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Topics

ISO/TC 150 (Implants for surgery)

Masanori Kikuchi ^{1*}

¹ Bioceramics Group, Research Center for Functional Materials
 National Institute for Materials Science (NIMS)

The ISO/TC 150 is a technical committee (TC) that deals with whole surgical implantats, so it IS an interdisciplinary TC that needs to be actively linked with IEEE and other technical committees. Recently, the TC has been promoting linkage with Additive manufacturing and Biotechnology, and has a strong appetite for new technologies. This paper reports on the current status of Subcommittee 1 (Materials) and its working groups, of which the author is a convener of Working Group 3.

1. Introduction

As of December 15, 2022, the ISO/TC 150 “Implant for surgery” consists of 24 participating members (countries) and 22 observing members (countries). It consists of 9 working

groups (WG) directly under the TC and 6 subcommittees (SC). The WG 13, which had been suspended after creation of an umbrella document on absorbable metals as WG for “Absorbable metals”, was re-activated to create a standard document for whold “Absorbable implants.”

Chair of ISO/TC 150 is Mr. Hany Demian of the U. S. Food and Drug Administration (FDA). Mr. Klaus Zeier has been appointed as the Committee Manager (CM) from Germany (DE), the secretariat country. Among the SCs, the secretariat of SC 7 is Japan, and Dr. Ryusuke Nakaoka of the National Institute of Health Sciences serves as the CM. In addition, Prof. Kohei Murase of Osaka University is the convener for JWG 1 of TC 150 side, Prof. Makoto Ota of Tohoku University is the convener for WG 14, Dr. Junji Ikeda of Kyocera Corporation is co-convener with Dr. Jone Rose of the United States in WG16, and the author is the convener for SC 1/WG 3. The author is also the chairman of the Japanese National Committee and the head of the Japanese delegation.

This year, as last year, due to the COVID-19 pandemic, all of the meetings were either online or cancelled. This year’s TC 150 Annual Meeting was held online on December 2-3, after the annual meetings of all scheduled subcommittees and working groups. In addition, SC 1, SC 7, JWG 1, WG 14, and WG 16, all of which were convened by the aforementioned Japanese CM or convener, were held via online meetings.

Table 1. Structure of ISO/TC 150

JWG 1	Joint ISO/TC 150 - ISO/TC 261 WG: Additive manufacturing in surgical implant applications
WG 7	Fundamental standards
WG 8	Breast Implants
WG 10	Use and retrieval of surgical implants
WG 12	Implant coatings
WG 13	Bioabsorbable implants
WG 14	Models of tissues for mechanical testing of implants
WG 15	Neurosurgical implants
WG 16	Antimicrobial properties of 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

2. Activities of TC 150

2.1 SC 1/WG 3 (Ceramics)

WG 3 was held on November 7 (Mon.) and 8 (Tue.) from 21:00 to 23:00 JST, with 22 participants, including 20 experts from eight countries: Germany (2 members), Japan (6 members), India (2 members), UK (1 member), USA (8 members), Australia (1 member) and a convener from Japan

*E-mail: KIKUCHI.Masanori@nims.go.jp

Affiliation after April 2023: Bioceramics Group, Research Center for Macromolecules and Biomaterials

and a committee manager from Germany.

Attending from Japan were Dr. Ikeda, Dr. Sakoda, Dr. Hashimoto, Dr. Oyane, Dr. Kikuchi, and Ms. Koyanagi, Mr. Takemura of JFCA.

Dr. Kikuchi organized the meeting as convener (no co-convener due to the passing of Dr. Andy McCabe).

- (1) **ISO/PWI 13175-3**, *Implants for surgery — Calcium phosphates — Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes*

Dr. Gary Fischman and Dr. Richard White, led by PL Dr. Ian Dunkley, are working on a revised final draft of this proposal. They reported that it will still take some time, e.g., figures need to be revised. From February 9 to April 3, 2022, a questionnaire was circulated on whether the compression test and ball indenter indentation test proposed by WG3 last year would be effective in measuring what the user community actually wants to know, but few responses were received. (Japan has already responded from the companies, but not in time for the plenary session.) Three people, led by Ian, were to finalize a draft based on these results.

- (2) **ISO/PWI 4403**, *Implants for surgery — Test method for flexural strength of porous calcium salt bone void filler after preconditioning in deaerated phosphate buffered saline*
- (3) **ISO/NP**, *Implants for surgery — Easy-to-Use test method for torsional strength of porous calcium salt bone void filler after preconditioning in deaerated phosphate buffered saline*

It has taken some time to respond to the comments in the Preliminary Consultation on these two issues, and a revised proposal will be submitted to the CM by the end of March 2023.

- (4) **ISO/PWI 18531**, *Implants for surgery — Calcium phosphate bioceramics — Characterization of hardening bone paste materials*

Since some parts of PL Dr. Asaoka's revised proposal had not been corrected, and since Dr. Asaoka was not present at the meeting, it was decided to wait for him to resubmit his proposal.

- (5) **ISO/PWI 23317:2014**, *Implants for surgery — In vitro evaluation for apatite-forming ability of implant materials*

Dr. Hashimoto, JFCC, explained the modifications that were reached by consensus at the Task Group e-meeting. As a result, the revised document will be put to CD ballot as a proposed revision of ISO 23317:2014. The revision period is

24 months, and Dr. Hashimoto and Dr. Oyane of AIST will serve as PLs.

- (6) **ISO/NP 18368**, *Implants for surgery — Nitride ceramic materials — Monolithic materials made of beta silicon nitride*

The NP ballot was held from June 23 to September 16, 2022. Despite the negative vote of US, 9 countries approved (7 countries in favor of expert nomination), and it was registered as a new work item. The nominated experts are Dr. Marinis Pirpiris of Australia, Dr. Patricia Ortega C. and Dr. Rafael Trommer of Brazil, Dr. Lu Jianxi of China, Dr. David Grossin of France, Dr. Norbert Schneider of Germany, and Dr. Junji Ikeda of Japan, Dr. Gary Fischman and Dr. John Goode of USA; and Dr. Richard White of UK.

Dr. Gary Fischman explained the responses to the comments. A comparison with the relevant ASTM documents was to be made.

- (7) Preliminary consultation, **ISO/PPWI xxxx**, *Implants for surgery — Ceramic materials — Part x: Composite materials based on a zirconia matrix with alumina reinforcement*

Preliminary consultation took place from March 19 to May 31, 2022, with 35 comments.

Dr. Karen Hans, PL, responded to comments and provided background on her research on alumina-enhanced tetragonal zirconia (ATZ) implants. Participants discussed the limitations of tetragonal stabilizers. Several agreed that "any stabilizer is acceptable as long as the performance requirements are met," but the discussion was inconclusive.

This case is registered as ISO/PWI 13356-2, *Implants for surgery - Zirconia ceramics - Part 2: Name to be defined (ATZ ceramic)* and decided to register Dr. Karen Hans as PL.

ISO 13356 *Implants for surgery - Zirconia ceramics - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)* was recommended for revision under WG 3 as the new ISO/PWI 13356-1.

PL to be determined; participants are Mr. Ikeda, Dr. Gary Fischman, Dr. Karen Hans, Dr. Norbert Schneider, and Dr. Richard White.

- (8) Report on ASTM activities

Dr. Gary Fischman reported that no significant ASTM projects for ceramics are currently being developed. He also reported that the vote to rename F 1185-2003(2014) Specification for Composition of Hydroxylapatite for Surgical Implants to F 1185 Standard Specification for Composition of Medical-grade Hydroxylapatite for Surgical

Implants.

(9) Next Meeting

It is possible to schedule a virtual meeting for document preparation in the spring of 2023. Next year's TC 150 in-person meetings have not yet been scheduled, but web meetings of working group and project groups can be set up at any time. If a TC 150 face-to-face meeting is held, a face-to-face meeting will be held at the same time.

(10) Others

Due to the absence of a Co-convenor following the passing of Dr. Andy McCabe, Dr. Gary Fishman was asked to assume the role of Co-convenor to support Dr. Kikuchi.

2.2 SC 1/WG 4 (Metals)

WG 4 was held on Tuesday, October 25 and Wednesday, October 26 from 20:00 to 22:00 JST with 21 participants from 9 countries: Brazil (2), Germany (1), Japan (3), France (1), UK (2), USA (7), China (1), India (1), Australia (1) plus the committee manager and the convenor. Dr. Ikeda, Dr. Sakoda and Dr. Kikuchi participated from Japan. Dr. Michael Roach of the United States led the meeting as convenor.

(1) **ISO/PWI 5832-1** Implants for surgery —Metallic materials —Part 1: Wrought stainless steel

Since all comments have been addressed and the Draft has been updated, we will proceed to DIS. Since the deadline for the DIS has already passed, the term was extended to 36 months.

(2) **ISO/PWI 5832-4**, Implants for surgery — Metallic materials —Part 4: Cobalt-chromium-molybdenum casting alloy

Since all comments have been addressed and the Draft has been updated, we will proceed to DIS. Since the deadline for the DIS has already passed, the term was extended to 36 months.

(3) **ISO/PWI 5832-7** Implants for surgery — Metallic materials —Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy

Since all comments have been addressed and the Draft has been updated, we will proceed to DIS. Since the deadline for the DIS has already passed, the term was extended to 36 months.

(4) **ISO/PWI 5832-11** Implants for surgery — Metallic materials —Part 11: Wrought titanium 6-aluminium 7-niobium alloy

Since all comments have been addressed and the Draft has been updated, we will proceed to DIS. Since the deadline for

the DIS has already passed, the term was extended to 36 months.

(5) **ISO/PWI 15374** Implants for surgery — Requirements for production of forgings

Dr. Karen McKinlay (project team: Dr. Karen McKinlay, Dr. Michael Roach, Dr. Jon Moseley, Dr. Lawrence Kay) reported that duplicate checks were made with the following documents.

- **ISO 15374**, Implants for surgery – Requirements for production of forgings
- **ASTM F620**, Standard Specification for Titanium Alloy Forgings for Surgical Implants in the Alpha Plus Beta Condition
- **ASTM F621**, Standard Specification for Stainless Steel Forgings for Surgical Implants
- **ASTM F799**, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)
- **ASTM F961**, Standard Specification for 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy Forgings for Surgical Implants (UNS R30035)

(6) **ISO/DIS 9584** Implants for surgery —Non-destructive testing — Radiographic examination of cast metallic surgical implants

It was decided to extend this project for 9 months and proceed to 2nd DIS.

(7) **Report on ASTM activities**

Dr. Michael Roach reported on current activities at ASTM.

- They are working on a revision of the **ASTM F90** standard for the same alloys as the **ISO 5832-5** standard.
- They are working on future revisions of the **ASTM F5832** standard for 316L stainless steel wire materials covered by the **ISO 1350-316** standard.
- Working on a new standard for Nitinol wire materials, with a draft to be voted on in early 2023
- He reviewed ASTM F601 and ISO 9583 standards for possible duplication. As a result, they found potential duplicate items in both the ASTM and ISO standards that will need to be resolved in future revisions.
- ASTM F04.12 has a comprehensive standard ASTM F899 that covers materials used in surgical instruments (not implants) that have limited contact with human tissue or the body. Recently, Ugitech 4116N alloy was added to this standard as a new standardized material for surgical instruments.
- They are looking for a project team for future ISO 9583 / ASTM F 601-13 duplicate verification work. Dr. Lawrence

Kay will respond.

(8) **Future work items**

Dr. Michael Roach reported that if ISO 20160, Implants for surgery - Metallic materials - Classification of microstructures for alpha + beta titanium alloy bars and the interpretation of microstructures are discussed in ISO, it has provided information that this topic will be disclosed to ASTM. Further information on microstructure may need to be added to the material standard. This issue will be discussed further at the ASTM meeting.

(9) **Next Meeting**

Virtual meetings are planned for spring 2023 on the following projects

- Documentation of **ISO/DIS 5332** Series
- Results and Responses to the Second DIS of **ISO DIS 9584**
- Update on duplicate verification efforts

Next year's TC 150 in-person meetings have not yet been scheduled. If a TC 150 face-to-face meeting is held, a face-to-face meeting will be held at the same time.

(10) **Others**

A systematic review of ISO 5832-2:2018, Implants for surgery - Metallic materials - Part 2: Unalloyed titanium, will be initiated in the future. Voting will begin on January 15, 2023. Duplicate checks may be necessary.

2.3 SC 1/WG 5 (plastic)

SC 1/WG 5 is convened by Dr. Ryan Siskey, USA. This year's online meeting was held from 20:00 to 22:00 JST on Thursday, October 27 and Friday, October 28 with 21 participants from 8 countries: Brazil (1), France (2), Japan (3), China (1), India (1), UK (1), USA (9), Australia (1) with the committee manager and the convener.

Dr. Ikeda, Dr. Sakoda and Dr. Kikuchi participated from Japan. Dr. Ryan Siskey of the United States led the meeting as convener.

(1) **ISO/PWI 14949**, Implants for surgery — Two-part addition-cure silicone elastomers

The CM noted that a NWIP vote would be needed to change Scope to include texture and texture analysis. (Revisions that do not change the Title and Scope may be decided by SC 1 resolution.) The project was then ready for activation. At this point, a project timeframe and target date should be determined.

The project has been registered as a PWI since November 16, 2020. A duplicate check with ASTM F2038 was performed by Dr. Jon Moseley and Dr. Heitor Neto Luz. Dr. Marie-Ange Roux

gave a brief oral report on the results. There was no overlap between the ASTM and ISO documents because the Scope is fundamentally different and the ISO standard, in contrast to the ASTM document, focuses on material properties, test methods, and specifications. Dr. Marie-Ange suggested E-Harmonization because some terms could be reconciled between both ASTM and ISO documents.

The experts agreed that more time was needed to review the duplicate comparisons and asked for two months of internal WG 5 consultation on this question. The results were to be sent together with the document comparison documents. The project team is as follows.

- Heitor Luz, DSc
- Carolina Carvalho
- Roberto Carvalho
- Mrs. Liu Lili
- Jeremy Decker

(2) **ISO/PWI 5833** Implants for surgery — Acrylic resin cements

The result of the ISO 5833 / ASTM F 451 overlap verification work done by the project group (Dr. Hany Damian, Dr. Jon Moseley, Dr. Ryan Siskey) to produce the first draft is harmonization. The updated document still needs to be discussed by the PG and cannot be referenced. An updated document will be available in February 2023 for the May 2023 meeting.

(3) **ISO/PPWI xxxxx** Accelerated test method to evaluate delamination resistance of ultra-high molecular weight polyethylene used for orthopaedic implants

This Project has not been registered yet.

It was discussed that the Scope needs to be redefined. It was suggested that by creating more stringent test conditions or extending them to include realistic conditions that reflect variables that affect the body, it should be possible to find test conditions that also destroy the material and more accurately assess the suitability of the material for the intended use. On the other hand, it was noted that the project only provides a method/tool to compare materials and the results of the tests are considered by the user. Proponent Mr. Sakoda countered that in vitro testing cannot evaluate everything and that this test is a materials test and must be kept simple. Dr. Jason noted that the test is to evaluate whether the material is fit for purpose. As a result, the following recommendations were adopted.

WG 5 will further investigate and discuss accelerated testing methods to evaluate the delamination resistance of ultra-high molecular weight polyethylene used in orthopedic

implants and define the appropriate Scope of the project. Register the project as a preliminary work item. The Experts agreed to detail his expectations and requirements for testing/documentation and email them to Mr. Sakoda by the end of 2022.

(4) Report on ASTM activities

Dr. Ryan Siskey reported.

- **ISO 13781**, Implants for surgery — Homopolymers, copolymers and blends on poly(lactide) — In vitro degradation testing needs to be revised at the same time as the ASTM F1635 document.

- **ASTM F3336-22**, Standard Practice for Lipid Preconditioning of Ultra-High-Molecular- Weight Polyethylene for Accelerated Aging is under revision.

(5) Next Meeting

Virtual meetings for documentation purposes are always available. Next year's TC 150 in-person meetings have not yet been scheduled. If a TC 150 face-to-face meeting is held, a face-to-face meeting will be held at the same time.

2.4 SC 1 (Materials)

SC 1 is chaired by Dr. Richard White from the UK, and Dr. Petra Bischoff from Germany is the CM. This year, the 1st Plenary was held on Monday, October 24 from 20:00 to 22:00 JST, and the 2nd Plenary was held on Friday, November 11 from 21:00 to 23:00 JST. The 1st Plenary had 30 participants from 9 countries: Brazil (1), USA (12), UK (4), Germany (4), Japan (3), China (2), Australia (1), Saudi Arabia (1), and India (2). Mr. Ikeda, Mr. Sakoda, and Dr. Kikuchi participated from Japan. The 2nd Plenary had 20 participants from 6 countries: Brazil (1), USA (9), UK (2), Germany (4), Japan (3), and India (1). From Japan, Dr. Ikeda, Dr. Kikuchi, and Mr. Takemura of JFCA participated.

This year, the resolution was to accept the recommendation of the WG mentioned above.

The contribution of Japan to SC 1 is that there are many PLs including those during the revision work by SRs, etc., the aspect of Japan leading other countries in bioceramics research, such as the fact that many of the new proposals are from Japan, although they are mainly for ceramics, is also considered to be in the right direction in terms of standardization. On the other hand, there are few new proposals, especially for metallic and plastic materials, but we believe that we need to pay attention to future developments, as a delamination test for ultra-high molecular weight polyethylene has been proposed from Japan and

additive manufacturing of surgical implantation agents is being discussed in JWG 1, where a Japanese national serves as convener. On the other hand, it is necessary to sort out "biodegradable implants" to be handled between WG 13 and SC 1, and to discuss how to handle bio-derived materials such as collagen, which is a topic in SC 7 (since SC 1 does not handle bio-derived materials although there are examples of their use in bone replacement material composite, etc.).

2.5 SC7 (Tissue Engineering Products)

SC7 is chaired by Dr. Carolyn Yong of the U.S. and, as noted above, Dr. Ryusuke Nakaoka of Japan is the CM. This year's event was held on Thursday, October 20 from 21:00 to 24:00 JST with 20 participants from 7 countries: Brazil (2), Japan (5), UK (2), USA (1), and China (4). From Japan, Dr. Nakaoka of CM, Dr. Hirose and Dr. Kikuchi of WG 3 convener, as well as Ms. Koyanagi and Mr. Takemura of JFCA participated. The meeting was led by Dr. Chair Carolyn Yong.

It was reported that Belgium has changed from P-member to O-member, P-member for SC 7 was 9 and O-member was 13. Also, a new ISO/TS 24560-1 Tissue engineered medical products — MRI evaluation of cartilage — Part 1: Clinical evaluation of regenerative knee articular cartilage using delayed gadolinium-enhanced MRI of cartilage (dGEMRIC) and T2 mapping was issued.

Japanese proposals, "Test Method for Cell Attachment to Bioceramics - Part 1: Cell Seeding on Dense Bioceramics Scaffolds" and "Tissue engineered medical products - MRI evaluation of cartilage - Part 2: Preclinical evaluation of regenerative knee articular cartilage" is to enter into pre-consultation as soon as the document is ready. In addition, both Chinese proposals, "ISO/AWI 6631 Tissue engineered medical products - Quantification of type I collagen from bovine: Liquid chromatography - mass spectrometry" and "ISO/AWI 7614 Tissue engineered medical products - The method for quantification of remnant DNA in decellularized ECM scaffolds" were approved as new projects.

Dr. Carolyn Young will serve as WG1 convener until Dr. David Kaplan's replacement is determined. Dr. Kikuchi made an advance on the "DNA Extraction Method for Specimens Containing Nano Hydroxyapatite Crystals," which is being promoted as a METI project. It was received relatively well.

3. Summary

As mentioned above, in several fields, including bioceramics, there are many proposals from Japan, and active discussions are underway. In the TC as a whole, 1 CM and 4 conveners. We would like to aim for more Japanese chairs (not only in the TC but also in the SC) and continue to promote Japanese proposals from new viewpoints that are scientifically more valid than those of other countries. On the other hand, the age of participants, including PLs, is gradually getting older, and it is considered necessary to recruit the next generation. To this end, we hope that the government, research periods, and universities will provide greater incentives for involvement in standardization activities.

On the other hand, due to COVID-19, face-to-face meetings could not be held and breaks were not available for project-related explanations, negotiation, etc. Japanese boader measures have been finally relaxed, and I have traveled to NIST and DIN for negotiation. We were able to exchange information with a complementary standardization project in the U.S., which resulted in cooperation, including international interlaboratory testing, on the standardization of our proposal at NIST. It was surprising to see that the importance of physical meetings is well understood and that, due to the time difference, many in the U.S., Japan, and other Asian countries want a physical meeting for next year's TC 150 meeting (despite the travel costs), while many in Europe, where the time difference is less of a concern, want a virtual meeting.

Finally, we regret to report the passing this year of Dr. Andy McCabe of the U.K., who served for many years as chairman of SC 1 and co-convenor of SC 1/WG 3, and Dr. Heitor Neto Luz of Brazil, who actively worked in TC 150. Andy had been suffering from cancer for some time and passed away before all the meetings this year, while Heitor passed away suddenly after being in good health at the time of the WG 3 meeting. I would like to express my gratitude and deepest condolences to both of them for their support (not only for TC 150 but also for the author personally).