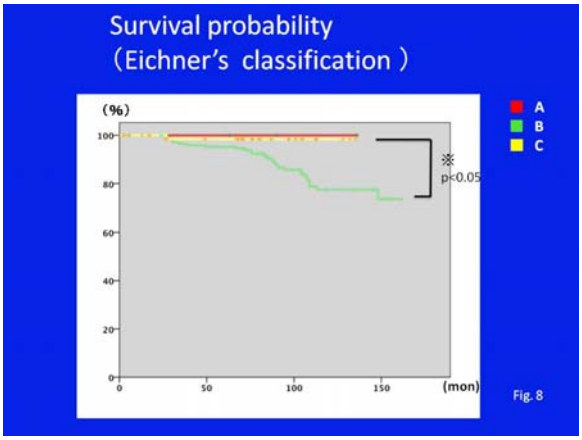


Fig8：Comparison of the life extension rate of abutment teeth by defect type (all 83 abutment teeth)

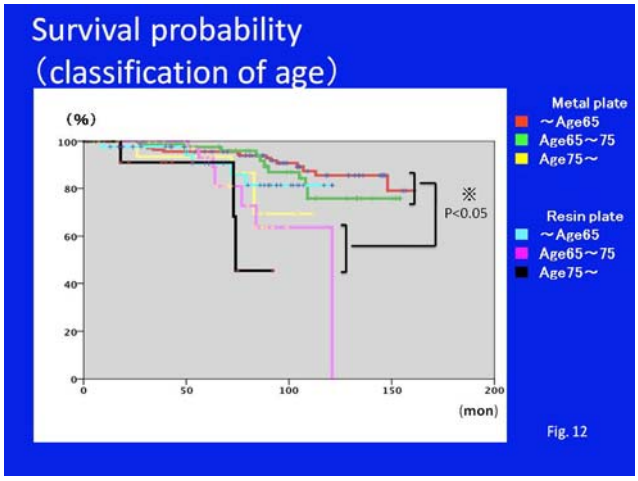


Fig 9：Comparison of the survival rate of abutment teeth of metal and resin dentures by age group (all 83 abutment teeth)

4. Clinical evaluation of Physio-magnet (After 8-12 years)

In 2015, the long-term course of patients wearing Physio-magnets (Hitachi Metals) at Tsurumi University was published in the Journal of the Japanese Society of Magnetic Dentistry, with the following results[5,6] .

1) A survey was conducted on 46 people (mean age 65.4 years) with detailed records of 80 teeth who wore magnetic attachments during the 5-year period from 2002 to 2006 (Fig. 10), of which 19 people and 34 teeth were analyzed (Table 6).

2) Canine teeth were the most common abutment teeth, followed by first bicuspids and second bicuspids (Fig. 11).

3) The average age since implantation was 10.3±1.4 years, 11 (32.4%) of the abutment teeth were lost, and 15 (44.1%, including 4 missing teeth) of the magnetic structure were lost.

4) After approximately 10 years of implantation, 67.6% of the abutment teeth and 55.9% of the magnetic structures were long-lived (Table 7).

5) Comparison of the life expectancy of the abutment teeth after approximately 10 years of implantation by denture base showed that the life expectancy of the metal base was 70.4% and that of the resin base was 57.1%. The metal base showed a better survival rate.

6) Regarding the progress of the periodontal tissues of the abutment teeth, an increase in periodontal pocket depth was observed in approximately 60% of the patients, with 35% having an increase of 1 mm at the deepest point and 26% having an increase of 2 mm (Figure 12).

7) In the survey of abutment teeth at the time of magnetic attachment, 42% of the abutment teeth were upset and about half of the abutment teeth had pocket depths of 3 mm or greater, indicating that the condition of the abutment teeth was not good.

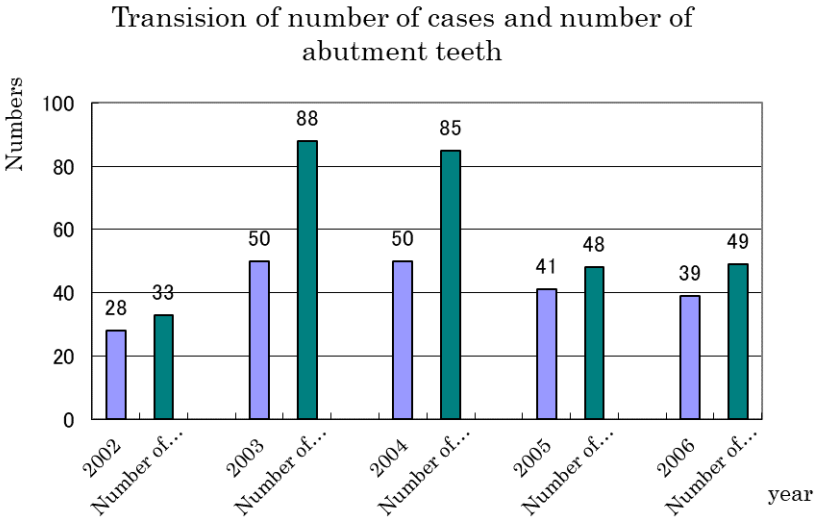


Fig10：Number of MA denture cases and abutment teeth during the study period

	Male	Female	Totale
Number of Cases	1	18	19
Rate	2.2%	39.1%	41.3%
(In 43 total surveyed cases)			

Table 6：Number of cases that responded to the investigation among the recalled cases with complete progress records (43 cases in total)

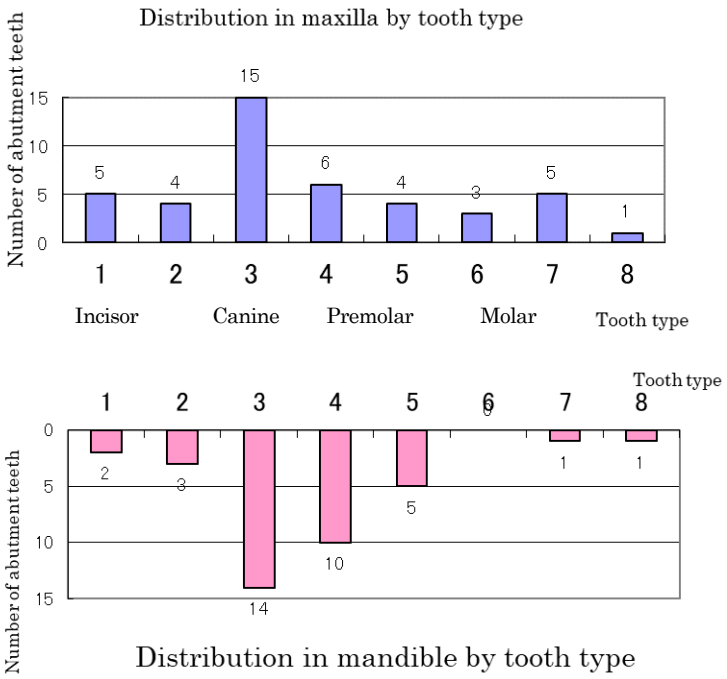


Fig 11：Distribution of upper and lower jaw by tooth type
(total 34 teeth)

	Extructed teeth	Loss of magnet structure	Totale
Number of abutment teeth	11	4	15
Rate	32.4%	11.8%	44.1%
(In 34 abutment teeth of 19 cases)			

Table 7：Progress of abutment teeth
(34 teeth in 19 cases in total)

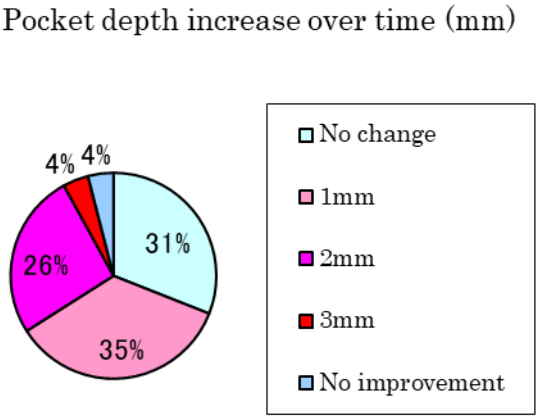


Fig12：Progress of periodontal pocket depth (mm) for each abutment tooth (all 34 teeth)

5. Clinical evaluation of magnetic attachment abutment teeth at multiple institutions

In 2003, the Japanese Society of Magnetic Dentistry began postoperative analysis at each institution using a common protocol developed by the Clinical Evaluation Committee, especially the analysis of periodontal pocket depth of abutment teeth.)

1) Probing values (PD values) of abutment teeth after 5 years of magnetic attachment were

measured using the 6-point method, and cases with a 5-year follow-up by June 2009 were analyzed.

2) At the start of the study, 44 cases were included, but 12 cases were censored, and finally 29 cases, 62 teeth, 16 maxillary and 19 mandibular rests were included (Table 8).

3) The abutment tooth types were 12 incisors, 24 canines, 17 bicuspids, and 9 molars, and the denture bases were 21 resin bases and 14 metal bases (Table 9).

4) The percentage of patients with free end defects was about 90%, and the percentage of patients with loss of occlusal support was about 70% (Fig. 13).

5) PD values of abutment teeth increased significantly after 5 years (Figure 14). In pre- and postoperative comparisons, the PD value of the deepest pocket significantly increased in the maxillary, female, resin-floored abutment teeth (Figs. 15-17).

	Number of cases
Base line at start	44
suspension of investigation	12
	32
Extructed teeth	14

	Number of denture plates	Number of abutment teeth
Maxilla	16	32
Mandible	19	30
	35	62

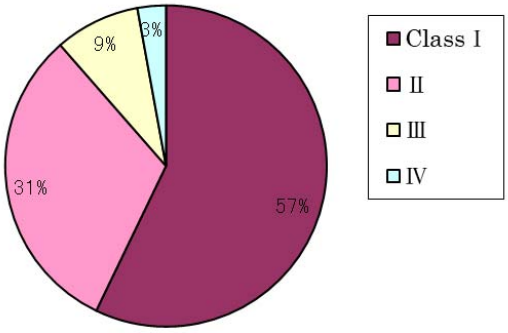
Table 8：Process of the investigation and comparison of all 29 cases analyzed, 35 dentures, and 62 teeth by upper and lower jaws

Tooth type	Incisor	Canine	Premolar	Molar
Number of abutment teeth	12	24	17	9

	Number of denture plates
Metal plate dentures	14
Resin plate dentures	21
	35

Table 9：Distribution by tooth type and comparison by floor (all 29 cases)

Distribution of cases by defect type of dentition
(Kennedy classification)



Distribution of cases by defect type of dentition
(Eichiner classification)

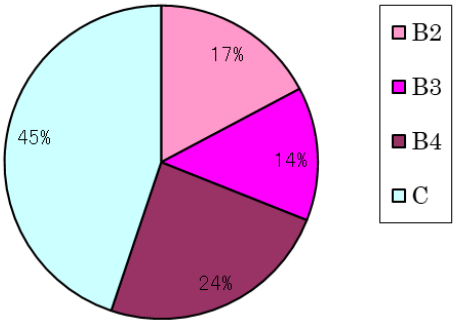


Fig13：Comparison of the survival rate of abutment teeth by defect type of remaining dentition (all 29 cases)

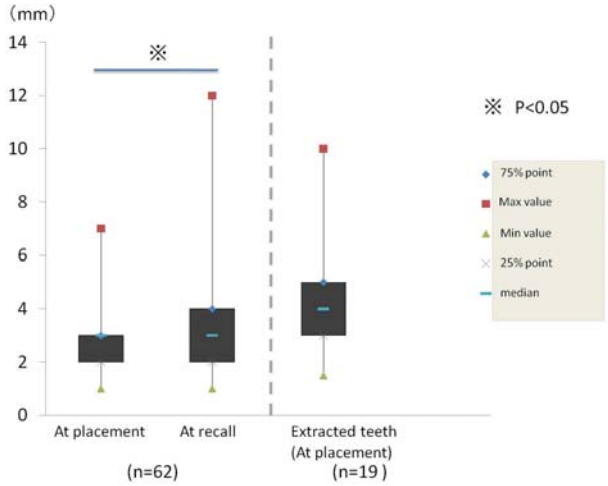


Fig14：Change in pocket depth after 5 years
(all 29 cases, 62 abutment teeth)

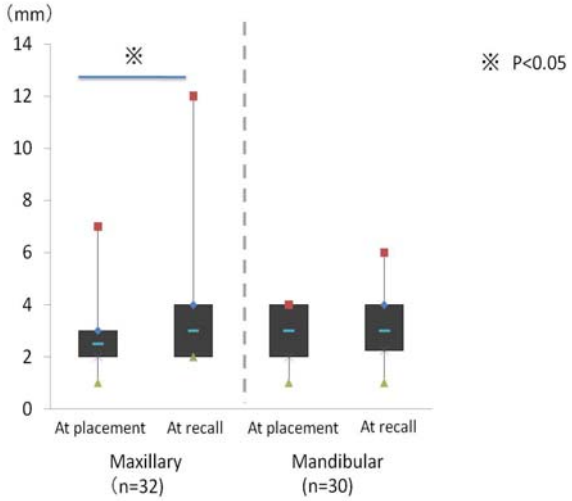


Fig15：Comparison of pocket depth in upper and lower jaws (all 29 cases, 62 abutment teeth)

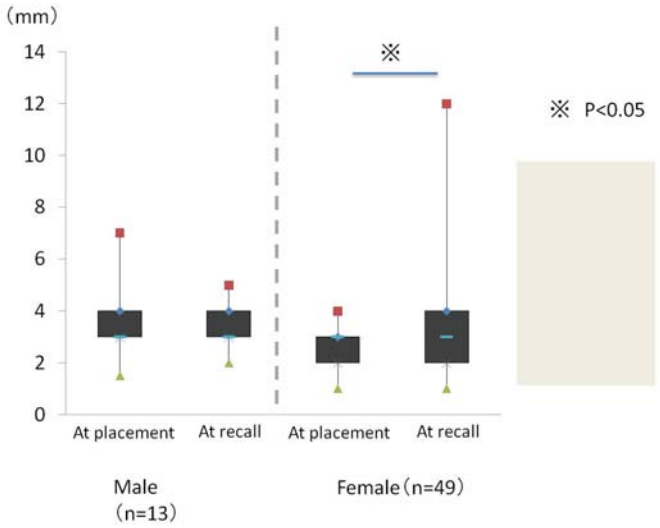


Fig 16：Comparison of pocket depth by gender
(all 29 cases, 62 abutment teeth)

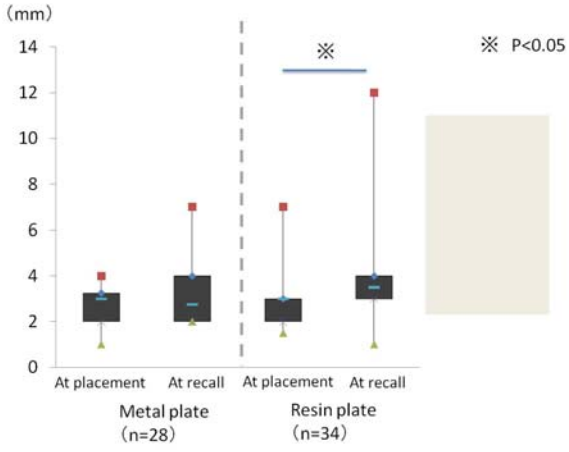


Fig 17：Comparison of pocket depth by denture type
(all 29 cases, 62 teeth)

6. Multicenter clinical evaluation of magnetic attachment abutment teeth (continuation of 5.)

Additional survey of 5. was published in 2012[8,9].

1) At the beginning of the survey, 70 cases were included, but 28 cases were censored, and finally 42 cases, 75 teeth, 24 maxillary abutments and 21 mandibular abutments were included (Table 10).

2) The abutment tooth types were 12 incisors, 29 canines, 25 bicuspids, and 9 molars, and the denture bases were 23 resin and 22 metal (Table 11).

3) The PD values of the abutment teeth increased significantly after 5 years (Figure 17). In pre- and postoperative comparisons, the PD values of the deepest pockets significantly increased in the maxillary, female, and resin-bed abutment teeth, and also significantly increased in the canine abutment teeth and female resin-bed abutment teeth (Figures 18-20).

	Number of cases
Base line at start	70
Suspension of investigation	28
	42
Extructed teeth	18

	Number of denture plates	Number of abutment teeth
Metal plate dentures	24	45
Resin plate dentures	21	30
	45	75

Table 10：Process of the investigation and comparison of all 42 cases analyzed, 45 dentures, and 75 abutment teeth by upper and lower jaws

Tooth type	Incisor	Canine	Premolar	Molar
Number of abutment teeth	12	29	25	9

	Number of denture plates
Metal plate dentures	22
Resin plate dentures	23
	45

Table 11：Distribution by tooth type and comparison by floor (all 42 cases)

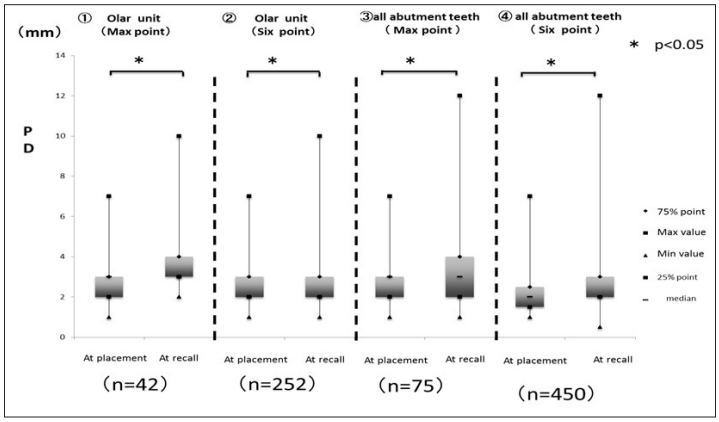


Fig 17：Change in pocket depth after 5 years (all 42 cases, 75 abutment teeth). Comparison between the deepest point of the 6-point method and all measurement points

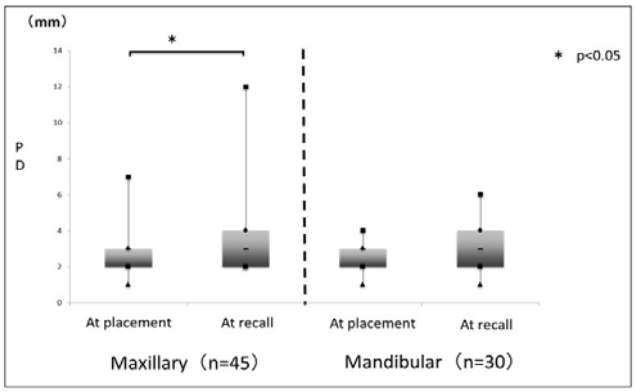


Fig 18：Comparison of pocket depth in upper and lower jaws (total 42 cases, 75 abutment teeth)

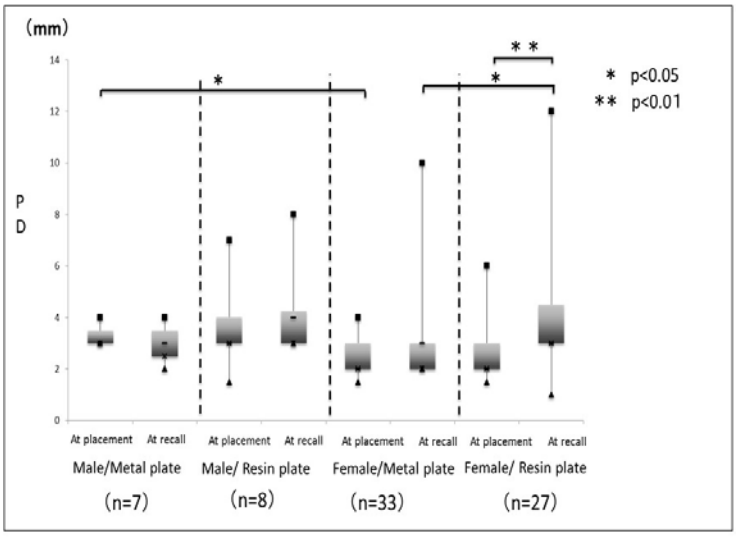


Fig6. .Transition of Pocket Depth (metal and resin plate/gender)

Fig19：Comparison of pocket depth by gender and denture type (all 42 cases, 75 abutment teeth)

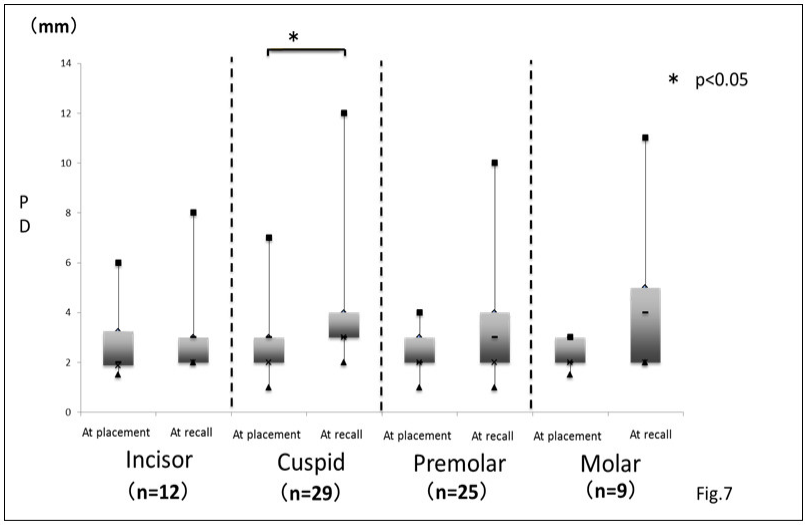


Fig 20：Comparison of pocket depth by tooth type (all 42 cases, 75 abutment teeth)

7. References

1) Mizutani A, Nakamura K, Ai M. A Follow-up Study of Dentures with Magnetic Attachments Using a Surgeon's Questionnaire (in Japanese). Journal of the Japan Prosthodontic Society. 1997; 41:902-909.

2) K. Hoshiai, T. Tanaka, N. Hasegawa, M. Kawakita, W. Fujinami, K. Wakayama, T. Hikosaka, H. Hirai, T. Miyata, K. Kumano, R. Sakane. Postoperative survey of magnetic attachments in metal dentures (in Japanese). Journal of Magnetic Dentistry. 2004; 13(1): 1-8.

3) Hoshiai K, Tanaka Y, Hasegawa N, Kawakita M, Fujinami W, Wakayama K, Imaizumi Y, Matumoto T, Sakane M. Longitudinal Study of Metal Plate Denture with Magnetic Attachments. JJ Mag Dent. 2004; 13(2): 26-29.

4) Ito R, Hoshiai K, Hasegawa N, Muraji N, Kaaguchi T, Noda K, Watanabe N, Tanaka Y.: Longitudinal Study on Metal Plate Denture with Magnetic Attachments. J J Mag Dent. 2009; 18(2): 8-14.

5) Shigeko Takayama: Special feature: Reexamination of magnetic attachments based on long-term follow-up, Current status of magnetic attachments from the viewpoint of prognosis study (in Japanese), Journal of Magnetic Dentistry., 24(1): 30-31, 2015.

6) Shuji Okawa: Special feature: Reexamination of magnetic attachments after long-term follow-up - Summary of the symposium (in Japanese) -, Journal of Magnetic Dentistry 24(1): 30-31, 2015.

7) Ito R, Hoshiai K, Tanaka Y, Ishigami T, Ishibashi T, Bando E, Sasaki H. Longitudinal Study of Magnetic Attachments -Investigation ob Probing Depth on J J Mag Dent. 2010; 22(3):321-322. J J Mag Dent. 2010; 19(2): 35-39.

8) Miwata M, Ito R, Hoshiai K, Tanaka Y, Ishigami T, Ishibashi K, Bando E, Sasaki H. Mizutani H, Hosoi T: Longitudinal Study of Magnetic Attachments - Investigation ob Probing Depth on Abutment teeth-. J J Mag Dent. 2010; 20(2): 73-78.

9) Ito R, Miwata M, Hoshiai K, Tanaka Y, Ishigami T, Ishibashi T, Bando E, Sasaki H. Longitudinal Study of Magnetic Attachments -Investigation ob Probing Depth on Abutment teeth Part.2-. Depth on Abutment teeth Part.3-. J J Mag Dent. 2011; 20(2): 69-72.

Ⅲ. International Standardization of Magnetic Attachments

1. History of International Standardization

In 2005, the Japanese Society of Magnetic Dentistry, led by the Japan Society of Magnetic Dentistry, obtained a grant from the New Energy and Industrial Technology Development Organization (NEDO) under the research theme of "Optimization of Magnetic Attachments for Dental Use and Creation of International Standards" and launched an effort toward international standardization of magnetic attachments by establishing the Magnetic Attachment Standardization Committee. The efforts toward the international standardization of magnetic attachments began with the establishment of the Magnetic Attachment Standardization Committee (Fig. 1).

Optimization and International Standardization of the Magnetic Dental Attachment

by New Energy and Industrial Technology Development Organization (NEDO)

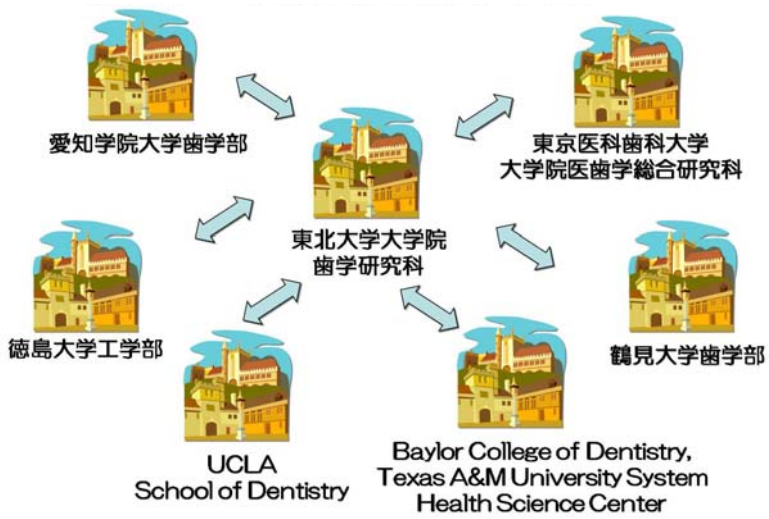


Fig 1: Participating organizations at the time of the establishment of the Magnetic Attachment Standardization Committee

In 2007, at the ISO/TC106 Berlin meeting, a New Work Item Proposal (NP) was submitted to Subcommittee 2 (SC2), which develops standards for prosthetic materials. At the following meeting of ISO/TC106 in Gothenburg in 2008, WG22 (Working group 22) Magnetic attachments was newly organized in SC2. Japan became the chairing country of WG22, and the Magnetic Attachments Standardization Committee produced a convener (chairperson) and a Japanese expert. At this meeting, the Japanese draft standard (Dentistry - Magnetic Attachments) was adopted as a working draft (WD) and approved as ISO/ WD 13017[1]. In the same year, the NEDO support was terminated, and an ISO task force committee was established in the Japan Society of Magnetic Dentistry to take over the

development of the ISO standard (Figure 2).

In May 2009, the NEDO-supported follow-up project was selected as the next grant, and the Standardization Committee for Magnetic Dental Attachments was reorganized with the members of the ISO task force committee. At the ISO/ TC106 Osaka meeting in September of the same year, the CD (committee draft) ballot for ISO/ WD 13017 was approved, and the committee was promoted to ISO/CD 13017 in the CD ballot held in March 2010. The DIS (draft International Standard) ballot for ISO/CD 13017 was approved at the ISO/ TC106 General Assembly, and the standard was promoted to ISO/DIS 13017 in the June 2011 DIS ballot without any negative votes. Furthermore, ISO/ FDIS 13017 was approved through FDIS (Final Draft International Standard) balloting in June 2012, and ISO 13017 was published as an international standard on July 15, 2012, thus achieving the international standardization of magnetic attachments[2] (Figure 3).

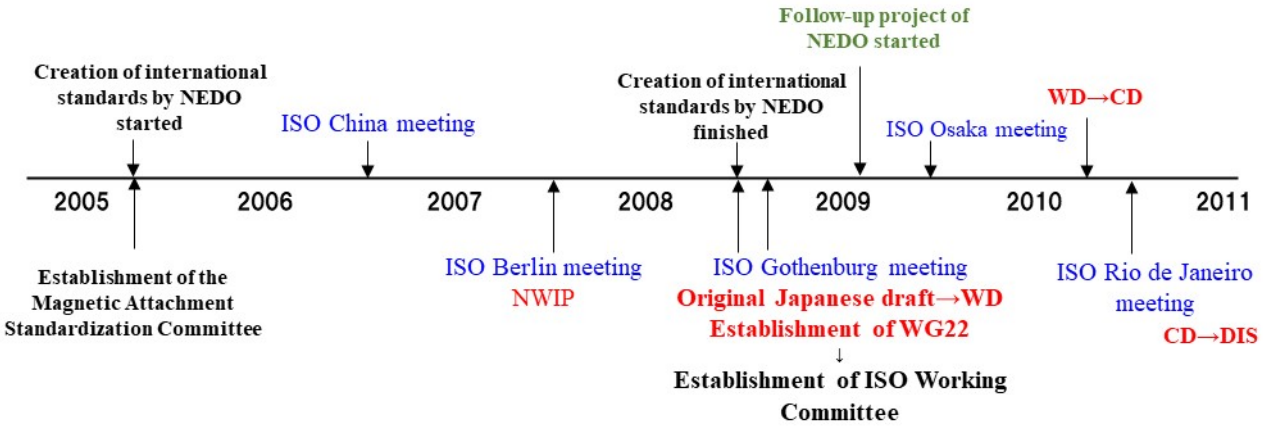


Fig 2. International standardization of magnetic attachments (2005-2011)

Ballot Information

Reference	ISO/FDIS 13017	**Committee**	ISO/TC 106/SC 2
Edition number	1		
English title	Dentistry -- Magnetic attachments		
French title	Médecine bucco-dentaire -- Attaches magnétiques		
Start date	2012-04-26	**End date**	2012-06-26
Opened by ISO/CS on	2012-04-26 00:04:07	**Closed by ISO/CS on**	2012-06-28 00:24:18
Status	Closed		
Voting stage	Approval	**Version number**	1
Note			
Vienna agreement	ISO lead	**CEN ballot type**	Formal Vote
CEN reference	FprEN ISO 13017	**CEN committee**	CEN/TC 55

Result of voting

P-Members voting: 18 in favour out of 18 = 100 % (requirement >= 66.66%)

(P-Members having abstained are not counted in this vote.)

Member bodies voting: 0 negative votes out of 21 = 0 % (requirement <= 25%)

Approved

Fig 3: ISO/FDIS 13017 voting results

However, it was developed in a short period of four years after the ISO task force was established, and in addition, there were points that were unsatisfactory as a provision for measuring retentive force that can fully evaluate the uniqueness of domestic magnetic attachments that show strong retentive force even though they are small in size. Therefore, based on the progress of international standardization of the maintenance force measurement method for magnetic attachments, which we have been working on in parallel since 2010, we started activities to apply for the supplemental version of ISO 13017 at the same time as the publication of the international standard. The draft standard was submitted with a high degree of completeness due to the preparations that had been made since 2010, and therefore, it is usually considered as a work in progress.

Although deliberation would be made from the Draft WD, the wish for deliberation from the Draft International Standard (DIS) was also passed at the same time (Figure 4).

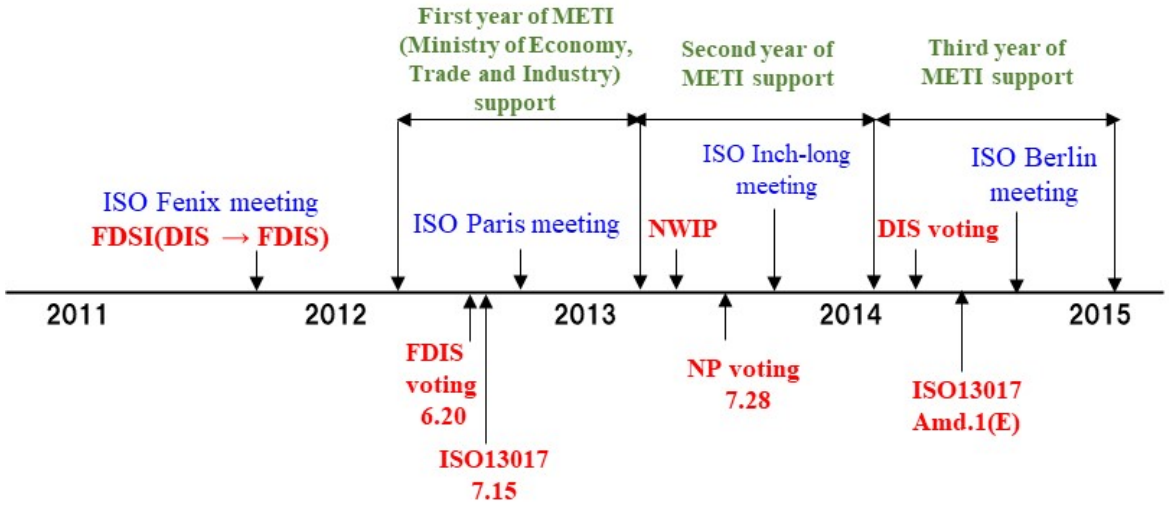
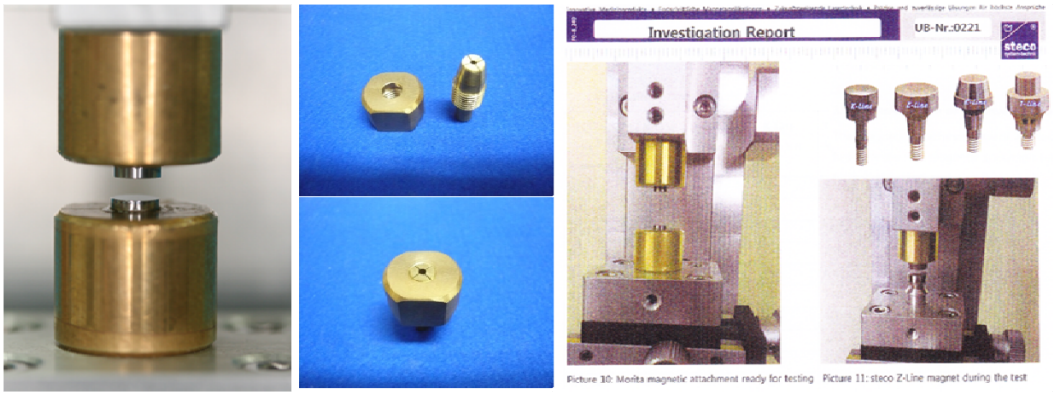


Figure 4: International standardization of magnetic attachments (2011-2015)

The draft Amendment was subsequently revised, and after the 2013 Inchon meeting, it was elevated to ISO13017: DAM.1 (Draft International Standard as supplement) through DAM ballot (DIS ballot as supplement) [4]. During the DAM ballot, Germany objected that the amendments made at the Inchon meeting were not fully reflected in the draft Amendment. However, it turned out that the draft Amendment circulated for DAM balloting before the Inchon meeting was a systemic deficiency caused by the fact that it was circulated before the Inchon meeting, and the German approval was obtained. In addition, Australia proposed a request for additional friction provisions, which was revised with sufficient evidence and approved for FDAM (draft final international standard for addendum) ballot at

the Berlin meeting in 2014. At the Berlin meeting, the results of interlaboratory tests conducted in three countries (Japan, Germany, and China) were reported (Figure 5) and discussed on the improvement of the specimen fixation method, the definition of maintenance force and its calculation method, and the definition of friction force during vertical specimen movement. After returning to Japan, we revised and added to the current DAM.1 according to the points raised and submitted the draft FDAM.1 to the SC2 secretariat[5].



(a) Japan (b) China (c) Germany

Fig 5. Interlaboratory testing (specimen table and fixation method for post-keeper)

FDAM registration was completed in 2015, and in September, FDAM ballot elevated it to FDAM.1 (the final draft International Standard for the addendum). At that time, the integration of ISO 13017 and Amd.1 (the supplemental version) was pointed out by Germany, and a slight modification of the format was pointed out by the UK, but the revised version of FDAM was submitted after the Bangkok meeting in September 2015. The integration of ISO 13017 and Amd.1 (supplemental version) was proposed and approved at the time of the periodic review in 2017, which is conducted every five years after the publication of an international standard[6]. Thus, ISO 13017:2012/Amd.1 (the supplement to ISO 13017) was published in November 2015[7] (Figure 6).

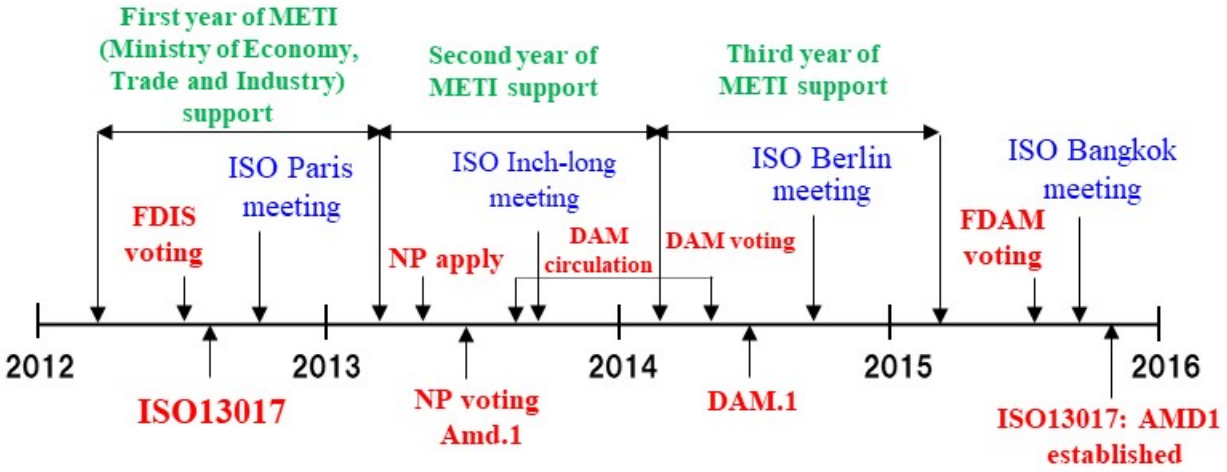


Fig 6　International standardization of magnetic attachments in dentistry (2012-2016)

The international standardization of magnetic attachments, which started in 2005, has been accomplished after 11 years with the publication of two international standards, ISO 13017 and ISO 13017:2012/Amd.1 (supplemental version). The two international standards will be integrated for the periodic review in 2017 (Figure 7) .

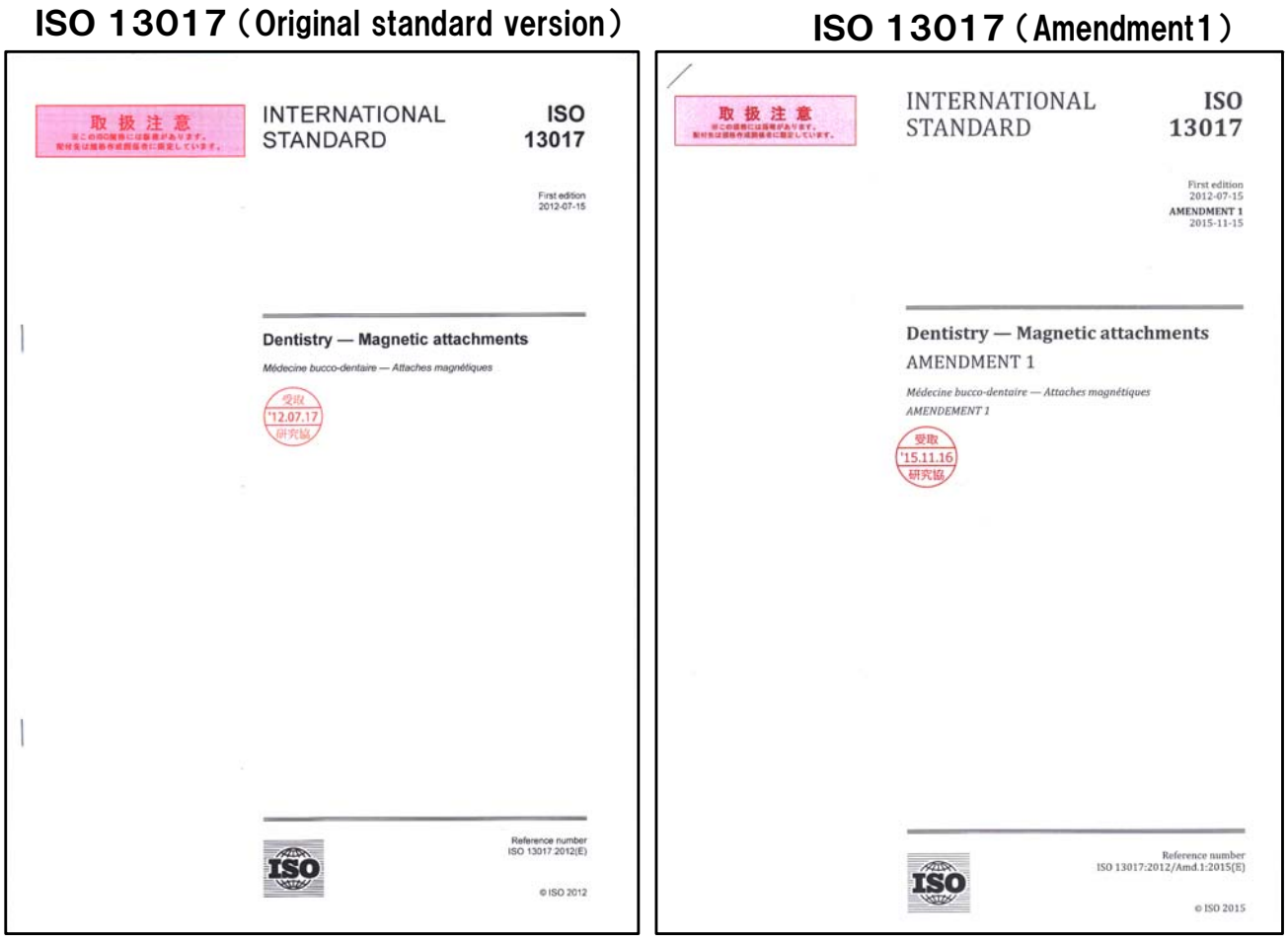


Fig 7　ISO 13017and Amendment 1(Supplemental ed.)

2. Structure of ISO 13017 and outline of the supplemental edition

Figure 8 shows the structure of ISO 13017 and the supplement to the standard by Amd. 1 (supplement). Underlines indicate the parts supplemented by Amd.1.

ISO 13017 consists of items 1 to 8, and is mainly supplemented by Amd. 1, which covers the preparation of specimens (5.1 Maintenance force) in 5. and test methods (6.3 Maintenance force, 6.4 Corrosion resistance) in 6.

In 3. Terms and definitions, terms and definitions related to dental magnetic attachment types, magnets and magnetic structures, keepers, magnetic circuits, etc. are given. For example, magnetic attachments without a magnetic circuit are defined as "magnet" and those with a magnetic circuit as "magnet structure (magnet) assembly" to clarify that magnetic attachments in Japan are magnet structures.

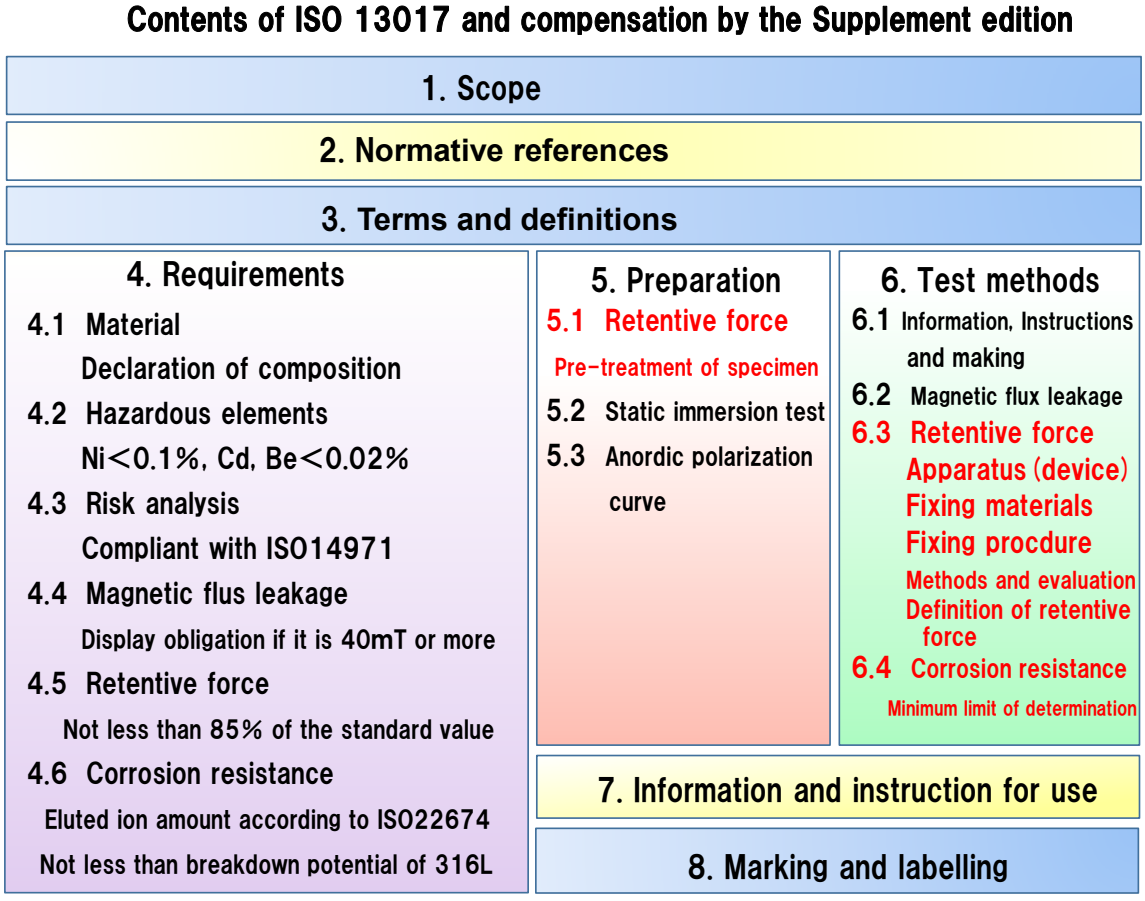


Fig 8 Contents of ISO 13017 and compensation by the Supplement edition.

The requirements in Section 4 consist of 4.1 Materials, 4.2 Hazardous Elements, 4.3 Risk Analysis, 4.4 Leakage Field, 4.5 Maintenance Force, and 4.6 Corrosion Resistance. 4.1 Materials uses the

ISO standard classification that defines magnets, and only major constituent elements are indicated to prevent leakage of trade secrets. 4.6 Corrosion resistance: Corrosion resistance of stainless steel 316L or higher for orthopedic use for biological use was specified to maintain quality and to prevent distribution of pirated copies.

In 5. Preparation of specimens, preparation of specimens at the time of testing is specified, and in 5.1 Sustaining force, the pretreatment method is added according to Amd. 1.

Amd. 1 specified in detail the method of measuring 6.3 maintenance force, the jig to be used (Figs. 9 and 10), the method of calculating the maintenance force (Fig. 11), and the measurement method with high accuracy and reproducibility (Fig. 12). 6.4. In corrosion resistance, in order to clarify the quantitative analysis of impurity element ions in static immersion tests, the lower limit of quantification and detection limit of the chemical analysis method were introduced, and accurate quantification was specified.

7. and 8. specify descriptions and labeling contents to support the product.

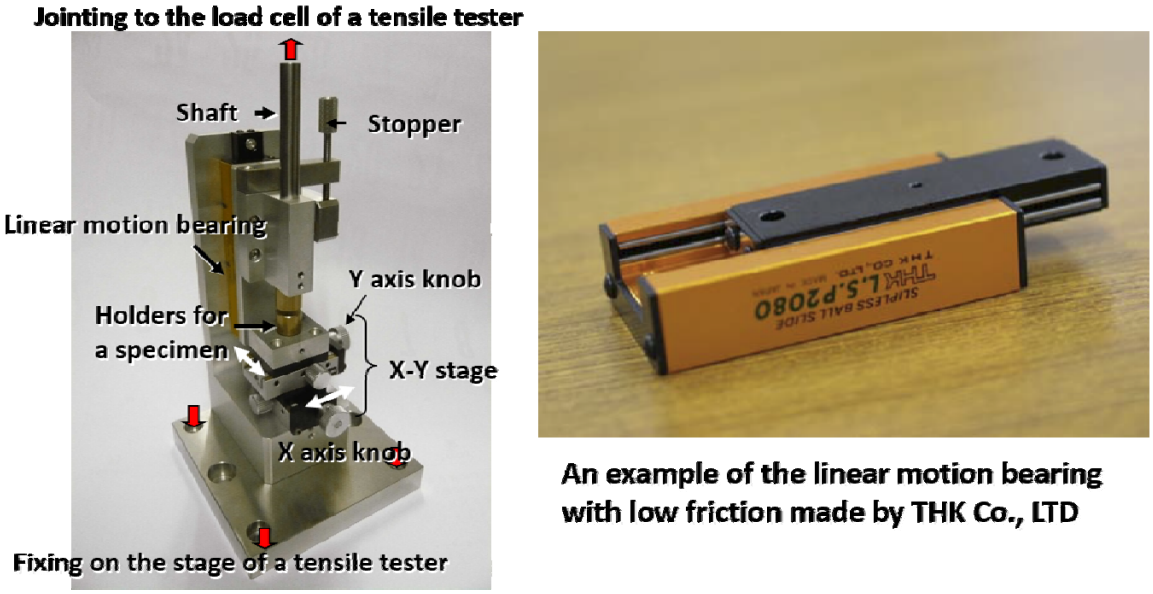


Fig 9 Overview of the jig for measuring retention force (left) and the low-friction linear slider (right)

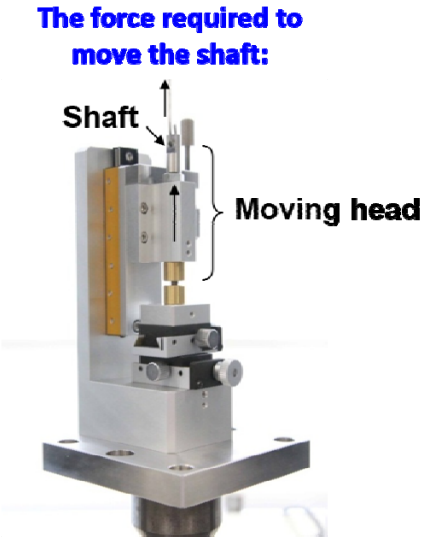


Fig 10. Retentive Force Measuring Jig

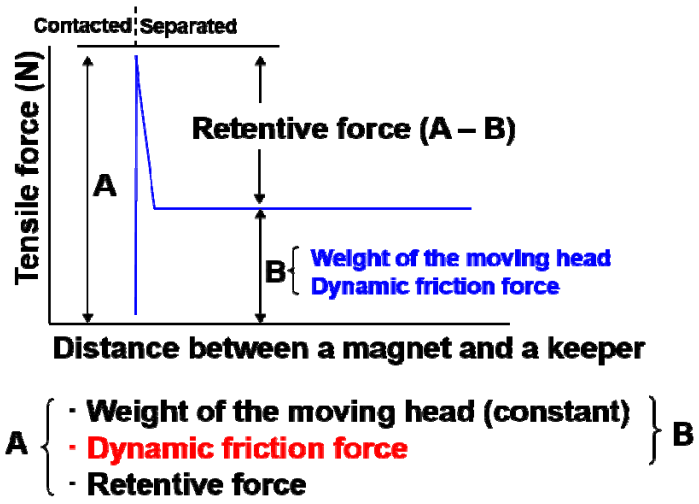


Fig 11. Retentive Force Curve

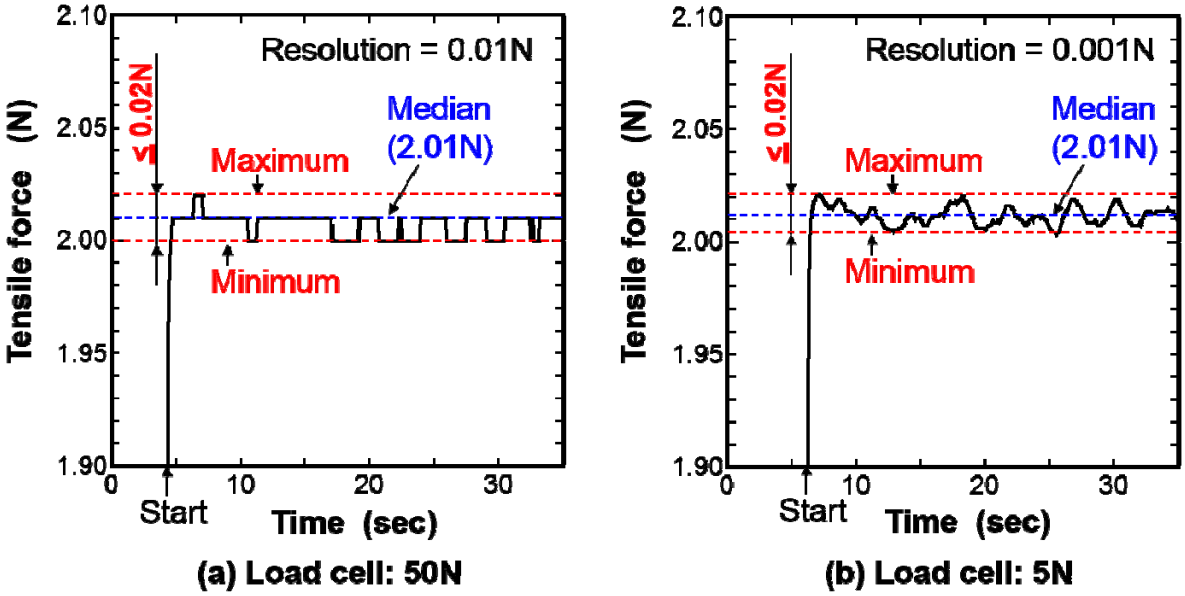


Fig12: Dynamic frictional force and change in the jig for measuring maintenance force

3. References

1) ISO 13017: 2012(E), Dentistry -Magnetic attachments.

2) Y. Takada: ISO Task Force Report: Toward International Standardization of Magnetic Attachments for Dental Use (in Japanese), Journal of Magnetic Dentistry, 20(1): 81-85, 2011.

3) Y. Takada: Report of the ISO Task Force Committee: Toward the International Standardization of Magnetic Dental Attachments, - ISO/TC 106 Paris Conference - (in Japanese), Journal of Magnetic Dentistry, 22(1): 65-68, 2013.

4) Takada, Y.: Report of the ISO Task Force Committee: Toward International Standardization of Magnetic Dental Attachments, - ISO/TC 106 Inchon Meeting -, (in Japanese). Journal of Magnetic Dentistry, 23(1): 72-76, 2014.

5) Takada, Y.: Report of the ISO Task Force Committee: Toward International Standardization of Magnetic Dental Attachments, - ISO/TC 106 Berlin Meeting , (in Japanese) . Journal of Magnetic Dentistry, 24(1): 48-53, 2015.

6) Y. Takada: Report of the ISO Task Force Committee Toward International Standardization of Magnetic Dental Attachments, - ISO/TC 106 Bangkok Conference (in Japanese)-, Journal of Magnetic Dentistry 25(1): 39-44, 2016.

7) ISO 13017: 2012(E)/Amd.1, Dentistry -Magnetic attachments.

IV. Development of Clinical Practice Guidelines for Magnetic Attachments

1. Background of the development of medical practice guideline

In recent years, rapid changes in the composition of the population and the structure of disease, as well as the need for evidence-based medicine and improvement in the quality of medical care as a social accountability for clarifying human rights and the right to choose medical care, have prompted various academic societies to develop guidelines for medical practice. In the Japanese Society of Magnetic Dentistry, the Medical Committee has been playing a central role in the formulation of practice guidelines for magnetic attachments since 2009.

However, unlike general dentistry, the application of magnetic attachments to complete dentures is not covered by insurance, so there are various restrictions on the conditions and selection of applicable cases, and on the facilities where they are used. Therefore, the Medical Committee first conducted a questionnaire survey on the pros and cons of introducing magnetic attachments to the insurance system, mainly among those who had served on the board of directors of academic societies. As a result, of the 116 responses, 26 were in favor, 29 were conditionally in favor, and 37 were opposed, indicating that many were both in favor and opposed[1)].

In Phase I, the Medical Committee surveyed CQs that raised clinical questions and collected 147 questions, from which 14 representative CQs were selected: 4 on implants, 3 on defect styles, 3 on occlusion/periodontal disease, 2 on abutment placement/form, and 2 on management/others[1-4)]. In the second year of the project, eight courses were asked to develop guidelines in accordance with the GRADE system[5,6)]. In addition, in order to inform the public about the significance of medical practice guidelines and the steps involved in their development, we requested lectures at the 21st Annual Meeting on the theme of "Development of Medical Practice Guidelines for Magnetic Attachments" by persons with experience in developing clinical practice guidelines in various specialties, introducing how to proceed with evidence collection and the Delphi method[7-9)] when evidence is insufficient, as well as discussion. The speakers introduced and discussed how to proceed with evidence collection and the Delphi method[7-9)] when there is a lack of evidence. At the 22nd Annual Meeting, an educational symposium was held by the former Vice President and the former President on the merits of magnetic attachment application, failures due to magnetic attachment application, and countermeasures against them under the theme of "If you have a problem with magnetic attachments "[9)] . Furthermore, at the 23rd Annual Conference, a practice guideline symposium was held under the theme of "Application of

Magnetic Attachments to Implants vs. Natural Teeth "[10].

Through the above process, we have raised awareness of the issue of practice guidelines among the members of the society and have tried to spread awareness of the significance of the practice guidelines.

“Clinical practice guidelines" are practice guidelines based on Evidence Based Medicine (EBM), which support dentists in general dental practice in making appropriate choices and decisions about prevention and treatment of dental diseases under specific clinical circumstances[11]. Therefore, they are different from procedural instructions or insurance guidelines, and they are not intended to regulate the discretion of dentists.

In recent years, the mainstream in the formulation of medical practice guidelines has been to evaluate evidence and determine recommendations using the system devised by the GRADE (Grading of Recommendations Assessment, Development and Evaluation) Group[5,6] , and the Japan Medical Evaluation Organization (JMEDO) has been working on the development of medical information guidelines. The MINDS (Medical Information Network Distribution Service)[12] of the Japan Medical Evaluation Organization and the Japanese Dental Association also recommend the GRADE system. This method takes into account 3 factors: the physician's expertise, experience, and skills; patient factors; and quality of evidence. Recommendations are determined by comprehensively judging four major factors: quality of evidence, balance of benefits and disadvantages, values and preferences, and cost and resource utilization[3,4].

However, because of the special nature of prosthetic dentistry and the lack of evidence in magnetic dentistry, which is a new field, we have incorporated evaluation methods that take advantage of the characteristics and originality of our society while referring to the GRADE system. For example, in the medical field, epidemiological verification is essential, but in the field of prosthodontics and magnetic attachments, model experiments and simulation experiments are more reproducible and can be cited as sufficient evidence for the maintenance and durability of outcomes, etc. Therefore, as one of the levels of evidence, S (very low), B (low) and C (very high) were added in addition to A (high), B (low) and C (very low). S (Simulated or model experiment) was added to A (high), B (low), and C (very low) as one of the levels of evidence[13].

In addition, when evidence was insufficient or conflicting, a questionnaire survey including the Delphi method was conducted to supplement the evidence. Furthermore, a consensus group was formed for each clinical question (CQ: Clinical Question) and asked to review the description of

the practice guideline for each CQ, which was finally summarized by the medical committee[8,9] .

At present, there are many CQs for which there is insufficient evidence, and we believe that not only the Magnetic Dentistry Society but also the dental community as a whole should urgently address these as research themes. It is necessary to continue to make many reorganizations, such as adding CQs, revising recommendations, and developing a system to accept users' opinions and suggestions on the contents of recommendations.

2. Survey and selection of clinical questions for magnetic attachments in dental practice

For the selection of clinical questions (CQ: Clinical Question) for magnetic attachments (MA), a questionnaire survey was sent by e-mail to experienced officers of the society, requesting a wide range of responses from dentists at their facilities and general clinicians in the community[1),]. In addition, we distributed the questionnaire to the participants of the 19th Annual Meeting, published it on the website of the Society and in the Journal of the Society[2)], and mailed the survey to the academic members of the dental associations in each prefecture.

The CQs consisted of Patient, Intervention, Comparison, and Outcome. The survey was conducted in accordance with the PICO format, with examples provided and multiple responses requested (Table 1).

In case of ～ (patient or problem:P)	is ～ (intervention:I)	compared to～ (comparison:C)	effective? (outcome:O)
1) In case of few remaining mandibular teeth	is a magnetic attachment	compared to applying clasps	effective?
2) In case of implant-supported overlay dentures,	is a magnetic attachment	compared to other types of retainers	effective?
3) When applying a magnetic attachment to a remaining abutment tooth	is a flat-type keeper	compared to dome-shaped keepers	effective for stability of the denture?
①			
②			
③			

Table 1: Questionnaire regarding clinical questions

The results of the survey revealed that 117 respondents responded to the questionnaire, and a total of 147 CQs were collected[1-4)]. Of the 117 respondents, 77 had more than 10 years of clinical experience, 18 had 5 to 10 years, 21 had 2 to 5 years, and 1 was a resident. Sixty-seven respondents were working in general dentistry or clinics, and 50 were working at university hospitals. Fifty-two were members of the university, 64 were non-members, and one was not listed. Fifty-eight patients

had more than 10 cases of magnetic attachments, 12 had 5 to 10 cases, 24 had less than 5 cases, and 23 had no experience.

The number of CQs categorized into five groups according to content is as follows.

1) Implant-related: 21

2) Comparison with other systems in terms of defect style: 51

3) Comparison with other systems in terms of occlusion and periodontal disease: 17

4) Placement and form of abutment teeth: 27

5) Management and others: 31

From the above CQs, a total of 14 CQs were selected as representative CQs: 4 on implants, 3 on deficiency styles, 3 on occlusion/periodontal disease, 2 on abutment placement/form, and 2 on management/others. The CQs were reviewed and discussed during the formulation process, and responses to the 12 CQs were finally prepared[8-10] (Table 2).

Ⅰ. Implant

1. In case of implant-supported overlay dentures, is magnetic attachments (MAs) more effective than applying other type of retainers?
2. In implant-supported overlay dentures, are applying MAs to implant abutments more successful than applying them to natural teeth?
3. Applying MAs to implant-supported overlay denture cases, are maxillary cases more successful than mandibular ones?
4. Applying MAs to implant-supported overlay denture cases, are multiple abutments with MAs more effective than a single abutment?

Ⅱ. Defects

5. In few remaining mandibular teeth, are applying MAs more effective than other type of retainers?
6. In free-end saddle removable partial dentures, are applying MAs more effective than other type of retainers?

Ⅲ. Occlusion/Periodontics

7. In partially edentulous without occlusal contact, are applying MAs more successful than other type of retainers?
8. In partially edentulous with undulating occlusal planes, are applying MAs more effective than other type of retainers?
9. When remaining abutments are with periodontal disease, are applying MAs more successful than other type of retainers?

Ⅳ. Arrange / Form

10. Applying MA s to multiple abutment teeth, are symmetrical arrangements more effective than asymmetrical ones?
11. Applying MA s to remaining abutment teeth, is flat type keeper more effective than dome-shaped keeper for stability of the denture?

Ⅴ. Manage/etc

12. When setting MAs to removable partial dentures, is the applied pressure method more successful than the minimum pressure ones?

Table 2: 12 CQs (Clinical Questions) and the formulating process
(MA：Magnetic Attachment, DM：Delphi Method)
Other devices refer to various attachments other than clasps and magnetic attachments

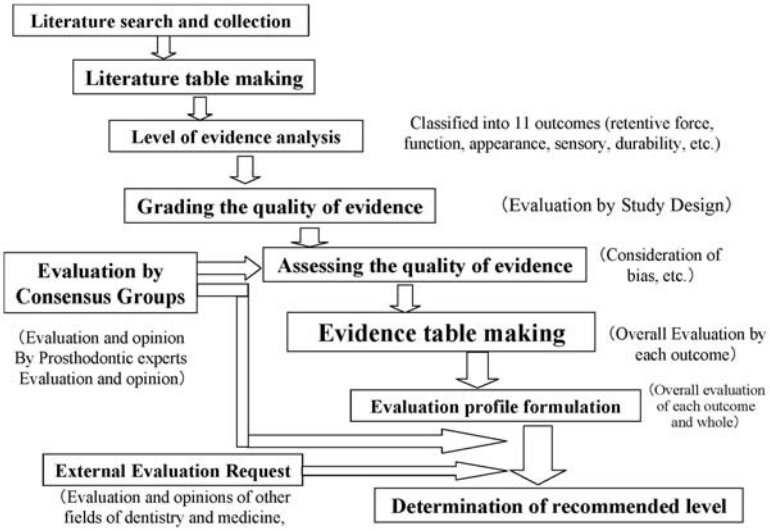
3. Methods of evidence collection

Literature searches were conducted using MEDLINE, Medical Journal Web (Ver. 4), Cochrane Oral Health Group Trials Register, Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE, UMIN Clinical Trials Registry (UMIN-CTR), etc. The search principle was to search for references that were searchable in the databases by October 2012. Randomized controlled trials (RCTs), cohort studies, case-control studies, cross-sectional studies, observational studies, and case reports were searched, and their citations were hand-searched.

4. Process and criteria for determining the level of recommendation

The most important role of a guideline is to clearly state the level of recommendation. In this guideline, the GRADE system was used as a reference, and the following process was used to determine the level of recommendation, taking into consideration the special characteristics of prosthodontics.

Process for determining the level of recommendation



Factors Considered in Making Recommendations

Level of evidence in terms of study design

Level of Evidence	Research Design
A（High）	Randomized controlled trials, Systematic review
B（Low）	observational study

C（Very Low）	Case Reports, Case Studies
S	Model experiments and demonstrations using engineering methods

Quality of Evidence

Quality of Evidence	Meaning
H（High）	Little to no change in estimated effects
M（Midle）	There may be a possibility of changing in estimated effect
L（Low）	Possible change in estimated effect
VL（Very Low）	Estimated effects are very uncertain

In the case of evidence from engineering methods, the possibility of changing the estimated effect was evaluated based on whether the environment was fully realized in vivo and whether the estimation was based on an understanding of the problems with engineering methods[13].

5. Consensus method

Due to the clinical specificity of prosthetic dental practice, there is not always a high level of evidence for many CQs. When the quality of evidence is not sufficiently high for a guideline for each CQ, or when there are conflicting opinions, recommendations and opinions based on expert consensus were appended.

The consensus was formed by choosing between the Delphi method for the consensus group (determined by the subcommittee for each CQ, taking into account the areas of expertise) and a standard questionnaire survey of members.

*About the Delphi method

Questionnaire surveys using the Delphi method were conducted in the following cases[7-10].

As a result of collecting evidence by the aforementioned methods

・When no references could be found at all

・When the number of references is small and the quality of evidence is very low (VL)

・When the literature search results in conflicting opinions and it is difficult to make a judgment.

The Delphi method was conducted in the following steps.

・Phase 1: Questionnaires were solicited from guideline developers for each CQ for which no evidence could be obtained from the literature search. The questionnaires were compiled and the first questionnaire was prepared.

・Phase 2: Questionnaires were distributed to the consensus group, who were asked to predict the numerical value of each item and to indicate their level of agreement by giving a score. The second questionnaire was prepared by tabulating the scores and expressing them in a frequency distribution for each question, as well as improving the points raised by the consensus members.

・Phase 3: The results of the first questionnaire (results for the consensus group as a whole, with the questions distributed by frequency distribution) and the second questionnaire were distributed to the consensus group, and the respondents were asked to indicate their level of agreement with the content of each item again by giving a score. Here, respondents were allowed to change their scores based on the results of the first survey. The scores were tabulated, and the degree of convergence of the responses and the degree of agreement between the first and second responses were used as references to examine the overall degree of agreement.

Following the above procedure, the effectiveness of magnetic attachments was evaluated for each of the 9 CQs for which no relevant literature was found or the quality of evidence was low, using an 11-point scale from -5 to +5 for the following 11 outcomes: maintenance, mastication, pronunciation, esthetics, comfort, responsiveness, durability, periodontal health, burden, harm, and cost. A Delphi questionnaire was used to evaluate the 11 outcomes on a scale of -5 to +5.

Thirty-six members and 35 non-members of the consensus group were selected for the survey, and questionnaires were sent by e-mail or mail. A total of 38 respondents, 25 of whom answered all questions including implants and 13 of whom answered only general prosthetics, were obtained in two surveys[8-10].

Selection of recommendations by the Delphi method

	median≦－2	－2＜median＜＋2	＋2≦median

Degree of convergence：High	NN	U	PP
Degree of convergence：Middle	N	U	P
Degree of convergence：Low	U	U	U

Convergence: High Distribution range of 3 or less after excluding those with frequencies of 2 or less

Convergence: Medium The distribution range is 4-6 when the frequencies less than or equal to 2 are excluded.

Convergence: Low The distribution range is more than 7 when those with a frequency of 2 or less are excluded

Outcome Factors for Magnetic Attachment

Treatment Outcomes	Classification among the primary factors in determining the level of recommendation
Retentive force	Effectiveness (denture maintenance and stability)
Masticatory function	Effectiveness (Treatment Outcome)
Pronunciation	Effectiveness (Treatment Outcome)
Aesthetics (appearance)	Effectiveness (Treatment Outcome)
Comfort (fit)	Downsides
Repairability (Repair)	Downsides (ease of repair)
Durability (prolongation of abutment teeth, etc.)	Downsides (ability to maintain prosthetic dentition)
Periodontal health	Downsides (Does it induce gingival inflammation?)
Overload	Downsides (burden on abutment teeth, periodontal tissues, etc.)
Harm (tooth damage, pain)	Downsides (treatment time, discomfort and pain associated with treatment)

Expression of degree of recommendation

PP：Recommended (positive strong recommendation)

P: Recommendable (weak positive recommendation)

N: Not recommended (negative weak recommendation)

NN: Not recommended (negative strong recommendation)

U: Unable to determine

6. determination of recommendation and evaluation profile

Evaluation profile

Outcome	Quality of Evidence	Evaluation (validity, etc.)	Delphi method evaluation
1.Retentive force			
2.Masticatory function			
3.Pronunciation			
4.Aesthetics (appearance)			
5.Comfort (fit)			
6.Repairability (Repair)			
7.Durability (prolongation of abutment teeth, etc.)			
8.Periodontal condition			
9.Overload			
10. Harm (tooth damage, pain)			
11.Cost			
Recommendation	Judgment as a whole		

As for the overall recommendation, as mentioned above, clinical decisions and outcomes of prosthodontic practice are greatly influenced by the patient's own values and other factors, so that in practice it is necessary to match this recommended profile with the profile of the patient's values. However, in this guideline, an overall recommendation level was purposely presented after consultation by the guideline development committee to provide suggestions to users. Therefore, it must be understood that the above assumptions must be made when using this overall recommendation.

In addition, when multiple recommendations are described in the overall recommendation (e.g., N to P), it indicates that the importance of each treatment outcome based on the evidence is competing and that it is difficult to select a single recommendation. In this case, it means that the

decision should be based on a thorough understanding of the patient's own values, medical resources, and the skill of the practitioner.

7. References

1) Hideshima M, Igarashi Y, Ichikawa T, et al: Preliminary Questionnaire Survey for formulating Clinical Practice Guidelines for Magnetic Attachments Applications - Analysis and Selection of the Clinical Questions (CQ) -. J J Mag Dent 19: 29-34, 2010.

2) Medical Committee of the Japanese Society of Magnetic Dentistry: Request for Preliminary Questionnaire Survey for Formulating Clinical Practice Guidelines for Magnetic Attachments Applications - Analysis and Selection of the Clinical Questions (CQ) - (in Japanese), Journal of Magnetic Dentistry, Vol. 19, No. 1, 119-120, 2010.

3) Hideshima M, Igarashi J, Ichikawa T, et al: Questionnaire survey on practice guidelines for magnetic attachments - Survey and selection of clinical questions (CQ) (in Japanese). Journal of Magnetic Dentistry, Vol. 20, No. 1, 114, 2011.

4) Hideshima M, Igarashi Y, Ichikawa T, et al: Questionnaire Survey for Formulating Clinical Practice Guidelines for Magnetic Attachments Applications - Analysis and Selection of the Clinical Questions (CQ) -. J J Mag Dent 20: 5-10, 2011.

5) Atkins D, et al. GRADE Working Group. Grading quality of evidence and strength of recommendations. BMJ ; 328 : 1490, 2004..

6) Aihara M, Mihara K, GRADE Working Group, et al. GRADE System for Clinical Practice Guidelines (in Japanese). Toppan Media Co.

7) Nagao K, Goto T, Ishida Y, Ichikawa T: What is the Delphi method? (in Japanese). Journal of Magnetic Dentistry, Vol. 21, No. 1, 32-36, 2012.

8) M. Hideshima, T. Ichikawa, H. Koshino, K. Hoshiai, J. Tanaka, S. Ozawa, Y. Suzuki, Y. Umekawa, T. Ishigami, K. Nagao, M. Sone, M. Kono, J. Wada, J. Wadachi Y. Suzuki, Y. Umekawa, T. Ishigami, K. Nagao, M. Sone, M. Kono, J. Wada, J. Wadachi: Formulating clinical practice guidelines for magnetic attachment applications: The process and results of a survey using the Delphi J J Mag Dent 22: 47-53, 2013.

9) Hideshima M: If you have a problem with magnetic attachments: Based on the clinical practice guidelines. (in Japanese). Journal of Magnetic Dentistry, Vol. 22, No. 1, 19-23, 2013.

10) Hideshima M.: Medical Committee [Practice guideline project] Application of magnetic attachments to implants vs. natural teeth, background of guideline development and practice guideline for application of magnetic attachments to free end dentures.(in Japanese). Journal of Magnetic Dentistry, Vol. 23, No. 1, 45-49, 2014.

11) Nakayama T. Practice guidelines using EBM: A guide to preparation and utilization (in Japanse), Kanehara Shuppan 2004.

12) Fukui, T., Yoshida, M., and Yamaguchi, N. A Guide to the Preparation of Minds Clinical Practice Guidelines 2007(in Japanse). Igaku Shoin, 2007.

13) The Japanese Society for Prosthetic Dentistry (ed.): Guidelines for Prosthetic Dental Practice; Guidelines for Prosthetic Dental Practice of Missing Teeth 2008 (in Japanse). 1-117, Tokyo, 2009. 120.

V. Clinical Questions and Evaluation/Recommendation Profiles

The following is a list of 12 CQs, their evaluation profiles, and recommended profiles. For details, please refer to the website of the Japanese Dental Association and the Clinical Guideline Library of the Japanese Association for Dental Science.

＊MA: Magnetic Attachment
＊Other devices described in each CQ refer to various attachments other than clasps and MAs.

CQ1: In case of implant-supported overlay dentures, are magnetic attachments (MAs) more effective than other types of retainers?

【Recommended profile】
Although MAs are slightly inferior to bar and O-ring attachments in terms of retentive force and masticatory function, they are effective in terms of comfort and maintenance of periodontal health. Long-term follow-up reports indicate that MAs are as effective as other attachments as abutment teeth for implant overdentures, and may be recommended in appropriate cases after fully explaining the current available evidence to the patient.

Outcome	Quality of Evidence	Evaluation (validity, etc.)	Delphi method evaluation
1.Retentive force	M	N	
2.Masticatory function	M	N	
3.Pronunciation	M	U	
4.Aesthetics (appearance)	L	U	
5.Comfort (fit)	M	P (for female)	
6.Repairability (Repair)	L	U	
7.Durability (prolongation of abutment teeth, etc.)	M	U	
8.Periodontal condition	L	P	
9.Overload			
10. Harm (tooth damage, pain)			
11.Cost			
Recommendation	Judgment as a whole P		

CQ2: In case of implant-supported overlay dentures, is the application of MAs to implant abutments superior to applying them to natural teeth?

(Composite defect of mandibular bilateral free end and middle, and abutment teeth should be bicuspids or premolars adjacent to the defect.)

【Recommended profile】

(In a composite defect of mandibular bilateral free ends and middle, application of MA may be recommended in terms of retentive force, masticatory function, etc. (weak level of recommendation).

Outcome	Quality of Evidence	Evaluation (validity, etc.)	Delphi method evaluation
1.Retentive force	M	U	P
2.Masticatory function	M	U	PP
3.Pronunciation			U
4.Aesthetics (appearance)			U
5.Comfort (fit)	M	U	U
6.Repairability (Repair)			U
7.Durability (prolongation of abutment teeth, etc.)	M	U	U
8.Periodontal condition			U
9.Overload			U
10. Harm (tooth damage, pain)	M	U	U
11.Cost			U
Recommendation	Judgment as a whole P		

CQ3: When applying magnetic MAs to implant-supported overlay dentures, are maxillary applications superior to than mandibular ones?

【Recommended profile】

There seems to be no clear difference in the prognosis of maxillary and mandibular implant overdentures to which MA is applied. The effect of MA application to maxillary implant overdentures is expected to be an improvement in phonatory function and comfort. The reason for

this is that the application of MA in the maxilla allows the release of the palatal portion of the denture, which may reduce the patient's pronunciation-related problems and discomfort.

Outcome	Delphi method evaluation (25 persons)		
	median	degree of convergence	recommendation
1.Retentive force	0	H	U
2.Masticatory function	0	H	U
3.Pronunciation	0	H	U
4.Aesthetics (appearance)	0	H	U
5.Comfort (fit)	0	H	U
6.Repairability (Repair)	0	H	U
7.Durability (prolongation of abutment teeth, etc.)	0	H	U
8.Periodontal condition	0	H	U
9.Overload	0	H	U
10. Harm (tooth damage, pain)	0	H	U
11.Cost	0	H	U
Recommendation	Judgment as a whole U		

CQ4: When applying magnetic MAs to implant-supported overlay dentures, are multiple abutments with MAs more effective than single abutments?

【Recommended profile】

The application of MAs to multiple implant-over-denture abutments seems to be effective in terms of retentive force.

Outcome	Quality of Evidence	Evaluation (validity, etc.)	Delphi method evaluation
1.Retentive force	H	P	P

2.Masticatory function			P
3.Pronunciation			U
4.Aesthetics (appearance)			U
5.Comfort (fit)			U
6.Repairability (Repair)			U
7.Durability (prolongation of abutment teeth, etc.)			PP
8.Periodontal condition			U
9.Overload			U
10. Harm (tooth damage, pain)	H	U	U
11.Cost			NN
Recommendation	Judgment as a whole P		

【CQ５】In cases in which individuals have few mandibular teeth, is the application of MAs more effective than the use of other types of retainers?

【Recommended profile】

MAs application to overdentures with a few remaining teeth may be recommended in terms of denture maintenance, esthetics, comfort, and overload (weak level of recommendation).

Outcome	Quality of Evidence	Evaluation (validity, etc.)	Delphi method evaluation
1.Retentive force	M	P	
2.Masticatory function	M	P	
3.Pronunciation			
4.Aesthetics (appearance)	VL	U	
5.Comfort (fit)	M	P	
6.Repairability (Repair)			
7.Durability (prolongation of	VL	U	

abutment teeth, etc.)			
8.Periodontal condition	VL	U	
9.Overload	L	U	
10. Harm (tooth damage, pain)			
11.Cost			
Recommendation	Judgment as a whole P		

【CQ 6】

In cases involving removable partial dentures with a free-end saddle, is the application of MAs more effective than the use of other types of retainers?

(In case of Bilateral free end defects with bicuspids or canines as abutment teeth)

【Recommended profile】

Application of MA s to free end dentures may be recommended in terms of denture maintenance, esthetics, comfort, responsiveness, and durability (weak level of recommendation).

Outcome	Quality of Evidence	Evaluation (validity, etc.)	Delphi method evaluation
1.Retentive force	H	P	P
2.Masticatory function	H	U	U
3.Pronunciation			U
4.Aesthetics (appearance)	L	P	P
5.Comfort (fit)	H	P or U	P
6.Repairability (Repair)	L	P	P
7.Durability (prolongation of abutment teeth, etc.)	M	P	U
8.Periodontal condition	L	U or N	U
9.Overload	S, L	P or U	U
10. Harm (tooth damage, pain)	M	P or U	U

11.Cost	M	N	U
Recommendation	Judgment as a whole P		

CQ7：In case of partially edentulous patients without occlusal contact, are MAs superior to other type of retainers?

(In case of a horizontal crossbite with only one molar remaining on each side of the upper and lower jaws, or a bicuspid or premolar adjacent to the defect as abutment.)

【Recommended profile】

The application of MAs to cases of misaligned occlusion may be recommended in terms of the maintenance of the prosthetic device, masticatory function, esthetics, comfort, responsiveness, durability, and periodontal health in terms of prognostic outcomes. (Weak level recommendation)

Outcome	Delphi method evaluation (38 persons)		
	median	degree of convergence	recommendation
1.Retentive force	3	M	**P**
2.Masticatory function	3	M	**P**
3.Pronunciation	0	M	**U**
4.Aesthetics (appearance)	4	M	**P**
5.Comfort (fit)	3	M	**P**
6.Repairability (Repair)	3	M	**P**
7.Durability (prolongation of abutment teeth, etc.)	3	M	**P**
8.Periodontal condition	2	M	**P**
9.Overload	0	M	**U**
10. Harm (tooth damage, pain)	0	M	**U**
11.Cost	0	M	**U**
Recommendation	Judgment as a whole **P**		

CQ8：In cases of partially edentulous with undulating occlusal planes, is the application of MAs more effective than the use of other types of retainers?

(In case of a composite defect of the maxillary free end and middle, with an erupted premolar or anterior tooth as abutment.)

【Recommended profile】

In cases with a disturbed occlusal plane, occlusal reconstruction with the application of MAs is more effective than with annular or bar clasps.

Outcome	Delphi method evaluation (38 persons)		
	median	degree of convergence	recommendation
1.Retentive force	1	M	U
2.Masticatory function	1	M	U
3.Pronunciation	1	M	U
4.Aesthetics (appearance)	3	M	P
5.Comfort (fit)	2	M	P
6.Repairability (Repair)	2	M	P
7.Durability (prolongation of abutment teeth, etc.)	1	M	U
8.Periodontal condition	1	M	U
9.Overload	0	M	U
10. Harm (tooth damage, pain)	0	M	U
11.Cost	−1	M	U
Recommendation	Judgment as a whole P		

CQ9：When periodontal disease is affecting remaining abutments, is the application of MAs superior to the use of other types of retainers?

(In case of the periodontal condition of the abutment tooth adjacent to the defect is P1 or P2 in a case of bilateral free end defects in the mandible.)

【Recommended profile】

The application of MAs on abutment teeth with early periodontal disease is not well documented, but it is highly regarded. The Delphi technique received generally good evaluations, except for cost, and the overall recommendation was judged to be P.

Outcome	Quality of Evidence	Evaluation (validity, etc.)	Delphi method evaluation
1.Retentive force			PP
2.Masticatory function			P
3.Pronunciation			P
4.Aesthetics (appearance)			PP
5.Comfort (fit)			P
6.Repairability (Repair)			P
7.Durability (prolongation of abutment teeth, etc.)	M	PP	PP
8.Periodontal condition	M	P	P
9.Overload			U
10. Harm (tooth damage, pain)	M	P	U
11.Cost	M	PP	N
Recommendation	Judgment as a whole P		

CQ10：When applying MAs to multiple abutment teeth, are symmetrical arrangements more effective than asymmetrical ones?

【Recommended profile】

Symmetrical placement of abutment teeth for overdentures is recommended over asymmetrical placement.

Outcome	Quality of Evidence	Evaluation (validity, etc.)	Delphi method evaluation
1.Retentive force			PP
2.Masticatory function			PP
3.Pronunciation			U
4.Aesthetics (appearance)			U
5.Comfort (fit)			U
6.Repairability (Repair)			U
7.Durability (prolongation of abutment teeth, etc.)	L	U	U
8.Periodontal condition			U
9.Overload			U
10. Harm (tooth damage, pain)			U
11.Cost			U
Recommendation	Judgment as a whole P		

CQ11：When applying MAs to remaining abutment teeth, are flat type keepers more effective than dome-shaped keepers for stability of the denture?

【Recommended profile】

The flat type is recommended over the dome type depending on the number of abutments and loading points.

Outcome	Quality of Evidence	Evaluation (validity, etc.)	Delphi method evaluation
1.Retentive force			

2.Masticatory function			
3.Pronunciation			
4.Aesthetics (appearance)			
5.Comfort (fit)			
6.Repairability (Repair)			
7.Durability (prolongation of abutment teeth, etc.)			
8.Periodontal condition			
9.Overload	H	P	
10. Harm (tooth damage, pain)			
11.Cost			
Recommendation	Judgment as a whole P		

CQ12：When applying MAs to removable partial dentures, is the applied pressure method superior to minimum pressure ones?

(In cases with a small number of remaining maxillary teeth, the abutment should be one or two premolars or bicuspids.)

【Recommended profile】

Since the attachment of MAs (or magnetic structures) to dentures without pressure has a slightly negative effect on the life of the abutment and denture and on periodontal disease and dental caries of the abutment teeth, it may be recommended that MAs be attached under pressurized conditions.

Outcome	Delphi method evaluation (38 persons)		
	median	degree of convergence	recommendation
1.Retentive force	**-2**	**L**	**U**
2.Masticatory function	0	**L**	**U**
3.Pronunciation	0	**H**	**U**

4.Aesthetics (appearance)	0	**M**	**U**
5.Comfort (fit)	0	**H**	**U**
6.Repairability (Repair)	0	**M**	**U**
7.Durability (prolongation of abutment teeth, etc.)	**-2**	**M**	**N**
8.Periodontal condition	**-2**	**M**	**N**
9.Overload	0	**H**	**U**
10. Harm (tooth damage, pain)	0	**H**	**U**
11.Cost	0	**M**	**U**
Recommendation	Judgment as a whole **N**		

VI. Conclusion

We have reported an overview of the clinical evaluation, international standardization, and formulation of practice guidelines for magnetic dental attachments that the society has been working on. Magnetic attachments were approved as a medical device by the Ministry of Health, Labour and Welfare in 1990, and have since been improved through industry-academia collaboration in order to improve retentive force, miniaturization, durability, and biocompatibility. ISO 13017:2012/Amd.1 (a supplement to ISO 13017) was published in 2015, and the ISO task force is currently preparing to integrate the two international standards at the time of the international standards review to be conducted in 2017.

As for clinical evaluation, each institution has conducted a prognostic survey of patients with magnetic attachments from each manufacturer, and the usefulness of the attachments was reported. Furthermore, a common protocol was established by the clinical evaluation committee, and long-term follow-up reports were made at multiple institutions. However, it was difficult to collect and analyze data systematically for the multicenter long-term follow-up survey due to the large number of elderly patients, uninsured treatment, and changes in investigators. Based on these circumstances, the Clinical Evaluation Committee has modified the protocol since 2015, and is now conducting a new multicenter survey while continuing the existing survey.

On the other hand, the Medical Committee began formulating guidelines for medical practice in 2009, and conducted a wide-ranging questionnaire survey of its members. In addition, oral presentations and symposiums were planned at the annual meeting, and the practice guideline was disseminated to the members, achieving a certain level of success. However, many CQs were difficult to collect evidence when developing the practice guideline, and it was necessary to supplement the CQs with a questionnaire survey of clinical specialists using the Delphi method, etc. We realized that it was too early to develop the practice guideline and there were many issues to be solved. However, the society will need to conduct related research, revise, and add to the guidelines.

The society has reported detailed studies on problems with magnetic attachments, such as artifacts on MRI images and reduced magnetic force in magnetic structures, and the Safety Standards Review Committee has published a report in the society's journal and a leaflet for medical professionals and the general public.

Dental magnetic attachments are clinically excellent in operability, durability, and corrosion resistance, and have good long-term results, but they are currently not widely used in general clinical

practice because they are not covered by insurance. The Society has taken a cautious approach to the introduction of insurance coverage, since there have been two sides to the issue, but the time has come to consider advanced medical treatment, selected medical treatments, insurance coverage, etc. We hope that this report will be of some help in this regard.

We would like to express our deepest gratitude to the members of the Society and all those involved in dental care, including the various committees, for their cooperation to date, and we sincerely hope for their further support and guidance.

March, 2017

Acknowledgments

This Project was supported by Japanese Dental Science Federation as JDSF-DSP1-2016-214-1.