CONSENSUS REPORT



Group 4 ITI Consensus Report: Patient benefits following implant treatment in partially and fully edentulous patients



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Abstract

Objectives: The aim of Working Group 4 was to address patient benefits associated with implant dentistry. Focused questions on (a) dental patient-reported outcomes (dPROs), (b) improvement in orofacial function, and (c) preservation of orofacial tissues in partially and fully edentulous patients following provision of implant-retained/supported dental prostheses were addressed.

Materials and Methods: Three systematic reviews formed the basis for discussion. Participants developed statements and recommendations determined by group consensus based on the findings of the systematic reviews. These were then presented and accepted following further discussion and modifications as required by the plenary of the 7th ITI Consensus Conference, taking place in 2023 in Lisbon, Portugal.

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Results: Edentulous patients wearing complete dentures (CD) experience substantial improvements in overall dPROs and orofacial function following treatment with either complete implant-supported fixed dental prostheses (CIFDP) or implant overdentures (IODs). With respect to dPROs, mandibular IODs retained by two implants are superior to IODs retained by one implant. However, increasing the number of implants beyond two, does not further improve dPROs. In fully edentulous patients, rehabilitation with CIFDP or IOD is recommended to benefit the preservation of alveolar bone and masseter muscle thickness.

Conclusions: Completely edentulous patients benefit substantially when at least the mandible is restored using an CIFDP or an IOD compared to CD. In fully edentulous patients, implant prostheses are the best option for tooth replacement. The availability of this treatment modality should be actively promoted in all edentulous communities, including those with limited access and means.

KEYWORDS

consensus report, dental patient-reported outcomes, meta-analysis, orofacial function, systematic review, tertiary prevention

1 | INTRODUCTION

The objectives of Group 4 of the 7th ITI Consensus Conference were to provide statements and recommendations for clinicians and researchers relating to patient benefits following implant treatment in partially and fully edentulous patients. Three systematic reviews, prepared and reviewed prior to the Consensus Conference, formed the basis for discussion within the working group. The working group formulated Consensus Statements and Clinical Recommendations that were then presented and accepted following further discussion and modifications when required by the plenary. Clinical Recommendations for future research were also prepared by the working group.

In addition, responses to questions considered relevant from a patient's perspective were made by the working group based on the findings of the systematic reviews.

The three systematic reviews are listed below:

- Treatment effect of implant-supported fixed complete dentures and implant overdentures on patient-reported outcomes: A systematic review and meta-analysis (Abou-Ayash et al., n.d.)
- 2. Oral function in completely edentulous patients rehabilitated with implant-supported dental prostheses: A systematic review and meta-analysis (Srinivasan et al., n.d.)
- 3. Effect of dental implant therapy on the preservation of orofacial tissues: a systematic review and meta-analysis (De Souza et al., n.d.).

2 | SYSTEMATIC REVIEW 1

Treatment effect of implant-supported fixed complete dentures and implant overdentures on patient-reported outcomes: A systematic review and meta-analysis (Abou-Ayash et al., n.d.).

3 | PREAMBLE

The patient's perspective of treatment is a key factor in analyzing treatment success. Patient-reported outcomes (PROs) are commonly used for such patient-centered success analyses. In the medical field, PROs describe health outcomes that come directly from patients without interpretation by another person. Those PROs are recorded using different patient-reported outcome measures (PROMs), which represent the tools to record PROs. In dentistry, specific dental patient-reported outcome measures (dPROMs) are used that measure the patient-reported outcome of dental treatment (dPROs). However, the terms PROs and PROMs are often used as synonyms (Table 1).

The treatment of edentulous patients using dental implants is well established as a treatment alternative to conventional removable complete dentures (CDs) (Feine et al., 2002). The advantages of implant-supported or implant-retained overdentures (IODs), and complete implant-supported fixed dental prostheses (CIFDPs) over CDs in terms of parameters such as oral function, oral health or dPROs have been demonstrated in numerous studies and are therefore considered today to be evidence-based (Hartmann et al., 2020). However,

Complete implant-supported fixed dental prostheses	CIFDP
Dental patient-reported outcome	dPRO
Dental patient-reported outcome measure	PROM
Denture satisfaction score	DSS
Effect size	ES
Implant-supported or implant-retained overdenture	IOD
Muscosa-borne removable complete denture	CD
Oral health impact profile	OHIP
Oral impact on daily performance questionnaire	OIDP
Partial implant-supported fixed dental prosthesis	IFDP
Randomized controlled trials	RCT
Tooth-retained/supported removable partial dental prosthesis	RDP
Tooth-supported fixed dental prosthesis	FDP
Visual analog scale	VAS

it is unclear whether there is a difference between CIFDPs and IODs with regard to the benefits mentioned. Especially in the field of dPROs, this question could not be conclusively clarified. Attempts to summarize the existing evidence by a meta-analysis have so far failed due to the use of various dPROMs for the analysis of dPROs. In the present systematic review, we summarized the data from different dPROMs by calculating the effect size (ES), making the results obtained from different dPROMs comparable. The ES is a quantitative measure of the treatment effect. The larger the ES, the stronger the treatment effect. Generally, ES>0.8 are considered to be large. The main requirement for ES calculation was the availability of baseline (before implant therapy) and follow-up dPROs. The systematic literature search resulted in 1608 records, and 28 studies with dPROs of 1457 patients were finally included. This number was sufficient to perform a meta-analysis. The different dPROMs used in the included studies were different versions of the oral health impact profile (OHIP), different visual analog scales (VAS), the Short Form 36 questionnaire, the Oral Impact on Daily Performance questionnaire (OIDP), a patient satisfaction score, and the Denture Satisfaction Score (DSS; n=2).

The following limitations should be considered when interpreting the results of the present study: (1) only four of the included studies reported dPROs in CIFDPs, (2) among the 15 RCTs included, only 2 RCTs directly compared CIFDPs with IODs, (3) only three studies referred to treatment of the edentulous maxilla. Furthermore, the quality assessment of the literature included showed considerable variation with a high risk of bias and moderate-to-low certainty of evidence.

CONSENSUS STATEMENTS

4.1 Consensus statement 1

In fully edentulous patients wearing removable complete dentures (CD), the use of dental implants to retain/support dental prostheses in the maxilla and/or the mandible leads to an improvement in overall dental patient-reported outcomes (dPROs).

This statement is based on a descriptive analysis of 2 RCTs and 26 prospective case series (1457 patients).

4.2 Consensus statement 2

Edentulous patients wearing complete dentures (CD) gain substantial improvements in overall dPROs following treatment which are comparable with either complete implant-supported fixed dental prostheses (CIFDPs) or implant overdentures (IODs).

This statement is based on a meta-analysis of 2 RCTs and 13 prospective case series (519 patients). Effect size (ES) CIFDPs: 1.68 [1.15, 2.20]; ES IODs: 1.26 [0.99, 1.52].

4.3 Consensus statement 3

When restoring the edentulous mandible with an IOD, both bar and non-splinted attachments lead to a similar improvement in dPROs.

This statement is based on a meta-analysis of 2 RCTs and 18 prospective case series (639 patients). ES bars: 1.33 [0.37, 2.29]; ES non-splinted attachments: 1.38 [1.17, 1.58].

Consensus statement 4

With respect to dPROs, mandibular IODs retained by two implants are superior to IODs retained by one implant.

This statement is based on a meta-analysis of 3 RCTs and 17 prospective case series (639 patients). ES difference: 0.72 [0.38, 1.06].

Consensus statement 5

Increasing the number of implants to more than two implants to retain a mandibular IOD does not further improve dPROs.

TABLE 2 Effect size in respect to the increase in dPROs in relation to the number of implants to support/retain a mandibular IOD.

Implants per reconstruction	Patients (n)	Effect size (95%-CI)
1 Implant	304	0.67 [0.43, 0.91]
2 Implants	395	1.40 [1.18, 1.62]
3 Implants	135	1.46 [1.19, 1.73]
4 Implants	68	0.65 [-0.21, 1.50]

This statement is based on a meta-analysis of 2 RCTs and 18 prospective case series (598 patients), (Table 2).

5 | CLINICAL RECOMMENDATIONS

5.1 | Clinical recommendation 1

In fully edentulous patients can a CIFDP or an IOD be recommended to provide optimal stability and comfort?

In fully edentulous patients, based on dPROs, both CIFDPs and IODs result in an improvement in stability and comfort compared to CDs. For the highest levels of stability, retention, and comfort, CIFDPs may be recommended over IODs, whenever clinically indicated. Clinical decisions should also consider other relevant factors including speech, esthetic concerns, prosthetic space requirements, costs, stability, retention, maintenance requirements, and manual dexterity. Continuous assessment of the patient's ability to manage the prosthesis and maintain plague control should be performed.

5.2 | Clinical recommendation 2

What is the ideal attachment for a mandibular IOD?

In fully edentulous patients, both splinted and unsplinted attachments are equally effective from a patient's perspective and can be recommended.

5.3 | Clinical recommendation 3

Based on dPROs, what is the ideal number of implants to retain/support a mandibular IOD?

In fully edentulous patients, mandibular IODs retained by one or two implants show positive effects on dPROs compared to a mandibular CD, with two implants being the optimal number. Additional implants do not offer further improvements in dPROs.

Based on expert opinion, if the opposing maxilla is dentate or restored with a fully implant-supported prosthesis, more than two standard-diameter implants in strategic positions are recommended to support the mandibular IOD to avoid complications and fractures of the implants and prosthetic components. More than two implants

are also recommended to enable implant support over mucosal support in compromised anatomical situations (e.g., highly resorbed posterior mandible) and/or compromised mucosal conditions (e.g., hyposalivation).

6 | PATIENT PERSPECTIVES

For the Patient Perspectives, please refer to the section below.

7 | RECOMMENDATIONS FOR FUTURE RESEARCH

- In future studies on patient perspectives, a clear distinction should be made between the abbreviations dPROMs and dPROs.
- Based on the small number of studies on maxillary CIFDPs/IODs, as well as studies directly comparing the treatment effect of CIFDPs vs. IODs on dPROs, more research is needed. RCTs that include the rehabilitation of the edentulous maxilla and compare CIFDP and IOD treatment directly would be especially valuable to provide a conclusive assessment of the treatment effect on dPROs.
- For the analysis of dPROs, reporting of pre-treatment and follow-up scores (including measures for central tendency, e.g., means, and for score variability, e.g., standard deviations) should be mandatory.
- Future studies should use dPROMs with sufficient psychometric properties and several validated language versions available to ensure high methodological quality and comparability, such as the Oral Health Impact Profile (OHIP). The use of some type of OHIP questionnaire should therefore be the minimum standard for the collection of dPROs. For further assessment of specific treatment outcomes, individual questions or questionnaires can be added. To ensure comparability, questions should be chosen that were already applied in other studies on the same or similar topic. Answers to these questions should be collected on commonly accepted response scales, such as VAS, ordinal response scales, or Likert scales.

8 | SYSTEMATIC REVIEW 2

Oral function in completely edentulous patients rehabilitated with implant-supported dental prostheses: A systematic review and meta-analysis (Srinivasan et al., n.d.).

9 | PREAMBLE

The purpose of this systematic review was to evaluate the literature reporting on the short- to long-term effects of rehabilitation with implant-retained/supported prostheses on the components

of oral function in completely edentulous patients. The outcomes of oral function assessed in this systematic review and meta-analysis were:

- Rite force
- Masticatory performance
- Swallowing function
- Muscle activity
- Lip force
- · Speech and articulation
- Oral tactile sensitivity
- · Oral diadochokinesis
- Salivary flow

The findings of the systematic review and meta-analysis were based on 30 prospective studies comparing the oral function of completely edentate individuals rehabilitated with CDs in both jaws and those edentate individuals rehabilitated with a conventional maxillary CD opposing implant-retained/supported mandibular prothesis. The follow-up periods of the included studies ranged between 6 months and 10 years after implant loading. Sufficient data were available to perform a meta-analysis for evaluating bite force, masticatory performance (sieve method, colorimetric method, swallowing threshold), stimulated salivary flow rate, mandibular movement, and chewing pattern (area of chewing pattern, opening and closing velocity, masticatory cycle/second, and vertical height). The time points considered in the analyses were grouped into 6–12 months, 12–36 months, and > 36 months.

The review identified records evaluating the effects of implant rehabilitation on lip force, speech, and oral tactile threshold. These studies were however excluded from the meta-analysis as they were either retrospective in design, with follow-up periods below 6 months, or with inadequate sample sizes. The review did not identify records evaluating effects of implant rehabilitation on tongue function, swallowing function, oral stereognosis, and oral diadochokineses. The current review was unable to identify studies reporting on maxillary implant-retained/supported prostheses for edentate individuals that satisfied the scope and inclusion criteria of this review.

10 | CONSENSUS STATEMENTS

10.1 | Consensus statement 1

Overall oral function improves significantly in edentulous patients rehabilitated with mandibular IODs/CIFDPs opposing a conventional maxillary CD when compared to those rehabilitated with CDs in both jaws.

This statement is based on the overall results of the meta-analyses performed for the investigated time points at 6–12 months (Z=-4.895, p<.001; 10 studies: 2 RCTs, 8 prospective studies; 443 patients), at 12–36 months (Z=-4.886, p<.001; 14 studies: 3 RCTs, 11 prospective studies; 586 patients) and at

more than 36 months (Z = -9.108, p < .001; 5 prospective studies; 179 patients) in function.

10.2 | Consensus statement 2

Bite force increases in edentulous patients rehabilitated with mandibular IODs/CIFDPs opposing a maxillary CD when compared to those rehabilitated with CDs in both jaws.

This statement is based on the meta-analysis performed for the investigated time points at 6–12 months (Z=-3.788, p<.001, 2 prospective studies, 52 patients), at 12–36 months (Z=-4.041, p<.001, 4 studies: 1 RCT and 3 prospective studies, 152 patients), and at more than 36 months (Z=-8.061, p<.001, 5 prospective studies, 179 patients).

10.3 | Consensus statement 3

Chewing (masticatory performance and efficiency) improves in edentulous patients rehabilitated with mandibular IODs/CIFDPs opposing a maxillary CD when compared to those rehabilitated with CDs in both jaws.

This statement is based on the meta-analysis of data provided by 7 studies (2 RCTs and 5 prospective studies; 327 patients) for the assessment of masticatory performance by mixing ability tests (variance of hue: Z=-2.283, p<.022, 5 studies: 2 RCTs and 3 prospective studies, 235 patients; mixing ability test: Z=-4.711, p<.001, 2 prospective studies, 92 patients) with a follow-up period of 12–36 months.

Assessment of chewing function using the sieving method (comminution tests) showed the largest effect size.

11 | CLINICAL RECOMMENDATIONS

11.1 | Clinical recommendation 1

With respect to oral function, should implant-retained/supported prostheses be considered the best treatment option in completely edentulous patients?

Oral function significantly improves in completely edentulous patients when the mandible is restored using an CIFDP or an IOD compared to CDs, therefore this should be recommended as the best treatment. The availability of this treatment modality should be actively promoted in all edentulous communities, including those with limited access and means.

12 | PATIENT PERSPECTIVES

In the following part, patient perspectives are formulated that are supported by the consensus statements from both systematic

reviews (Abou-Ayash et al., n.d.; Srinivasan et al., n.d.) and the clinical recommendations. The scenario below forms the basis for questions that an edentulous patient may pose when being considered for fixed or removable implant prostheses.

12.1 | Patient perspective 1

My upper denture fits well but I have problems with my lower denture, particularly when eating. Is there a better alternative than my current lower denture?

Response: Yes, there are removable dentures and fixed bridges attached to implants to replace your loose lower denture. There are many studies that show that these improve satisfaction and the ability to chew and bite. Implants will help to stabilize your dentures/bridges, making them more comfortable and less likely to move around.

12.2 | Patient perspective 2

As my upper denture fits well, should an implant denture/bridge be my first choice of treatment instead of a new lower full denture?

Response: Since you are not satisfied with your current lower denture, yes, a dental implant denture/bridge should be considered as your first option to help replace all of your missing lower teeth. Studies show that these are very beneficial to patients like you. However, a full assessment will be required to examine the amount of bone you have available to place implants and to consider your medical history.

12.3 | Patient perspective 3

If I keep my full denture as it is but want an implant denture in my lower jaw, how many implants will I need?

Response: If we are considering a removable implant denture, it is possible to use 1 implant, but we recommend 2, as the studies show us that this will provide you with greater satisfaction. Interestingly, the evidence also shows that putting in more than 2 implants will not lead to any improvements in your satisfaction.

12.4 | Patient perspective 4

Will I be happy with the removable implant denture in the long term? Response: Yes, the majority of patients in your situation remain satisfied with their removable implant dentures for at least 10 years.

12.5 | Patient perspective 5

What if I would like to have a fixed solution, something that I do not have to remove?

Response: If you prefer to have a fixed denture, then you will require a minimum of 4 implants to provide you with a fixed implant bridge. Many patients have reported that this option provides the highest degree of stability and comfort. However, you must understand that the fixed option makes daily cleaning more challenging and will be more expensive.

13 | RECOMMENDATIONS FOR FUTURE RESEARCH

- Future clinical studies and trials on implant therapy should include appropriate parameters of oral function as outcome measures.
 This will generate valuable prospective data for evaluating the true significance of implant therapy in edentulous patients.
- Data on the measurement of masticatory performance/efficiency
 was very heterogenous as it was performed using many different
 techniques and interpretations. A consensus on a single, validated
 technique for measuring masticatory performance/efficiency
 that is easy to perform, without an elaborate armamentarium, and
 that is universally scalable with other methods is warranted.
- There is a paucity of scientific evidence on the effects of implant therapy on components of oral functions such as speech, lip force, oral tactile sensitivity, oral didochokinesis, and salivary flow. It is recommended that outcomes addressing these parameters are included in future clinical implant studies.

14 | SYSTEMATIC REVIEW 3

Effect of dental implant therapy on the preservation of orofacial tissues: a systematic review and meta-analysis (De Souza et al., n.d.).

15 | PREAMBLE

With the increase in life expectancy, more patients are bound to present with missing teeth due to periodontitis, caries, fracture, or a combination of these (Sarafidou et al., 2022). Clinicians may recommend fixed or removable conventional or implant-supported rehabilitations to treat both partially and fully edentulous spaces, or even no restoration. The treatment of choice must be carefully considered based on its long-term impact on function and esthetics and to preserve the health of remaining teeth (Okuni et al., 2022). Logically, it would be expected that rehabilitations with implant-supported prostheses may also help to preserve orofacial tissues such as the alveolar bone, remaining teeth, and jaw muscles when compared to conventional treatment modalities, or no treatment, but data remains controversial. Such information can assist clinicians in their therapeutic recommendations, and also patients when weighing the long-term benefits and limitations of each type of intervention.

The present systematic review and meta-analyses were conducted to answer the following question: In partially or fully edentulous

patients, do implant-supported dental prostheses preserve orofacial tissues when compared to conventional prostheses or no therapy?

The main goals and primary outcomes of this systematic review and meta-analysis were to comparatively analyze the effect of implant therapy on the following:

- Alveolar bone resorption—area measurements conducted on digital panoramic radiographs in relative terms (%), or changes in the area index over time;
- Remaining teeth—survival rate (%), complication rates (caries or other type of tooth structure loss, periodontal lesions, and crown fracture); and
- Masseter muscles thickness—measured, in millimeters, with realtime linear ultrasound scanner and linear array transducer.

16 | CONSENSUS STATEMENTS

16.1 | Consensus statement 1

Patients rehabilitated with IODs or CDs present similar bone resorption values in the posterior region of the mandible of fully healed ridges as assessed in panoramic radiographs.

This statement is based on a meta-analysis including four studies (three retrospective, one prospective; 324 patients) ([CI -0.04; 0.06], p > .05).

16.2 | Consensus statement 2

There is less alveolar bone resorption on the posterior mandible in patients with CIFDPs compared to CDs and IODs.

This statement is based on one retrospective study with 140 patients (p < .05).

16.3 | Consensus statement 3

Partially edentulous patients who are rehabilitated with toothsupported removable dental prostheses (RDPs) present more tooth loss (mainly due to caries) than patients with implant-supported partial fixed partial dentures (IFPDs).

This statement is based on three retrospective studies (410 patients).

16.4 | Consensus statement 4

In fully edentulous patients using CDs, masseter muscle thickness increases after rehabilitation with mandibular IODs. The meta-analysis showed a significant benefit of IODs when compared to CDs.

This statement is based on three studies (one RCT, one cross-sectional, one prospective study; 108 patients). The effect size difference is 0.95 ([CI 1.53, 0.38], p = .0012).

17 | CLINICAL RECOMMENDATIONS

17.1 | Clinical recommendation 1

In edentulous patients, does implant treatment reduce alveolar bone resorption as compared to CD treatment?

Yes. In edentulous patients, rehabilitation with an CIFDP or IOD is also beneficial to reduce alveolar bone resorption. The evidence does not favor one treatment modality over another. Regular maintenance appointments to ensure peri-implant health and occlusal stability of the prosthesis are also recommended to minimize alveolar bone loss.

17.2 | Clinical recommendation 2

When tooth replacement is indicated in partially edentulous patients, can IFDPs be recommended over tooth-retained/supported removable partial dental prostheses (RDP) to preserve the health of the remaining teeth?

In periodontally stable, partially edentulous patients, when tooth replacement is indicated, treatment with IFDPs is recommended over the provision of RDPs to preserve the health of the remaining teeth.

17.3 | Clinical recommendation 3

In fully edentulous patients, can IODs/CIFDPs be recommended over CDs in the preservation of masticatory muscle?

In fully edentulous patients, rehabilitations with IODs/CIFDPs are recommended to increase masseter muscle thickness compared to CDs. It is plausible to infer that this may have a positive effect on chewing.

18 | PATIENT PERSPECTIVES

In the following part, patient perspectives are formulated that are supported by the consensus statements from both systematic reviews and the clinical recommendations. The scenario below forms the basis for questions that an edentulous patient may pose when being considered for fixed or removable implant prostheses.

18.1 | Patient perspective 1

Some of my teeth are missing, what will happen if I do not do anything?

Response: It depends on how many teeth are missing and where—functioning and esthetics may be impacted. Your teeth might move, and it might make it more difficult to clean them. Some studies show that not replacing missing teeth leads to bone loss. Furthermore, it may reduce the health of the remaining teeth and cause further

tooth loss. However, many patients are able to enjoy adequate function with some missing teeth.

18.2 | Patient perspective 2

I have complete dentures, and I heard about dental implants. I was wondering if those implants provide advantages related to the bone or the chewing muscles?

Response: Yes, many studies show that in patients without teeth, dental implants offer the advantage of preserving the jaw bone, as long as the implants are healthy. In addition, your chewing muscles become stronger compared to full dentures.

18.3 | Patient perspective 3

I have many missing teeth in my lower right jaw, and I would like to replace them. What is my best treatment option? Should I get a partial denture or a fixed implant bridge?

Response: Replacing the missing teeth with a fixed implant bridge will decrease the chances of further tooth loss when compared to a removable partial denture. With the partial denture in place, the remaining teeth are more prone to developing dental diseases. These partial dentures also require more maintenance. Therefore, I would advise you to get a fixed implant bridge.

19 | RECOMMENDATIONS FOR FUTURE RESEARCH

- Well-designed, clinical studies monitoring hard and soft tissue changes over time in partially and fully edentulous patients rehabilitated with an implant-supported prosthesis compared to a conventional fixed and removable prosthesis are strongly recommended. It is recommended that the alveolar bone dimensional changes should be evaluated by three-dimensional radiographs and include vertical, horizontal and bone volume alterations in both jaws. Soft tissue dimensional changes may be investigated by three-dimensional intra-oral surface scanbased imaging.
- Well-designed, clinical studies evaluating the effect of an implantsupported prosthesis compared to a conventional fixed or removable prosthesis or no treatment on remaining teeth should be investigated by means of periodontal health (e.g., periodontal bone level, periodontal disease), tooth health (e.g., incidence of caries, fracture, root canal treatment), tooth prognosis, and tooth survival.
- Well-designed prospective studies evaluating the effect of an implant-supported prosthesis compared to a conventional fixed or removable prosthesis or no treatment that analyzes the facial muscles of partially and fully edentulous patients.

AUTHOR CONTRIBUTIONS

Martin Schimmel: Conceptualization; Writing - original draft; Writing - review & editing; Supervision. Mauricio Araujo: Conceptualization; Writing - original draft; Writing - review & editing; Supervision. Samir Abou-Ayash: Writing - original draft; Writing - review & editing. Ramona Buser: Writing - original draft; Writing - review & editing. Supriya Ebenezer: Writing - original draft; Writing - review & editing; Supervision. Manrique Fonseca: Writing - original draft; Writing - review & editing. Lisa J. Heitz-Mayfield: Writing - original draft; Writing - review & editing; Supervision; Conceptualization; Project administration; Funding acquisition. Lucrezia Paterno Holtzman: Writing - original draft; Writing - review & editing; Supervision. Porawit Kamnoedboon: Writing - original draft; Writing - review & editing. Robert Levine: Writing - original draft; Writing - review & editing; Supervision. Gerry McKenna: Writing - original draft; Writing - review & editing. Sabrina Maniewicz: Writing - original draft; Writing - review & editing. Flavia Matarazzo: Writing - original draft; Writing - review & editing. Nikos Mattheos: Writing - original draft; Writing - review & editing; Supervision. Panos Papaspyridakos: Writing - original draft; Writing - review & editing. André Barbisan De Souza: Writing - original draft; Writing - review & editing. Murali Srinivasan: Writing - original draft; Writing - review & editing. Charlotte Stilwell: Writing - original draft; Writing - review & editing; Supervision. Hans Peter Weber: Writing - original draft; Writing - review & editing.

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CONFLICT OF INTEREST STATEMENT

The authors of the group 4 Consensus Report declared no conflicts regarding the content of the 7th ITI Consensus Conference.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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