Working toward the international standardization of dental magnetic attachments - Commission report of the ISO Corresponding Committee in 2017 -

Y. Takada

Chairman of the ISO corresponding committee Division of Dental Biomaterials, Tohoku University Graduate School of Dentistry

Introduction

The international standardization of dental magnetic attachments started by submitting NP (New Business Item Proposal) at the ISO/ TC 106 (Berlin meeting) in 2007 and proceeded officially from the ISO/ TC 106 (Gothenburg meeting) in 2008.¹) Four years later, the international standard ISO 13017 for dental magnetic attachment was established in July 2012.²)

Since ISO 13017 standard included some insufficient parts such as retentive force and so on because of its short-term formulation, the necessity of an amendment for ISO 13017 was suggested by Japanese members at the ISO/ TC 106 (Paris meeting) held in September 2012.

The suggestion was passed by NP voting in the following year and a draft of the amendment for ISO 13017 had been formulated.³⁾ After three years discussion, international standardization of retentive force measurement method was established as ISO 13017: 2012/ Amd. 1 (Amendment of ISO 13017) in November 2015.⁴⁾

It took finally over nine years to complete the ISO standards that can unfailingly demonstrate the merits of Japanese dental magnetic attachments that are compact, lightweight and have a large retentive force. Although the completion of the standards gave a halt of holding the SC 2/ WG 22 meeting at the ISO/ TC 106 (Tromsø meeting) in 2016, the WG 22 meeting in Hong Kong took place as the periodic revision of ISO 13017 in 2017.

This article outlines the state of the Hong Kong meeting in 2017 and the concept of ISO 13017 integrated with its amendment.

Activities

The completion of the standard gave a halt of holding the SC 2/ WG 22 meeting at the ISO/ TC 106 (Tromsø meeting) in 2016. Meanwhile, the ISO Corresponding Committee has formulated a revised version of the standard which is composed of the integration of ISO 13017 and ISO 13017: 2012/ Amd.1. The revised version was sent to SC 2 secretariat at early April, and the revised version was subjected to NP voting at end of June in 2017.

As a result, it was passed as a new business (Approval number: 14), the number of P member countries who agreed with the deliberation from the DIS stage (Draft of International Standard: stage 40.00) was 5. However, SC 2 secretariat recommended to deliberate from WD (Stage 20.00) because the number of P member countries who agreed with deliberations from WD (Stage 20.00 to 20.20) became 9. (Table 1)

Country (Member body)		1a. Agree to add to work programme							a	1b.Stakeholders		2. Relevant		3. Comments		4. Participation		
	*	Yes				No		Abs*		u c	consultation		uocuments					
	Status	20.00	20.20	30.00	40.00	PWI: Yes	PWI: No	NC	Exp	Marke eleva	Yes	No	Yes	No	Yes	No	Yes	No
United States (ANSI)	S				×						×			х		х	x	
Sub-Total Question 1a		7	2	0	5	0	0	0	7									
Totals		14				0		7		1	17	4	2	19	2	19	9	12

Table 1Result of the NP voting at the end of June 2017

As the comments of each country submitted at the time of NP voting, the answers were prepared and the modified WD was submitted to the SC2 secretariat in early August. The secretariat officially presented that it will formulate standards from WD (stage 20.00) over a three-year period. (Fig. 1) Since the standard has to reach to publishment (stage 60.60) in three years, we decided to aim for the passing of DIS entry (stage 40.00) at this Hong Kong meeting.

In light of results, the proposal is therefore:								
Approved (all approval criteria met) and the project will be registered:								
as new project in the committee's work programme (stage 20.00)								
as a Working Draft (WD – stage 20.20)	NP (20.00)							
as a Committee Draft (CD – stage 30.00)	WD (20.20)							
as a Draft International Standard (DIS – stage 40.00)	DIS (40.00)							
	FDIS (50.00)							
Disapproved (one or more approval criteria not met) Entry.00,	Start.20, Finish.60							
(note that if no option is selected, the default will be abandoned)								
The draft will be registered as a preliminary work item (stage 00.60)								
Abandoned.								

Fig.1 Results instructed by SC2 Secretariat

Working goal in 2017

The aim is decided to pass of DIS entry (stage 40.00) at this Hong Kong meeting.

ISO/TC 106 Hong Kong meeting

Six members of the ISO Corresponding Committee, Dr. S. Masumi (convener), Dr. T. Ishigami (expert), Dr. Y. Takada (expert assistant), Dr. M. Takahashi (obsever), Dr. E. Makihara (obsever), Dr. H. Sasaki (obsever) and Dr. Kent T. Ochiai (convener assistant) of an Aameican member, attended the ISO/TC 106 Hong Kong meeting held at Hong Kong University in 20-26 August, 2017.(Fig. 2)



Fig.2 Hong Kong University and Its position indicated on the map

The SC2/ WG22 meeting scheduled on August 23 was canceled on the unprecedented typhoon (Level 8) which was attacking Hong Kong and Macau from the previous day. (Fig. 3)



Fig. 3 Typhoon view from the hotel window

As the emergency plan for rescheduled WG meeting was informed in midnight on August 24, our members got the opportunity to propose deliberations from DIS entry at the SC 2/ WG 22 meeting on next day morning. (Fig. 4)

		P2	P3	P4	MB 141	MB142	MB121	MB122	MB151	
Time										
			SC3	SC7 WG	SC2 WG	SC7 WG	SC9 WG4	SC6 WG		
9:00	>	È	WG5	9	20	4		1		
	nar	nar	ene							
10:00	ple	s ц								
	8				SC2 WG 7 (Convenor not available)	SC2 WG SC2 22 14	SC2 WG	SC6 WG 9		
11:00	S	^ຑ ≥	≧.a.∽	≧4 ⊂			14			
	TC 106 WG 10	54 0:3(SC9 plena (10:3(12:30	:30 :30						
12:00		2 (1 pl S		5 d P S						
	WG2									
13:00	1102			E	meraen	cv Plan	for res	chedule	ed WG	
					actinga					
14:00		20	\ 6	ູ ຄ	ieeungs	.ievs				
		5:3 5:3 5:3		5:30						
15:00		0-1-	o-1	27 pler 3:30-1	8/24	1/2017	3.12 a	m		
		3:31	3:3		0,2		0			
16:00		C SC	S C	C SC						
18:00										

Fig.4 Emergency plan for rescheduled WG meetings at 3:12 am on 24 Aug.

Although the meeting from 10 a.m. was as chaotic as the weather, the nice wind seemed to blow to the Japanese side. We were able to obtain approval with almost Japanese proposal except for some modifications. The deliberation from DIS stage was also passed by WG 22 and SC 2 plenary. (Fig.5)



Fig. 5 SC2/WG 22 meeting and SC2 plenary

Currently, the revised draft was accepted by SC2 Secretariat on 24th October in 2017, and it is scheduled to be subject to DIS voting early next year.

Pleasure in Hong Kong such as dinner party of ISO/TC 106 and excellent night view are shown in Fig. 6.



Fig.6 Pleasure in Hong Kong

Overview of ISO 13017 integrated with ISO 13017: 2012/ Amd.1

The overview of ISO 13017 integrated with ISO 13017: 2012/ Amd.1 is shown in Table 2. ISO 13017 consists of clauses 1 to 8, and it is reinforced by the addition and revise of the clause 5 (5.1 Retentive force) and the clause 6 (6.3 Retentive force, 6.4 Corrosion resistance) according to the amendment (Amd. 1). (See underlines in Table 2)

The pretreatment of specimens was specified in the clause 5. Concretely, "Cleaning protocol" of the specimens for measuring retentive force was added to the sub-clause 5.1.

The clause 6 specified the test methods for evaluating that the magnetic attachment shall satisfy the requirements stated in the clause 4. Mainly specifies methods for measuring magnetic flux leakage, retentive force, and corrosion resistance.

The amendment (Amd. 1) enhanced the measuring method of retentive force in detail, making it possible to perform accurate and reproducible measurements. In particular, the measurement assisting device was specified to move vertically to the mating face, regulating the dynamic friction force within 0.01 N (1 g).

Furthermore, the retentive force curve obtained by the attractive force measurement is specified in order to clarify how to obtain the retentive force, and the difference between the measurement value and the baseline was defined as the true maintenance force.

Corrosion resistance in the clause 6.1 introduced the determination limit and the detection limit used in chemical analysis method in order to clarify the quantitative analysis of impurity element ions in the static immersion test.

1. Scope								
2. Normative references								
3. Terms and definitions								
4. Requairments	5. Preparation	6. Test methods						
4.1 Materials	5.1 Retentive force	6.1 Information						
Declaration of composition	Pre-treatment of	6.2 Magnetic flux						
4.2 Hazardous elements	<u>specimen</u>	leakage						
Ni<0.1%, Cd, Be<0.02%	5.2 Static immersion	6.3 Retentive force						
4.3 Risk analysis		Fixing materials						
Compliant with ISO 14971	polarization curve	Fixing procedure						
4.4 Magnetic flux leakage		Methods and evaluation						
Display obligation if it is 40 mT or more		Definition of retentive force						
4.5 Retentive force		6.4 Corrosion resistance						
Not less than 85% of the stated value		Minimum limit of determination						
4.6 Corrosion resistance	7. Information and instructions for use							
Eluted ion amount according to ISO 22674								
Not less than breakdown potential of 316L	8. Marking and labelling							

Table 2	Overview of ISO	13017 integrated with	ISO 13017: 2012/ Amd.1
---------	-----------------	-----------------------	------------------------

Finally

The international standardization of dental magnetic attachments, which started in 2005, took 12 years to establish international standards, including preparations. As we succeeded in establishing a

couple of international standards ISO 13017 and ISO 13017: 2012 / Amd.1 (Amendment edition) within the scheduled term, we were able to realize an exemplary formulation. We would like to ask for your continued support and cooperation in the future.

To readers,

Thank you very much.

From all members of the ISO corresponding committee in JSMAD

Reference

- 1) Y. Takada. Commission report of the ISO Corresponding Committee, JJ Mag Dent 2011; 20(1): 81-85.
- 2) ISO 13017: 2012(E), Dentistry-Magnetic Attachments.
- 3) Y. Takada. Commission report of the ISO Corresponding Committee, JJ Mag Dent 2013; 22(1): 65-68.
- 4) ISO 13017 : 2012(E)/Amd.1, Dentistry-Magnetic Attachments.