Projects of Japanese Dental Science Federation in 2018

Investigation of materials and research on new medical device and technology introduction

The Japanese Society of Magnetic Applications in Dentistry

Survey and Research for clinical evaluation of magnetic dental attachments and formulation (updating) of clinical practice guidelines

Clinical Practice Guidelines for Dental Magnetic Attachments 2018

Issue No. JDSF-DSP1-2018-2121-1

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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 was 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[1)] .

In recent years, the need for evidence-based medicine and improvement in the quality of medical care have prompted various academic societies to develop guidelines for medical practice, and in 2009, the Medical Committee of our society selected 12 representative CQs from 147 CQs and began formulating guidelines for medical practice[2-5)]. 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 of the survey [6-9)]. The "Practice Guidelines for Magnetic Attachments 2013" were completed by reflecting the evaluations of the internal consensus committee members and the external evaluation committee members[6-9)].

In this report, we revised the contents of each CQ in the "Guidelines for the Practice of Magnetic Attachments 2013" and added a CQ on MRI. The ISO Committee for the International Standardization of Magnetic Attachments has been working on the revision of ISO 13017 issued in 2012 and its supplement (ISO 13017: Amd.1) and its unification[1]. We have prepared a report as " Clinical Practice Guidelines for Dental Magnetic Attachments 2018".

We hope that this report will be of some help in the selection and treatment of magnetic attachments and in their inclusion in insurance coverage.

II. Development and Update of Practice Guidelines for Magnetic Attachments "Clinical Practice Guidelines for Magnetic Attachments 2018"

1. Background of the development of the clinical practice guideline

In recent years, the rapid changes in population composition and disease structure, as well as the need for evidence-based medical care and improvement in the quality of medical care as accountability to society for clarifying human rights and the right to choose medical care, have prompted various academic societies to develop practice guidelines. The Japanese Society of Magnetic Dentistry has also been developing practice guidelines over three phases (one phase: two years) since 2009, led by the Medical Committee. In the second phase, 8 courses were asked to develop practice guidelines in accordance with the GRADE system. In the meantime, symposia on practice guidelines were held under the themes of "Establishment of Practice Guidelines for Magnetic Attachments," "Troubles with Magnetic Attachments," and "Application of Magnetic Attachments to Implants vs. Natural Teeth" in order to inform members of the significance of practice guidelines and the method of formulation[8,9].

Because of the lack of relevant literature, especially for the selected CQs, the symposium introduced and discussed how to proceed with the work of evidence collection and the Delphi method[6-9] when there is a lack of evidence. In Phase II, 71 members of the consensus group were selected for the Delphi survey, and questions were developed to evaluate the effectiveness of magnetic attachments on 11 outcomes on a scale of -5 to +5, with 38 participants responding to two questionnaires, which resulted in a certain aggregate trend[7-9].

Of the 14 CQs, 2 CQs on missing forms were combined into 1 CQ, and the other CQs on MRI were excluded because they corresponded to TA (Technology Appraisals), and draft guidelines were developed for 12 CQs.

After the above process, in Phase III, we asked the consensus group that conducted the Delphi survey to evaluate the draft guideline, which was brushed up with feedback from the consensus group, and then asked external evaluators from other societies to conduct the final evaluation. The draft guideline was then finalized by asking external evaluators from other societies to make final evaluations.)

In recent years, the main method for formulating medical practice guidelines has been to evaluate the evidence and determine the level of recommendation using the system devised by the GRADE (Grading of Recommendations Assessment, Development and Evaluation) Group[11,12], and the system is now being used by the Japan Medical Evaluation Service (JMEDS). The MINDS (Medical Information Network Distribution Service)[12] of the Japan Medical Evaluation Organization and the Japanese Dental Association also recommend the GRADE system. In this method, three factors are taken into account: the physician's expertise, experience, and skills; patient factors; and the quality of evidence. The recommendation is determined by comprehensively judging four major factors: quality of evidence, balance of benefits and disadvantages, values and preferences, and cost and resource utilization[4,5].

However, because of the special nature of prosthetic dentistry and the difficulty of applying the GRADE system mutatis mutandis due to the lack of accumulated evidence in the new field of magnetic dentistry, we have also incorporated evaluation methods that take advantage of the characteristics and uniqueness of our society. For example, in prosthodontics and magnetic attachments, model experiments and simulation experiments are more reproducible and provide sufficient evidence for

outcomes such as maintenance and durability, etc. Therefore, S (simulated/model experiments) was added to A (high), B (low) and C (very low) as one of the evidence levels[13].

This time, we conducted a literature search again for the 12 CQs selected five years ago, revised the outlines, recommendations, and other contents, and added one CQ on MRI (IP: Interventional Procedure). Furthermore, the ISO Task Force Committee is now working on the revision and amendment of ISO 13017 (ISO 13017: Amd.1), which was published in 2012, and the history of the ISO 13017 standardization has been added[1]. The investigation of the Delphi method by the consensus group was not conducted this time due to time and expense constraints.

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 this issue as a research theme. It is necessary to continue many reorganization works such as addition of CQs, revision of recommendations, and development of 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[2]. The survey was also distributed to the participants of the 19th Annual Meeting, published on the Society's website and in the Society's journal[3] and sent by mail 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.

As a result of the survey, 117 respondents were obtained, and a total of 147 CQs were collected[1-4]. The number of CQs categorized into five groups according to content is as follows.

(1) Implant-related: 21 questions

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

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 missing styles, 3 on occlusion/periodontal disease, 2 on abutment placement/form, and 2 on management/others.

With the cooperation of the Safety Management Committee, we added CQ13 on MRI to 5. Management, and developed evaluation profiles and recommendation statements by referring to the "Manual of Safety Standards for MRI".

1. Implant

CQ1. In case of implant-supported overlay dentures, is magnetic attachments (MAs) more effective than applying other type of retainers?

CQ2. In implant-supported overlay dentures, are applying MAs to implant abutments more successful than applying them to natural teeth?

CQ3. Applying MAs to implant-supported overlay denture cases, are maxillary cases more successful

than mandibular ones?

CQ4. Applying MAs to implant-supported overlay denture cases, are multiple abutments with MAs more effective than a single abutment?

2. Defects

CQ5. In few remaining mandibular teeth, are applying MAs more effective than other type of retainers?

CQ6. In free-end saddle removable partial dentures, are applying MAs more effective than other type of retainers?

3. Occlusion/Periodontics

CQ7. In partially edentulous without occlusal contact, are applying MAs more successful than other type of retainers?

CQ8. In partially edentulous with undulating occlusal planes, are applying MAs more effective than other type of retainers?

CQ9. When remaining abutments are with periodontal disease, are applying MAs more successful than other type of retainers?

4. Arrange / Form

CQ 10.Applying MA s to multiple abutment teeth, are symmetrical arrangements more effective than asymmetrical ones?

CQ 11.Applying MA s to remaining abutment teeth, is flat type keeper more effective than dome-shaped keeper for stability of the denture?

5. Manage/etc

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

CQ 13. When undergoing MRI examination, do applying MAs cause more artifacts in the examined graphic images than other type of retainers?

＊Other devices refer to various attachments other than clasps and magnetic attachments

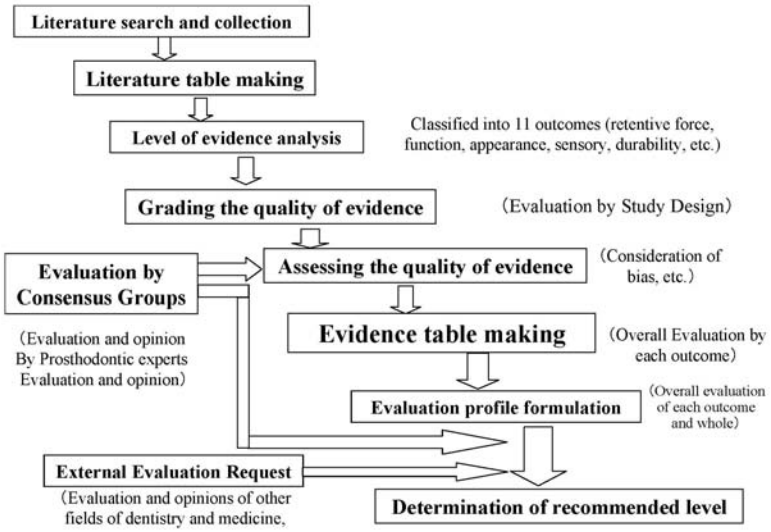
3. Methods of evidence collection

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.

The third step: 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. Consensus reached on practice guideline 2013 for magnetic attachments

(Application of magnetic attachments to implants vs. natural teeth)

The following consensus was obtained from the previously developed "Practice Guidelines for Magnetic Attachments 2013"[10] and the symposium "Application of Magnetic Attachments to Implants vs. Natural Teeth "[9].

The literature on the progress of MA application to implant abutments has been gradually increasing in recent years, and clinical reports by experts indicate that MA tends to have less overburden on implant abutments, better predictability, and better progress[9,10].

On the other hand, there is little literature on the progress of MA application to natural teeth, and since MA is sometimes applied to prolong the life of upset teeth, it is effective with weak recommendations, but its predictability and progress are inferior to those of implant abutments[9,10]. Therefore, a consensus was reached that MA on implant abutments is more predictable and has a better course than natural abutments[9,10] .

The consensus group, external evaluation committee members, and the Japanese Association of Dental Medicine have commented that this guideline is premature because of the paucity of literature on the subject. We plan to submit the information to the Japanese Dental Association, the Japan Federation of Dental Medicine, and other organizations for their evaluation. We are deeply grateful for the cooperation of our members and consensus committee members, and we hope for their further support.

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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)

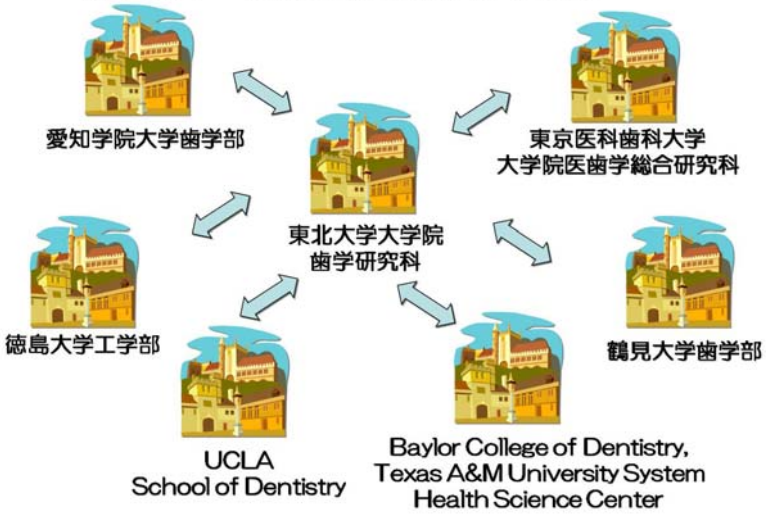


Fig 1: Participating organizations at the time of the establishment of the Magnetic Attachment Standardization Committee

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 130171. 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).

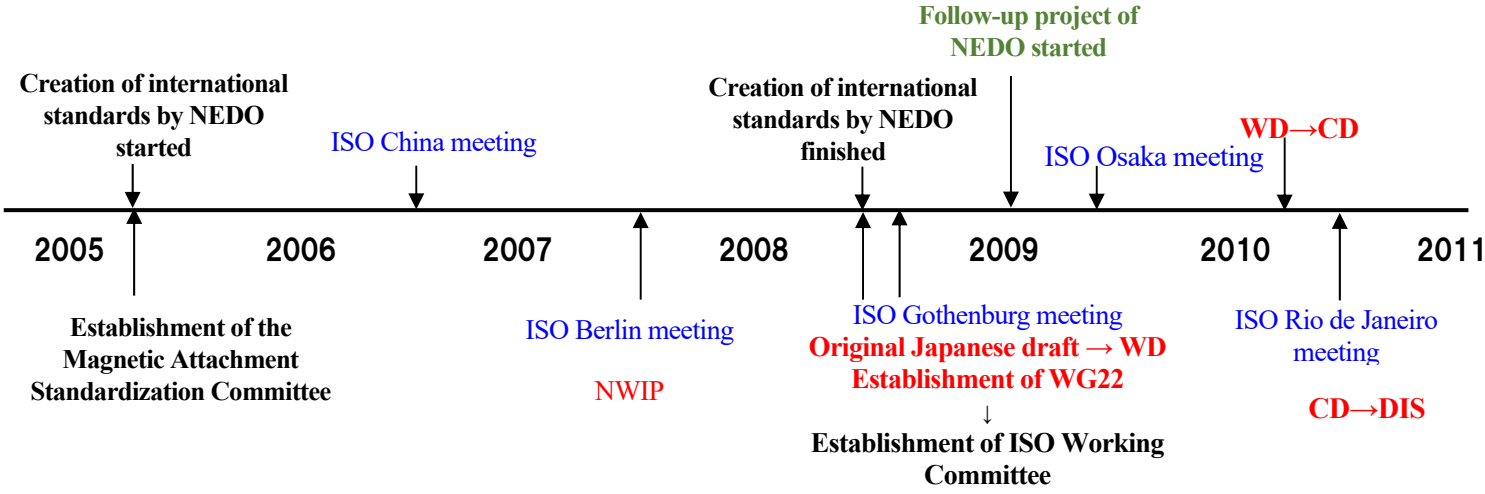


Fig 2. International standardization of magnetic attachments (2005-2011)

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)

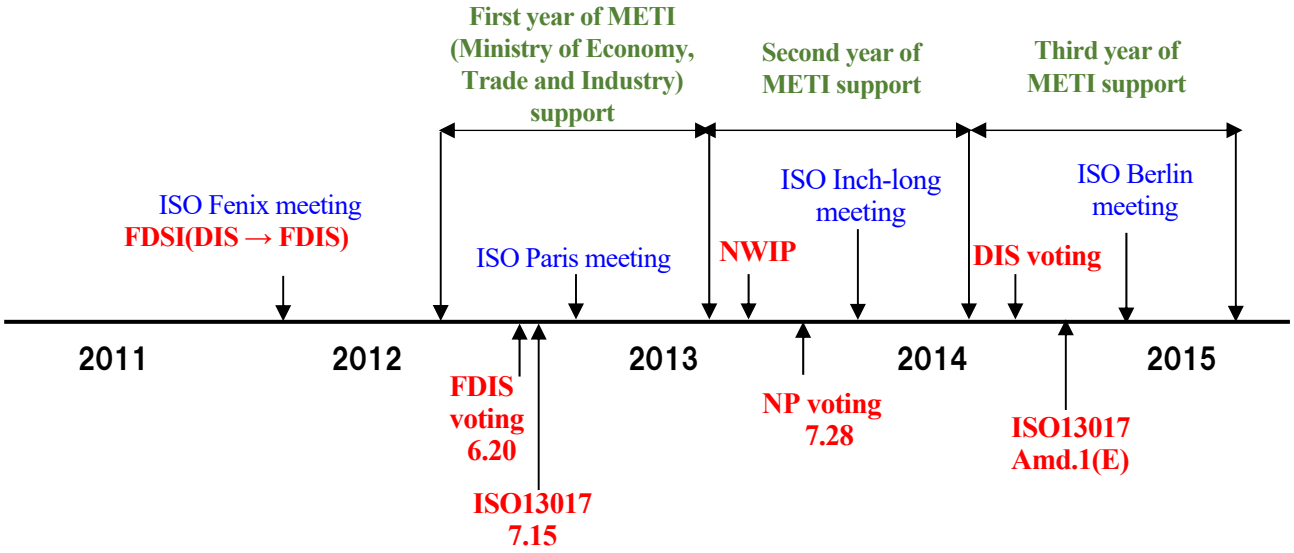
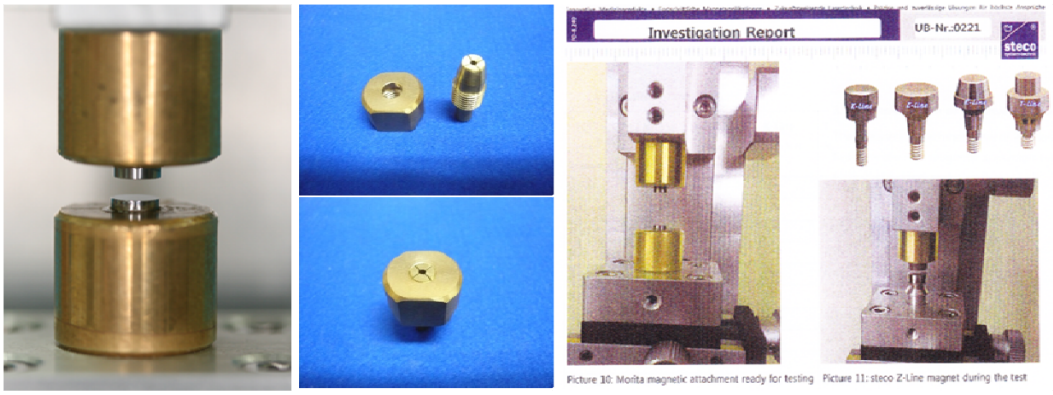


Figure 4: International standardization of magnetic attachments (2011-2015)

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 20157 (Figure 6).

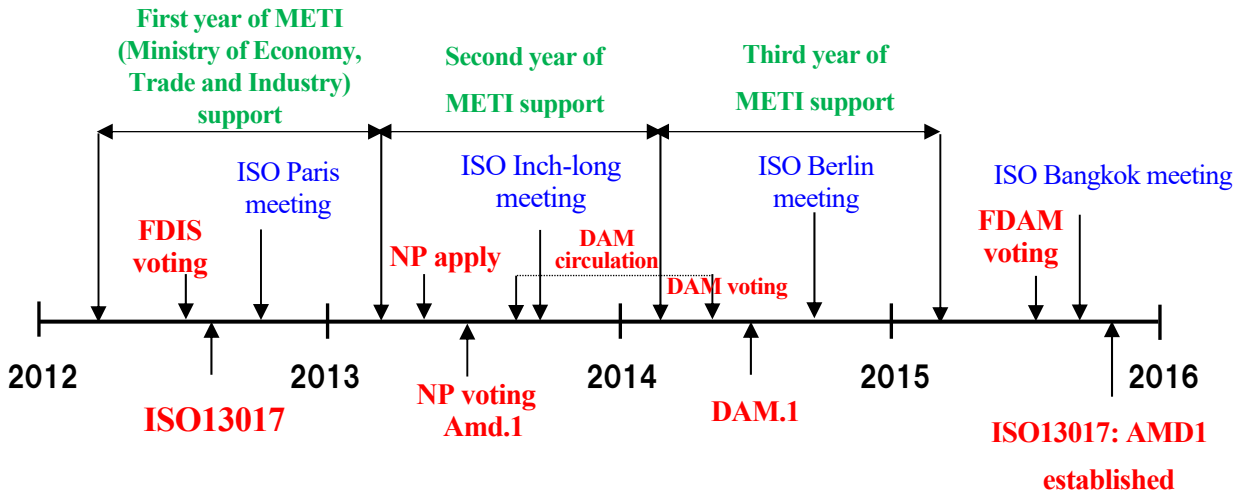


Fig 6　International standardization of magnetic attachments in dentistry (2012-2016)

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.

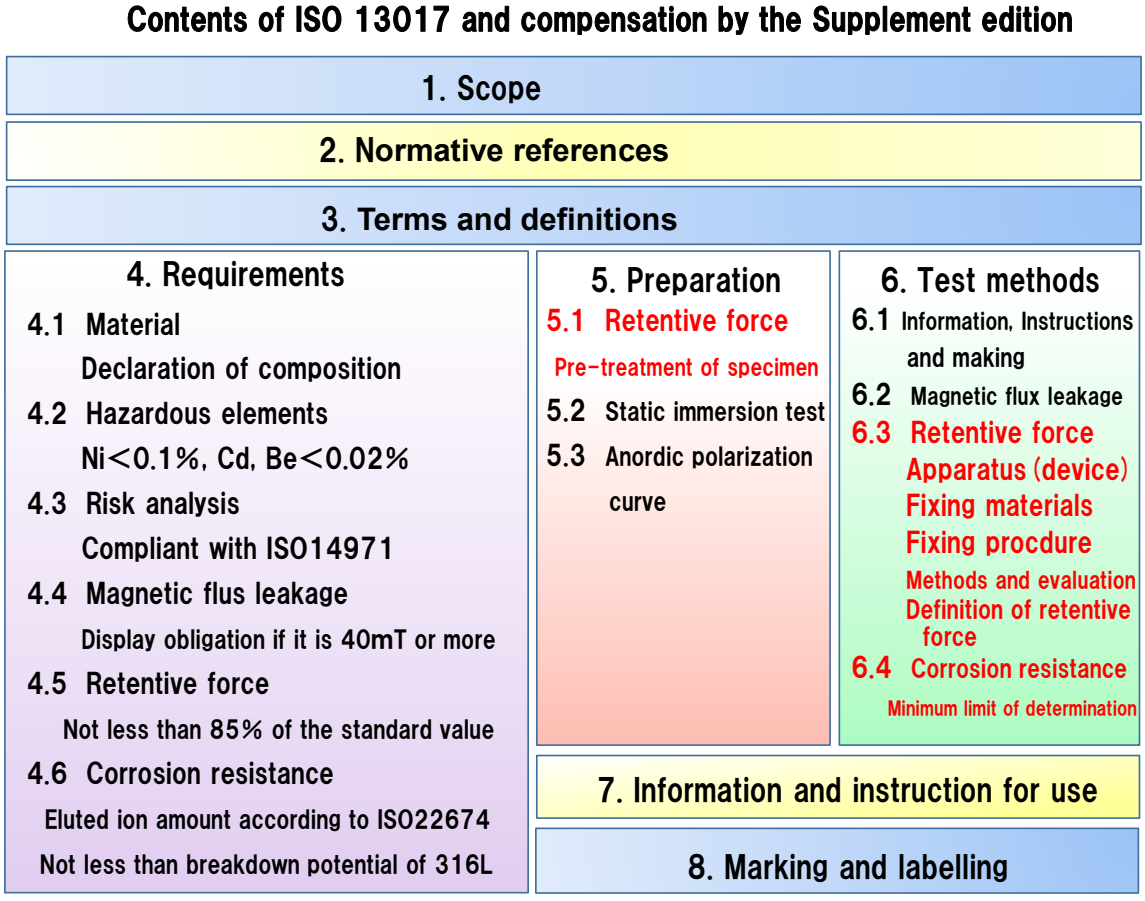


Fig 8 Contents of ISO 13017 and compensation by the Supplement edition.

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.

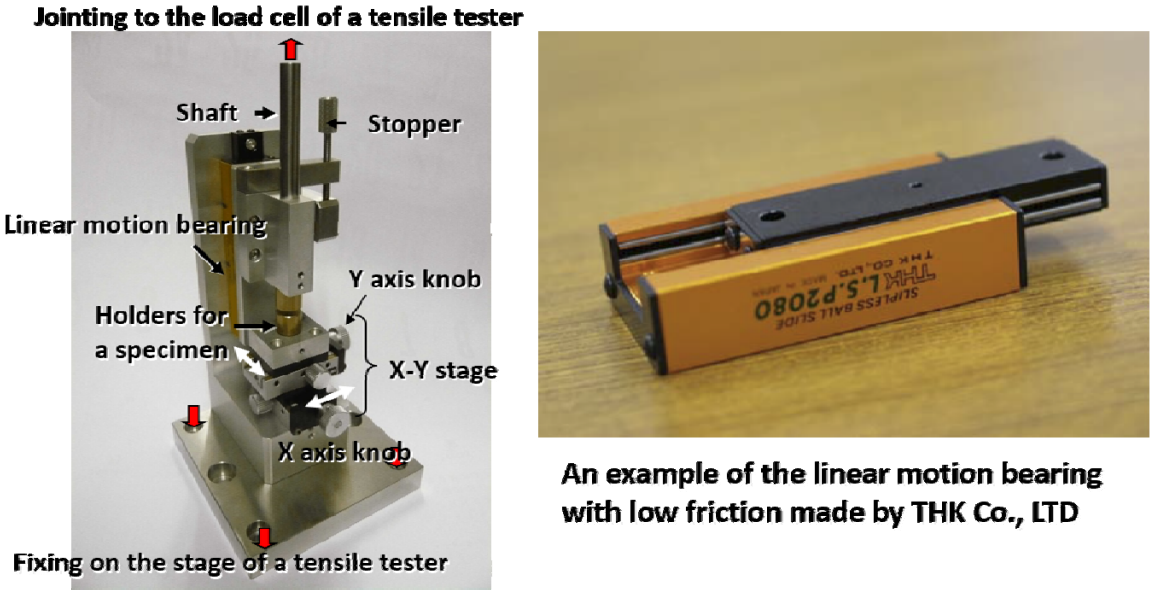


Fig 9 Overview of the jig for measuring retention force (left) and the low-friction linear slider (right)

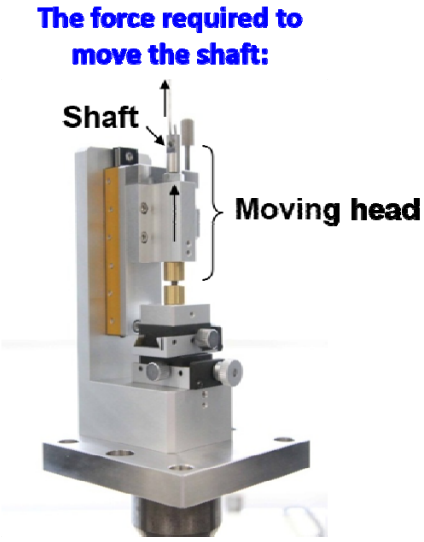


Fig 10. Retentive Force Measuring Jig

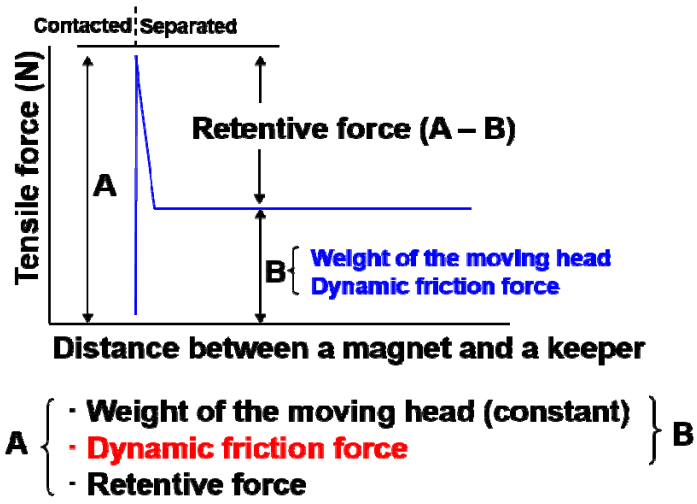


Fig 11. Retentive Force Curve

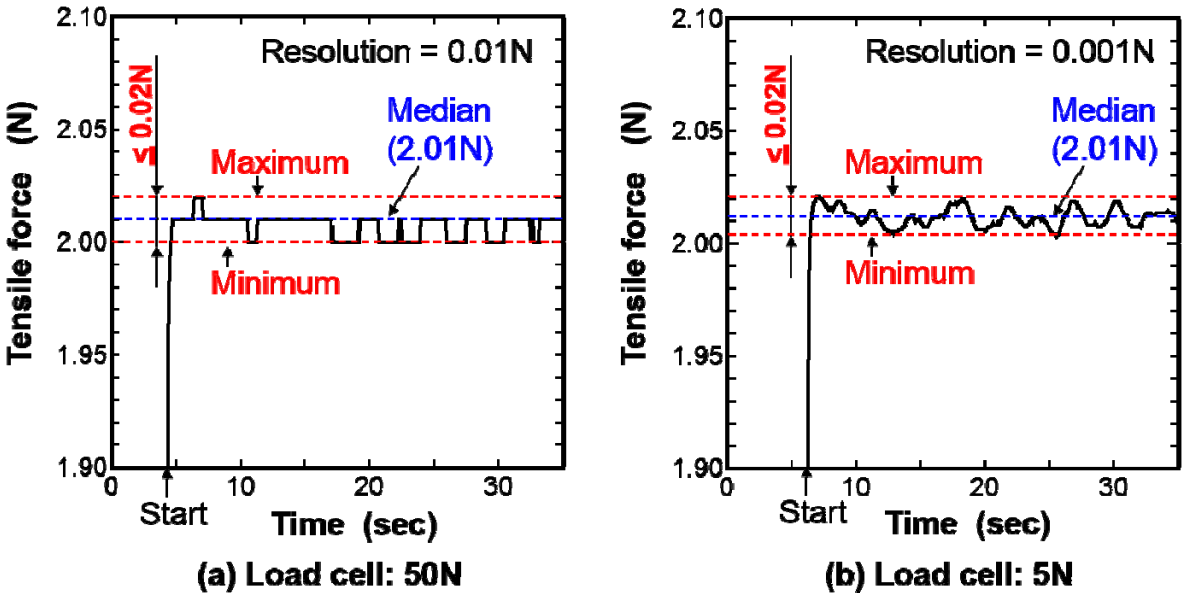


Fig12: Dynamic frictional force and change in the jig for measuring maintenance force

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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 of Dental Surgeons.

＊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		

【Background and Purpose】

Implant overdenture has become an important treatment option for the edentulous jaw. The paper

describes cases in which two implants are connected by a bar and given a sleeve attachment as an implant abutment, and cases in which a single implant is used, a ball attachment, or an MA is attached. The MAs reported in the paper are mainly used in Europe, and there are few reports with a high level of evidence regarding compact and magnetic Japanese-made MAs. Therefore, we analyzed various outcomes and examined the usefulness of MAs for implants.

【Outline】

Three comparative studies were reported in which two implants were placed in the edentulous mandible and overdentures were fabricated, and attachments including MAs were applied[1-6]. According to the results, after 5 years of use, the bar-type attachment had the highest retentive force, and MA had the lowest value among those compared[6]. In an evaluation using test foods, it was reported that masticatory function was significantly decreased after using MA compared to bar and ball attachments5) . On the other hand, no significant differences were observed between attachment types in the evaluation using jaw movement and electromyography[2].

There were no significant differences in periodontal parameters (bone resorption, attachment loss, plaque index, and periotest value) around the implants after 10 years. However, MA had the lowest bone resorption and attachment loss values[4]. In a study comparing the use of both ball and MA, 11 of 18 patients ultimately chose the ball attachment and 5 chose the MA. the group that chose the MA was mostly female, and they appreciated the comfort and ease of cleaning. These reports support the MA's features, such as the buffering mechanism against harmful lateral forces and the ease of operation. The usefulness of MA overdentures was also demonstrated by model experiments[7] and case studies[8].

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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		

Details of the Delphi method evaluation

Outcome	median	degree of convergence	recommendation
1.Retentive force	2	M	P
2.Masticatory function	3	H	PP
3.Pronunciation	0	H	U
4.Aesthetics (appearance)	0	H	U
5.Comfort (fit)	0	H	U
6.Repairability (Repair)	1.5	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	M	U
Recommendation	P		

【Background and Purpose】

Partial dentures with a periodontal ligament-mucosa-implant support mechanism with a small number of implants are effective in improving the esthetic problems of partial dentures due to clasps and denture movement during function. The purpose of this guideline is to establish an index to evaluate the effectiveness of MA as an implant-supported partial denture abutment compared with natural teeth.

【Outline】

In a prognostic study of MAs applied to natural teeth, problems with the Gingival Index, periodontal pocket deterioration, and fracture of the abutment tooth occurred in less than 9% of the cases studied,

and problems with the denture occurred in 4% of cases1). The results of a follow-up study of 36 edentulous patients with two mandibular overdentures with ball, bar, or magnet abutments at 4, 12, 60, and 120 months showed that marginal bone resorption at the end of the 10-year follow-up period of MA was comparable to that of healthy natural teeth, and that the survival of the implants was similar to that of healthy natural teeth. The survival rate of implants was also reported to be 100%2) . However, these literature search results did not compare implants and natural teeth in mandibular bilateral free edge and intermediate composite defects, so we conducted a questionnaire survey using the Delphi method. The results of the Delphi questionnaire showed that the application of MA to implant overdentures was effective in improving retentive force and masticatory function. The results of the questionnaire survey on the period of time when MA was applied to natural teeth and implant overdentures showed that it took 6.3 years for a partial denture with a free end defect, 10.4 years for an implant overdenture, 4.4 years for a difficult partial denture (misaligned bite), and 5.5 years for an implant overdenture. Implant overdentures showed a better outcome compared to natural teeth, with the implant overdenture showing 7.8 years.

From the above results, it was concluded that the application of MA to implant overdenture can be recommended in terms of retentive force and masticatory function in the case of bilateral free end and intermediate composite defects in the mandible.

Clinically, it is important to increase the interproximal line and realize a rectangular support distribution by placing implants in a position where the implant and abutment teeth are symmetrical as much as possible, taking into consideration the placement of the remaining teeth. If there is sufficient bone volume, it is important to place the implant posterior to the free end defect to take full advantage of the support capacity of the implant and to position the Fulcrum line as posteriorly as possible to widen the support area. If the anatomical constraints allow the placement of implants anterior to the free end defect and the application of MA, it is possible to contribute to esthetic improvement as a maintenance source.

Magnetic attachments are useful as an implant-supported partial denture for free end defects because they are expected to provide maintenance by magnetic force and support by plane-to-plane contact between the magnet and the keeper.

The disadvantage of implant-supported partial denture is denture fracture as well as root-supported overdenture. If the thickness of the denture base is thin enough to cover the implant, the denture is

likely to fracture at the implant as a fulcrum.

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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		

【Background and Purpose】

Compared to the mandible, the maxilla tends to have thinner cortical bone, more trabecular bone, and coarser bone quality. In general, the survival rate of maxillary implants is reported to be lower than that of mandibular implants. However, there have been no reports comparing the prognosis of implant-supported MA in the maxilla and mandible. Therefore, we conducted a questionnaire survey using the Delphi method in order to reach a consensus on the comparison between the maxilla and the mandible when an implant-supported overdenture is fabricated and MA is applied, based on the opinions of experts.

【Outline】

The overdenture with implants in the edentulous maxilla is expected to improve the maintenance stability of the denture, and it may be possible to fabricate an edentulous palatal denture that does not cover the palatal portion of the maxilla. The advantage of a palatal-free denture is that it is expected to improve comfort and pronunciation. On the other hand, there is no literature report on the comparison with implant overdentures in the mandible, so we conducted a questionnaire survey using the Delphi method. The results showed that there was no difference in the postoperative course of the maxilla and mandible for the 11 outcomes. The convergence of each outcome was high, suggesting that there were no differences between the maxillary and mandibular implant overdentures in terms of maintenance,

masticatory function, phonatory function, esthetics, comfort, responsiveness, durability, health of surrounding tissues, burden, harm, and cost.

When asked if they would choose MA as the abutment for a maxillary two implant overdenture, the two groups were divided into two groups: those who strongly recommended MA and those who did not. The two groups were strongly recommended and not recommended to use MA as the abutment for maxillary overdentures. No clear difference in postoperative course or functional outcome of each implant system has been reported. Clinically, MA should be applied to cases in which the characteristics of each attachment can be utilized, depending on factors such as the condition of the jaw crest and the condition of the appliance. The number of implants in the maxilla tends to be larger than that in the mandible when MA is applied to the maxilla. In general, four implants are recommended for the edentulous maxilla. A standardized study on the application of MA for maxillary implant overdenture is needed in the future.

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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		

Delphi method evaluation

Outcome	median	degree of convergence	recommendation
1.Retentive force	5	H	PP
2.Masticatory function	3	M	P
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.)	3	H	PP
8.Periodontal condition	0	H	U
9.Overload	0	H	U
10. Harm (tooth damage, pain)	0	H	U
11.Cost	-4	H	NN
Recommendation	P		

【Background and Purpose】

The mandibular implant overdenture is designed to have a minimum number of two implants, allowing

for rotational settling of the denture and requiring only maintenance. However, if function and safety can be ensured, fewer implants are preferable, and the application of a single implant overdenture with MA has been considered. The purpose of this guideline is to create an index to determine whether or not the application of MA to multiple implant overdentures is more effective than to single implant overdentures.

【Outline】

There are no in vivo studies comparing or analyzing the CQ of whether or not the application of MA to multiple implant overdentures is more effective than to single implant overdentures. All of them were in vitro studies. In a model experiment using an overdenture with two or one MA applied to a mandibular anterior abutment, the MA applied to two abutments showed approximately twice the retentive force compared to a single abutment[1]. The MA (flat or domed) applied to two or one implant abutment and the MA (flat or domed) applied to an overdenture showed approximately twice the retentive force when a load was applied to the overdenture. In a study on the lateral force to the implants when a load was applied to the overdenture with two or one MA (flat or domed), a larger lateral force was observed with one implant than with two implants when a unilateral load was applied in the median plane. However, different results were observed depending on the loading point and the type of MA[2] .

A questionnaire survey using the Delphi method showed that the MAs were effective in terms of retentive force, masticatory function, and durability, and that the application of MAs to multiple abutments was more expensive than to single abutments in terms of treatment cost. The results suggest that MAs are effective for the maintenance of multiple implant overdentures.

A clinical study comparing patient satisfaction, treatment cost, and treatment time of single and dual implant overdentures with ball attachments in edentulous mandible patients showed no significant difference in patient satisfaction between single and dual implant overdentures. No significant differences were found in patient satisfaction with either one- or two-tooth implants. In addition, it was reported that treatment costs and treatment time up to one year after surgery were particularly low for single abutment implants, and maintenance time was the same[3]. However, clinical evaluation is not yet complete[3]. However, clinical evaluation is not sufficient at present, and future clinical studies with a high level of scientific support and evidence regarding treatment efficacy and postoperative course are needed. Clinically, a one-supporting implant overdenture is placed in the midline of the mandible, and the implant is required to play a maintenance role. It is also important to fabricate a denture with

minimal movement.

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

[Background and Purpose]

Currently, clasps are the standard choice of abutment for partial dentures, but the choice of abutment varies widely, and there are no clear standards for the choice of abutment. The purpose of this guideline is to establish an index for the effectiveness of MA as an abutment device for overdentures with a few remaining teeth, compared to other clasp dentures.

[Outline]

There have been no studies that scientifically compared and analyzed the progress of the application of MAs to overdentures with a few remaining teeth with other devices. In a photoelastic experiment in which six types of maintenance devices (telescopic crown, Gerber system, Dolder bar system, Dalbo system, MA, and RPI clasp) were used on mandibular bilateral canine teeth, and loads were applied to the occlusal surfaces of overdentures, the load on the abutment teeth was MA was reported to have the lowest loading on the occlusal surface of the overdenture[1]. In an experiment in which stud attachments, Locator Root, OP anchors, and MAs were subjected to loading and unloading, the retentive force of all attachments decreased except for the OP anchor, but the MAs showed only a slight decrease in retentive force, and the retentive force was the most stable before and after loading[2]. The MA showed only a slight decrease in retentive force, and the retentive force was the most stable before and after loading[2]. In a model experiment using overdentures, OP anchors, MA, and metal copings were tested in air and water, and the results showed that the retentive force of OP anchors significantly decreased in water, while that of MA did not change. MAs have been reported to exhibit the same retentive force even in the oral cavity[3].

In a report on the effect of MA on abutment teeth, in a case with one mandibular canine tooth remaining, stress on the cortical bone under the denture base during occlusion was alleviated by designing the upper surface of the keeper root plate to be perpendicular to the tooth axis[4], and by increasing the height of the keeper root plate, the amount of displacement of the labially inclined abutment tooth was increased. Therefore, it has been reported that the height of the keeper root plate should be set as low as possible when prosthetic treatment with MA is performed on a tilted residual tooth[5].

In case reports, it has been reported that the use of an MA as an abutment device is esthetically much better than the use of a clasp, and that the use of an MA on an abutment tooth that was not suitable for the use of a clasp as a denture hook improved the crown-root ratio and was useful in protecting the abutment tooth.[6,7] In addition, it was also suggested that the use of an MA on an abutment tooth that was not suitable for the use of a clasp as a denture hook improved the crown-root ratio, which was useful in protecting the abutment tooth [6,7,8,9] .

The above results indicate that MAs are excellent in terms of maintenance and durability because they are resistant to lateral and rotational forces that are harmful to the abutment teeth and because the maintenance force is semi-permanent. Clinical reports indicate that MA is also effective in terms of burden and esthetics.

Based on the above points, it is recommended to make a comprehensive decision by considering the intraoral and abutment tooth conditions, the patient's needs, and the prognosis.

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【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		

【Background and Purpose】

Background and Purpose

In partial denture cases, the progress of the abutment tooth determines the success or failure of the denture, so it is important to diagnose the degree of pretreatment and the type of abutment device to be applied. Currently, the standard choice is a clasp denture, but the choice depends on the status of the abutment teeth, and no clear criteria have been established for the choice of pretreatment and abutment appliance. The purpose of this guideline is to establish an index to determine whether or not MA is more effective than other clasp dentures when applied to the abutment of a loose end denture.

【Outlines】

There have been no studies that scientifically compared and analyzed the progress of the application of MA to the abutment of a free end denture with that of other denture systems. However, a 10-year follow-up study of more than 100 metal-base dentures (84% loose end dentures) with MA applied showed that the survival rate of the abutment teeth was 95% at 5 years and 88% at 10 years, which was comparable to that of conus dentures reported by others and better than that of clasp dentures[1-4]. In addition, an RCT comparing three types of bilateral canine-supported overdentures (MA, root face plate, and edentulous) and analyzing the stability of the denture, masticatory efficiency, and patient satisfaction showed no significant differences among the three, suggesting that the stability of the denture itself is more influential than the device[5].

In a Delphi survey conducted by our society among experts, the results converged on the view that denture maintenance, esthetics, comfort, and responsiveness (e.g., repair) were effective. However, there are many negative opinions about the course of periodontal tissues, and literature shows an increasing trend in pocket depth[1-5].

The application of MA to free end dentures improves the crown-root ratio and reduces the anchorage point, thereby reducing tooth movement, extending the life (durability) of the abutment teeth, and stabilizing the denture. In addition, with the improvement of industrial technology, the closed circuit of MA has low attenuation of magnetic force, stable long-term retentive force, excellent esthetics because of its small size and fit within the prosthesis, and good fit and comfort when worn. Furthermore, it can be easily repaired in the event of breakage, and is judged to be highly adaptable.

On the other hand, MA is applied in the form of an overdenture, so the cleanability of the abutment teeth is poor, and periodic cleaning instructions are required.

Clinically, it is most frequently applied to bicuspids and canines adjacent to defects[1]. Therefore, clasp dentures are often applied to sound teeth unless there is concern about bone implantation or significant discordance in crown morphology, and MA is considered to be difficult to apply.

If the abutment tooth requires root canal treatment or crown restoration, the choice is between crown restoration and clasp denture or MA with a root faceplate, and the choice is equal in each case. In the case of gingival recession, imbalance of crown-root ratio, unstable occlusion, strong occlusal force, and fixed connection of the opposing dentition, it is desirable to apply MA because denture movement and overload of the abutment teeth are expected. However, in cases of tooth movement and poor periodontal tissues, MA is not applicable because the condition is aggravated by the application of MA.

In addition, a crown with an extra-dental crown attached to the crown is also recommended for crown restorations.

Based on the above points, it is recommended that a comprehensive judgment be made by taking into consideration the status of the abutment teeth and oral cavity (abutment teeth, periodontal tissues, occlusal condition, etc.), the patient's needs, psychological aspects, physical and social background, and other factors.

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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		

【Background and Purpose】

In cases of misaligned occlusion, it is often necessary to improve the occlusal plane and crown-root ratio due to the protrusion and movement of the remaining teeth. In addition, the denture cannot avoid sinking due to the deficiency of the bite, and the jaw position supported by the denture becomes unstable. The "magnetic attachment" is essentially a root-supporting appliance in the form of a root-supporting surface attachment that has a non-grasping retentive force based on the attractive force of a magnet, and can improve the crown-root ratio and reduce lateral forces. Furthermore, it can be applied to telescopic crowns as typified by the "Magno-telescopic crown", to extra-canonical attachments, and can be used in combination with other abutment devices, making it possible to design a "rigid support".

A literature search on "magnetic attachments" and "crossbite" revealed a few case reports in the literature and at academic conferences, but no useful case reports on long-term outcomes were found. Therefore, we conducted a questionnaire survey using the Delphi method. The results obtained from the Delphi method concluded that the application of magnetic attachments to patients with misaligned bites is recommended in terms of the maintenance of prosthetic appliances, masticatory function, esthetics, comfort, responsiveness, durability, and periodontal tissue health in terms of postoperative course.

In addition to this conclusion, considering the diversified forms of abutment devices using magnetic attachments and the fact that magnetic attachments can be used as abutment devices for implants as

well as natural teeth, it is recommended that magnetic attachments be used in cases of misaligned occlusion after a comprehensive examination and diagnosis of the oral and maxillofacial functions and periodontal tissue conditions. The application of magnetic attachments to cases of misaligned occlusion should be determined based on a comprehensive examination and diagnosis of the jaw and oral functions and the periodontal tissues.

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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		

【Background and Objective】

When performing occlusal reconstruction for cases with a disturbed occlusal plane, there are several choices of abutment devices, such as annular clasps, bar clasps, intracoronal attachments, extracoronal attachments, root attachments, bar attachments, telescopic crowns (cylinder and conus type), and so on. However, there are no clear criteria for their selection. Therefore, the purpose of this study was to develop an index for "whether occlusal reconstruction using MA is more effective than other systems in cases with a disturbed occlusal plane". A questionnaire survey using the Delphi method was conducted to reach a consensus based on the opinions of experts.

【Outline】

The CQ question of whether occlusal reconstruction using MA is more effective than other devices in cases with a disturbed occlusal plane was again answered by a literature search, but as in the previous study, no in vivo comparison or analysis could be found. All of the articles on occlusal reconstruction were case reports on the application of implant overdenture, and their contents did not seem to be consistent with this CQ. In light of the above, we reexamined the results of the Delphi method based on the results of the previous study.

The case with a disturbed occlusal plane was defined as "a case of a maxillary free end-medial composite defect with an erupted premolar or premolar as the abutment tooth.

In two surveys using the Delphi method, it was judged that occlusal reconstruction using MA could be recommended from the viewpoints of esthetics, comfort, and responsiveness. The results of the prognostic analysis for each abutment device showed that MAs had a better prognosis compared to annular and bar clasps. Therefore, it was judged that MAs could be recommended in comparison with clasps. When compared to other abutment devices, the condition of the abutment teeth and the crest of the missing tooth greatly affected the postoperative course, and the results were undecided (cannot judge). However, since there were few cases in which the prognosis was worse with MAs than with non-clasp abutment devices, we judged that the choice of MAs was unlikely to worsen the postoperative course of the patients.

However, when considered as a whole, at present, there is a lack of evidence to determine whether or not occlusal reconstruction with the application of MA is more effective than other devices in cases with

a disturbed occlusal plane, and many comparative studies and reports are desirable for future revisions of the guidelines.

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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		

Delphi method evaluation

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

【Background and Purpose】

When selecting an abutment tooth for a partial denture, it is necessary to confirm whether the remaining tooth is affected by periodontal disease. The purpose of this study is to develop an index to evaluate the usefulness of MA compared to other abutment systems when used with early-stage periodontium.

【Outline】

The problem was to define the extent of periodontal disease and the nature of the condition. In fact, in the first Delphi survey, the evaluators had different views on this issue, suggesting the need to unify their views. Therefore, in the second survey, "Periodontal disease of the abutment tooth adjacent to the defect in cases of bilateral mandibular free end defects was defined as P1 or P2" was added to the survey. As a result, it was possible to investigate the effectiveness of MA for the abutment teeth with early periodontal disease. The quality of the evidence was moderate.

Only a few case reports were found in the literature for the application to abutment teeth with periodontal disease. The MAs were applied to cases in which long-term survival was difficult, and the MAs were used effectively as abutments for partial dentures with good postoperative outcomes, suggesting that the MA-applied abutments were sufficiently durable. The literature shows that the cumulative survival of the abutment teeth is not significant. The literature shows that the cumulative survival of the abutment teeth is comparable to that of the conus abutment teeth, which does not suggest that MA harms the periodontal tissues. Although there is no literature available on the outcome of periodontal tissue damage, the results of long-term postoperative case reports suggest that the application of MAs does not appear to cause damage to the abutment teeth.

If we believe that any abutment should not be applied to abutment teeth with periodontal disease, it would be incompatible with the title of the CQ, and the effectiveness of MAs would not be evaluated. However, there are a few reports of good clinical results obtained using MA in cases with advanced periodontal disease and difficulty, so we judged that there is room to evaluate the effectiveness of MA. Based on the results of the above literature and the evaluation of the Delphi method, we judged the recommendation to be P (weak recommendation).

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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		

Delphi method evaluation

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

【Background and Objectives】

The placement of abutment teeth in full-arch overdentures is strongly influenced by the patient's own oral situation. However, it is unclear whether symmetrical or asymmetrical placement of abutment teeth has any effect on prognosis. The purpose of this study is to develop treatment guidelines under these circumstances.

【Outline】

There have been no in vivo studies comparing or analyzing the CQ of whether symmetrical abutment placement is more effective than asymmetrical placement in full-arch overdentures. However, some

clinical reports on various overdentures mention the placement of the abutment teeth. Although some of these studies can be read as showing symmetry, the level of evidence is low because of the difficulty of randomization due to the nature of the studies, and because the studies do not focus on symmetry and therefore cannot discuss causal relationships such as the incidence of caries in the abutment teeth. Many of the studies were not able to discuss the causal relationship, such as the study of caries incidence in the abutment teeth, because symmetry was not the main focus of the studies. However, since it is impossible to select the placement of remaining teeth in future studies by RCTs, it is expected to be necessary to conduct studies in a way that does not rely on the level of evidence in the papers.

In the model experiment, there are few papers focusing on symmetry, but Miyashita's paper, which was extracted by hand-search, discussed the symmetry of the stud-type attachment placed on the mandibular canine and the displacement of the denture base under load, and the difference in displacement under lateral loading of the denture between different designs is considered to be due to the form of the stud-type attachment. The differences in the displacement of dentures under lateral loading are attributed to the shape of the stud type attachments.

The Delphi questionnaire survey showed very few values less than 0, so it can be said that there were only a few opinions denying the validity of symmetrical placement. However, since many items had a score of 0, the opinions that acknowledged the superiority of symmetry were concentrated in items such as maintenance and mastication.

In this study, there were no literatures that reported the direct influence of MA on this CQ.

Based on the above points, there were few negative opinions about symmetry as a clinical realization, and many items were considered to be superior, and therefore, clinically, symmetrical placement is considered to be preferable. However, there are no clinical reports with a high level of evidence and directness, nor are there any reports of model experiments focusing on symmetry. Based on the above considerations, we do not strongly recommend the use of tooth autografting, for example, to ensure symmetry.

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Q11：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		

【Background and Purpose】

The root face plate (top face) of magnetic attachments can be flat, domed, or inverted-domed. However, there are no clear standards for their selection. The purpose of this guideline is to establish an index to determine whether a flat or a dome-shaped magnetic attachment is more effective in overdentures.

【Outline】

There are no human studies that have compared and analyzed the CQ of whether a flat or a dome-shaped magnetic attachment is more effective in overdentures. The results of these studies were

all in vitro, and all of them were model experiments of a full denture overdenture with two implants placed in the mandibular anterior region or one implant in the median region. The domed type showed smaller values than the flat type when unilateral loading was applied to the first molar[1], but the opposite was true when loading was applied to the median mandibular anterior tooth, i.e., the flat type showed smaller values than the domed type[2]. In terms of the load on the crest, it was reported that there was no significant difference between the two when unilateral loading was applied[3]. On the other hand, when bilateral loading was applied, the stress distribution on the crest of the domed denture was greater than that of the flat denture in the photoelastic stress analysis[4]. The three-dimensional displacement of the denture during loading was reported to be smaller for the domed denture than for the flat denture[2]. In other words, when the loading point is set at the first molar, the domed type is considered to be more effective in terms of reducing the lateral force on the implant and the amount of denture displacement.

Next, regarding the lateral force on the implant in an overdenture using a single implant as the abutment, it was reported that the domed type showed smaller values than the flat type when unilateral loading was applied to the median and cusp, and vice versa when loading was applied to the first molar[2].

The displacement of the domed denture was smaller than that of the flat denture, but there was no statistically significant difference between the domed and flat dentures. In other words, when the loading point is set at the first molar, the flat type is considered to be more effective in terms of reducing the lateral force on the implant body.

There are no epidemiological studies in the references for this CQ, and all of them are model experiments. In the field of prosthodontics, model experiments with high reproducibility and engineering techniques are considered to be reliable methods and can be used as evidence. However, it should be noted that the experimental conditions in the literature differ. In other words, when model experiments are incorporated in the development of guidelines, the experimental conditions must be properly understood and interpreted.

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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**		

【Background and Purpose]

Teeth and mucous membranes differ greatly in the amount of pressure displacement. It is easy to imagine that the force applied to the abutment teeth during function can vary greatly depending on whether the patient is allowed to occlude the denture when attaching the magnet to the denture or whether the magnet is attached without occlusion. However, there are no reports on the effects of magnet attachment methods on dentures (maintenance, function, esthetics) and abutment teeth (load bearing, periodontal tissue). Therefore, a questionnaire survey using the Delphi method was conducted with the aim of forming a consensus on the attachment method of magnets based on the opinions of experts.

【Outline]

When magnets were attached to dentures without pressure, "Disagreement (negative weak agreement)" was obtained for the questions, "It is effective for durability (extension of abutment and denture life, periodontal disease and dental caries)" and "It is effective for periodontal tissue health". The results suggest that the use of no-pressure adhesion has a slightly negative effect on the durability and health of periodontal tissues.

The experts' answers were highly convergent to "neither" for "phonetic function," "comfort," "burden on

the patient and surgeon," and "harm. In other words, the results suggest that no matter how the magnets are attached, there is no effect on the pronunciation function, wearing comfort and discomfort, physical and time burden on the patient and surgeon, or pain.

Because of the lack of evidence in this study, a questionnaire survey using the Delphi method was conducted, but no strong recommendation (agreement) was obtained. The opinions converged on the opinion that it would be better to adhere the magnets to the denture under pressure, but it is not known at all how much force to apply. Furthermore, when magnets are attached to dentures, the amount of pressure impression that was made before the denture was fabricated must also be taken into consideration. It is hoped that high quality evidence will be reported by the time the guidelines are revised in a few years.

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CQ (IP) 13: When performing MRI studies in MA-eligible cases, is the spin-echo method less artifactful?

(IP：Interventional Procedure)

【Recommendation profile】

The spin echo (SE) method has less artifacts than the gradient echo (GRE) method when MRI is performed in MA-eligible cases (weak level of recommendation).

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)	M	P	
11.Cost			
Recommendation	Judgment as a whole P		

【Background and Purpose]

Magnetic attachments may cause large metal artifacts in MRI examinations. The purpose of this guideline is to create an index to determine whether differences in imaging methods affect the reading method when magnetic attachments are used in MRI examinations.

【Outline]

The magnetic attachment keepers have significantly different magnetic susceptibility from that of a living body, causing artifacts such as distortion and loss of signal in MR images. There are many factors that affect the size of artifacts, and it is impossible to quantify the size of artifacts. To minimize the effect of artifacts, a sequence with a wide frequency range per pixel should be selected for the SE method, and in addition, an imaging method with a short echo time (TE) should be selected for the GRE method. If the BW setting is not available due to the type of equipment, it can be changed in conjunction with changing the TE. However, these settings reduce the SNR of the image and have a limited effect on the reduction of artifacts. Therefore, if the area to be diagnosed by MRI or the selected imaging method is strongly affected by the magnetic susceptibility, reading becomes difficult, and the keeper needs to be removed in the dental office.

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VI. Conclusion

We reported on the history of the development and revision of the medical practice guideline and the outline of international standardization that the JSME has been working on.

Magnetic attachments were approved as a medical device by the Ministry of Health, Labour and Welfare in 1990. Since then, improvements have been made in industry-academia collaboration to improve the retention force, miniaturization, durability, and biocompatibility, and the Japanese standard was approved for international standardization as ISO 13017 in 2012. ISO 13017:2012/Amd.1 (a supplement to ISO 13017), which includes standards for the measurement of maintenance force, was published in 2015, and the ISO task force committee is currently working to integrate the two international standards.

The protocol has been modified since 2015, and new multi-center investigations are being conducted while continuing the existing investigations. The protocol has been modified since 2015, and a new multicenter study is underway while the existing study continues.

The Medical Committee began formulating the guidelines in 2009, and conducted a wide-ranging questionnaire survey of 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 for when formulating the practice guideline, and we realized that it was too early to formulate the practice guideline and that there were many issues to be addressed, requiring supplementary surveys of clinical specialists using the Delphi method, etc. In 2014, the 2013 edition of the practice guideline for magnetic attachments was published in the Practice Guideline Library of the Japanese Dental Association. In 2014, the 2013 edition of the practice guidelines for magnetic attachments was published in the practice guideline library of the Japanese Association of Dental Surgeons.

This time, we conducted a literature search again for the 12 CQs selected five years ago, revised the outline, recommendations, and other content, and added one CQ on MRI to the "Practice Guidelines for Magnetic Attachments 2018," but further revisions and additions are necessary as the society continues to conduct related research.

Dental magnetic attachments are clinically excellent in operability, durability, and corrosion resistance, and have good long-term outcomes. 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.

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