ISO/TC 150 (Implants for surgery)

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The ISO/TC 150 is an interdisciplinary TC due to handling all surgical implants; thus it requires active collaboration with the IEEE and other technical committees (TCs). Nowadays, the TC is greedy for new technologies and collaboration with TCs handling additive manufacturing and biotechnology. This paper reports the current status of the subcommittee (SC) 1 (Materials) and its working groups (WGs), SC 7, and WG 14, where the author is contributing as a biomaterials (not a device) researcher.

1. Introduction

As of November 19, 2019, the ISO/TC 150 “Implant for surgery” consists of 29 participating countries and 17 observer countries. It consitsts of 6 working groups (WG) directly under the TC and 6 subcommittees (SC).

The chair of technical committee (TC) had been chaired by Mr. John Goode of United States (US) Food and Drug Administration (FDA) at maturity until the end of 2019, and Mr. Hany Demian of FDA is approved as a new chair from 2020. In addition, Mr. Klaus Zeier from Germany (DE), the secretariat country, has been appointed as a committee manager (CM, it was called as a secretary up to 2018). Among the SCs, Japan is the secretariat country for SC 7, and Dr. Ryusuke Nakaoka, National Institute of Health Sciences, serves as the CM. In addition, Prof. Makoto Ohta of Tohoku University and the author is the respective convener for WG 14 and for SC 1/WG 3. Chairman of the Japanese Working Committee and Head of the Japanese Delegation had been Dr. Sadami Tsutsumi, Emeritus Professor of Kyoto University, until the end of the fiscal year of 2019, and the author succeeds his positions from the fiscal year of 2020.

This paper describes the activities of Japan in SC 1, SC 7, and WG 14, which the author mainly participates as an expert, focusing on this year's Lund conference.

Table 1. Structure of ISO/TC 150

WG 7	Fundamental standards
WG 10	Use and retrieval of surgical implants
WG 12	Implant coatings
WG 13	Absorbable metal implants
WG 14	Models of tissues for mechanical testing of implants
WG 15	Neurosurgical implants
SC 1	Materials
SC 2	Cardiovascular implants and extracorporeal systems
SC 4	Bone and joint replacements
SC 5	Osteosynthesis and spinal devices
SC 6	Active implants
SC 7	Tissue-engineered medical products

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2. Activities of TC 150

2.1 SC 1/WG 3 (Ceramics)

Co-convenors of the SC 1/WG 3 are the author and Mr. Andy McCabe of the United Kingdom (UK). Unfortunately, Mr. McCabe was absent in 2019 due to his health issues, so the author had to proceed with the meeting alone, although he involved deeply in discussions for all documents as described below. In 2019 Lund meeting, seven standard drafts were discussed. The author was the project leader (PL) in three of them, and two other Japanese delegates are respective PL in other two of them (the author participated their discussion as an expert). In addition, the author was deeply involved in the other two drafts as an expert. As a result, it was very exhausting meeting because the author explained the documents in four cases at the same time he worked as the convener of the proceedings. The contents are briefly summarized as follows.

ISO/AWI 13175-3 (PL: Mr. Ian Dunkley, US) is under revision process after a systematic review (SR). Since the

author as a Japanese expert added methods of compressive test, sphere-indentation test, porosity, and pore size measurement in the documents at the original establishment of this International Standard, he participates in the revision as an expert. This is being revised almost by e-meeting.

The author serving as a PL for "Test method for flexural strength of porous calcium salt bone void filler after preconditioning in deaerated phosphate buffered saline " and "Test method for torsional strength of porous calcium salt bone void filler after preconditioning in deaerated phosphate buffered saline", the former is being revised the preliminary work item (PWI) document to be working draft (WD) or committee draft (CD), and the latter is being reorganized the document for PWI.

ISO/DIS 18531 is the standard test method for bone paste and cancelled in 2017 due to limitation of time frame with agreement of participating countries that the draft international standard (DIS) will be reactivated as the DIS stage after appropriate revision was made. The author discusses the revision as a co-PL (another co-PL is Mr. Nobuyuki Asaoka of Hoya Technosurgical Co.) and it will be circulated and voted as a PWI for the DIS stage in the near future.

ISO 23317 is a standard for testing the apatite-forming ability of materials using the simulated body fluid. Since there was a strong "discontinuation" intention from the US at the time of the SR, we are entering the revision work including the discontinuation option. The PL is Dr. Masami Hashimoto of Japan Fine Ceramics Center, but she could not attend the Lund conference, so this matter will be discussed in the future e-meeting.

As a future proposal, Mr. Junji Ikeda of Kyocera Co. explained the antibacterial activity test of implants. The draft will be circulated for preliminary consultation after finish of the interlaboratory test.

A technical error was found after the publication of new edition of ISO 13779-3 last year, so we decided to make amendment with Mr. Richard White of the UK as PL.

2.2 SC 1/WG 5 (Plastics)

SC 1/WG 5 is convened by Mr. Ryan Siskey of the US. There are almost no discussion items, and Dr. Hideyuki Sakoda of the National Institute of Health Sciences explained the "Delamination test of ultra-high molecular weight polyethylene" as a future proposal as in the last year. Unfortunately it couldn't proceed to PWI because the potential experts required further test results of the new method.

2.3 SC 1 (Materials)

SC 1 is chaired by Mr. Andy McCabe of the UK (Mr. Gary Fishman of US served as an acting chair in the Lund meeting) and is the committee manager of Petra Bischoff of DE. Most decisions this year was accepting the above WG recommendations, but the following was decided to describe in the strategic business plan for whole SC 1: “Joint WG with ISO/TC 261 Additive Manufacturing is not at SC 1 but at TC 150 (Convenor is Prof. Kohei Murase of Osaka University)”, and "Antibacterial testing", "Bioglass®", and "Composite" will be considered as topics of international standardization."

The contribution of Japan to SC 1 is that there are many PLs, including those for revision according to the decision of SRs. Most of the new proposals are on ceramics and came from Japan. The fact that Japanese bioceramics researches have been leading other countries in this field shows a good sign in terms of international standardization. On the other hand, there are few new proposals, especially for metallic materials. Absorbable metal implant materials have been discussed independently in TC 150/WG 13 (currently, e-meeting only WG) and it is necessary to pay attention to future actions (Dr. Kotaro Hanada of Institute of Advanced Industrial Science and Technology (AIST) served as a Japanese expert).

2.4 SC 7 (Tissue-engineered medical products)

SC 7 was chaired by Dr. David Kaplan of the FDA, US until the end of 2019 by maturity, Dr. Carolyn Young of the FDA, US then succeeds Dr. Kaplan from the 2020, and Dr. Ryusuke Nakaoka, National Institute of Health Sciences, is the CM.

At present, “general requirements" is the only item under discussion as an international standard in WG 1 (convenor is Dr. Kaplan from 2020), and the evaluation of "regenerated cartilage" using magnetic resonance images, which is under discussion in Japan, the U.S. and China, will be documented as technical specifications for both non-clinical (US/Japan) and clinical (China) use. In addition, Dr. Motohiro Hirose of AIST explained "cell seeding method on bioceramics" at the Lund meeting as a future proposal (expert, participation in round robin test, the author also cooperated).

2.5 WG 14 (Models of tissues for mechanical testing of implants)

The convener is Prof. Makoto Ohta of Tohoku University and the secretary is Dr. Kiyoyuki Chinzei of AIST. Currently, PWI 22926 (Design and development of synthetic anatomical bone models for testing) is in preliminarily consulted, and "Biofidelity" and " Cancellous bone model" are described as future projects.

A roadmap was mainly discussed at the Lund meeting and we agreed that the standardization will proceed with the following classifications.

- Test method for "material" of tissue model
- Test method for "implant" using block-shaped tissue model
- Test method for "synthetic anatomical tissue model" used for mechanical test method of implant
  - Method using average tissue model
  - Method using patient-specific model

3. Summary

As mentioned above, in several fields including the bioceramics, many drafts are proposed from Japan and active discussions are underway. Although the total number of Japanese CM and convenors in the TC are one and three, respectively and it is not a small number, but we would like to aim for the Japanese chair (SC as well as TC) in this TC in accordance with the guidelines of the Ministry of Economy, Trade and Industry.