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How to cite

TONETTI, Maurizio S et al. Relevant domains, core outcome sets and measurements for implant dentistry clinical trials : the implant dentistry core outcome set and measurement (ID-COSM) international consensus report. In: Clinical oral implants research, 2023, vol. 34, p. 4–21. doi: 10.1111/clr.14074

This publication URL: https://archive-ouverte.unige.ch/unige:171688

Publication DOI: 10.1111/clr.14074

Received: 29 December 2022 | Accepted: 9 March 2023

DOI: 10.1111/clr.14074

ORIGINAL ARTICLE

CLINICAL ORAL IMPLANTS RESEARCH WILEY

Relevant domains, core outcome sets and measurements for implant dentistry clinical trials: The Implant Dentistry Core Outcome Set and Measurement (ID-COSM) international consensus report

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Funding information
National Natural Science Foundation of China, Grant/Award Number: 82171005;

Abstract

Aim: Lack of consistently reported outcomes limits progress in evidence-based implant dentistry and quality of care. The objective of this initiative was to develop a core outcome set (COS) and measurements for implant dentistry clinical trials (ID-COSM).

Materials and Methods: This Core Outcome Measures in Effectiveness Trials (COMET)-registered international initiative comprised six steps over 24 months: (i) systematic reviews of outcomes reported in the last 10 years; (ii) international patient

Science and Technology Commission of Shanghai Municipality, Grant/Award Number: 19411950100; Shanghai Innovative Research Team Award of High-Level University, Grant/Award Number: SHSMU-ZDCX202125000; National Clinical Research Center for Oral Diseases; Clinical Research Program of Ninth People's Hospital affiliated with Shanghai Jiao Tong University School of Medicine, Grant/Award Number: JYLJ201909; European Research Group on Periodontology, Switzerland

This manuscript was simultaneously and jointly published in *Clinical Oral Implants Research and the Journal of Clinical Periodontology*

focus groups; (iii) a Delphi project with a broad range of stakeholders (care providers, clinical researchers, methodologists, patients and industry representatives); (iv) expert group discussions organizing the outcomes in domains using a theoretical framework and identifying the COSs; (v) identification of valid measurement systems to capture the different domains and (vi) final consensus and formal approval involving experts and patients. The methods were modified from the best practice approach following the Outcome Measures in Rheumatoid Arthritis Clinical Trial and COMET manuals.

Results: The systematic reviews and patient focus groups identified 754 (665 + 89, respectively) relevant outcome measures. After elimination of redundancies and duplicates, 111 were formally assessed in the Delphi project. By applying pre-specified filters, the Delphi process identified 22 essential outcomes. These were reduced to 13 after aggregating alternative assessments of the same features. The expert committee organized them into four core outcome areas: (i) pathophysiology, (ii) implant/prosthesis lifespan, (iii) life impact and (iv) access to care. In each area, core outcomes were identified to capture both the benefits and harms of therapy. Mandatory outcome domains included assessment of surgical morbidity and complications, peri-implant tissue health status, intervention-related adverse events, complication-free survival and overall patient satisfaction and comfort. Outcomes deemed mandatory in specific circumstances comprised function (mastication, speech, aesthetics and denture retention), quality of life, effort for treatment and maintenance and cost effectiveness. Specialized COSs were identified for bone and soft-tissue augmentation procedures. The validity of measurement instruments ranged from international consensus (peri-implant tissue health status) to early identification of important outcomes (patient-reported outcomes identified by the focus groups).

Conclusions: The ID-COSM initiative reached a consensus on a core set of mandatory outcomes for clinical trials in implant dentistry and/or soft tissue/bone augmentation. Adoption in future protocols and reporting on the respective domain areas by currently ongoing trials will contribute to improving evidence-informed implant dentistry and quality of care.

KEYWORDS
clinical trials, consensus conference, core outcome set, implant dentistry, outcome domain

1 | INTRODUCTION

Outcome research is critically important to improving the quality of care. It comprises the accurate identification of the full spectrum of benefits and harms of interventions, the organization of key features in domains and the identification of valid measurement instruments to capture them accurately. A core outcome set (COS) is an agreed, standardized set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care (Core Outcome Measures in Effectiveness Trials [COMET] initiative—www.comet-initiative.org).

The 2012 European Federation of Periodontology workshop on implant dentistry research identified key areas for improvement in research design and reporting. Focusing on clinical research, the key recommendations included using high-quality randomized clinical trials (RCTs) to establish efficacy and reporting common outcome domains to adequately assess benefits and harms (Tonetti & Palmer, 2012). At the time, RCTs were rather infrequent in implant dentistry, but a dramatic increase in interventional research has been noted in recent years. A recent systematic analysis covering publications between 2005 and 2020 identified 1538 unique RCTs in this field. Of these, 238 were published during 2005–2010, 486 during 2011–2015 and 809 during 2016–2020 (Shi, Zhang, et al., 2022). In parallel to the increase in numbers, systematic reviews have also shown an improvement in the quality of reporting (Cairo et al., 2012; Lieber et al., 2020; Shi, Zhang, et al., 2022).

Consolidation of these efforts into a systematic evidence base supporting the development of robust clinical practice guidelines

in implant dentistry (Faggion et al., 2017), however, has been hampered by difficulties in synthesizing research data in analyses. This is mainly due to the lack of consistently reported outcomes, which results in the inability to perform meaningful meta-analyses in most of the published systematic reviews. Data from the five recent systematic reviews on implant dentistry clinical trial outcomes commissioned in the context of the Implant Dentistry Core Outcome Set and Measurements (ID-COSM) initiative (Avila-Ortiz et al., 2022; Derks et al., 2022; Messias et al., 2022; Sailer et al., 2022; Shi, Montero, et al., 2022) show an extensive list of reported outcomes. Additionally, the assessment of these outcomes was frequently based on different methodologies.

Despite growing attention to patient-reported outcomes in dentistry, patient and public participation in the evidence-informed process has lagged behind other areas of medicine, partly due to the lack of patient associations focusing on aspects of oral health. Consequently, the patient perspective of what is important in assessing different treatments or the outcomes of clinical decision making has yet to be systematically considered in oral health research and in implant dentistry.

In other areas of medicine, the above limitations have been addressed by defining COSs and measurement systems and involving patients and/or the public in the process. Pioneering work dating back more than 30 years in fields like rheumatoid arthritis led to the establishment of organizations focused on the development and refinement of core outcomes, such as the Outcome Measures in Rheumatoid Arthritis Clinical Trials (OMERACT; Tugwell & Boers, 1993) in musculoskeletal diseases or the COMET, focused on the methodology across disciplines and diseases. Such work has been instrumental in improving the quality and the clinical relevance of the evidence gathered in clinical trials and has effectively promoted outcome research in multiple disciplines.

This consensus report presents the first generation of standardized outcome domains and measurements for implant dentistry clinical research. It describes the process, the scientific evidence and the patient's perspectives informing the process, its rigorous methodology and the agreed-upon core outcome areas and domains. It also provides a list of measurement instruments for capturing benefits and harms in the relevant domains.

2 | MATERIALS AND METHODS

2.1 | Protocol and registration

The present COS and measurement development process was registered with COMET (No. 1765 accessible at https://comet-initiative.org/Studies/Details/1765). The protocol followed the COS-STAP statement (Kirkham et al., 2019), and the process followed modifications of the COS-STAD guidelines (Kirkham et al., 2016) and the COMET and OMERACT handbooks (Beaton et al., 2021; Williamson et al., 2017).

2.2 | Project outline

The project consisted of several elements: (i) evidence-based reviews, (ii) international patient focus groups, (iii) a three-round Delphi process, (iv) semi-structured expert group discussions and (v) a formal consensus meeting. It was carried out between November 2020 and October 2022. Figure 1 shows the overall organization and timeline of the project and reports the number of involved stakeholders in all stages of the process. Throughout the process, all participants had the opportunity to review the material and propose amendments before moving to the next stage.

2.3 | Systematic reviews

Five systematic reviews covering the main areas of clinical research in implant dentistry were commissioned to identify the outcomes used in publications from the 10-year period between 2011 and

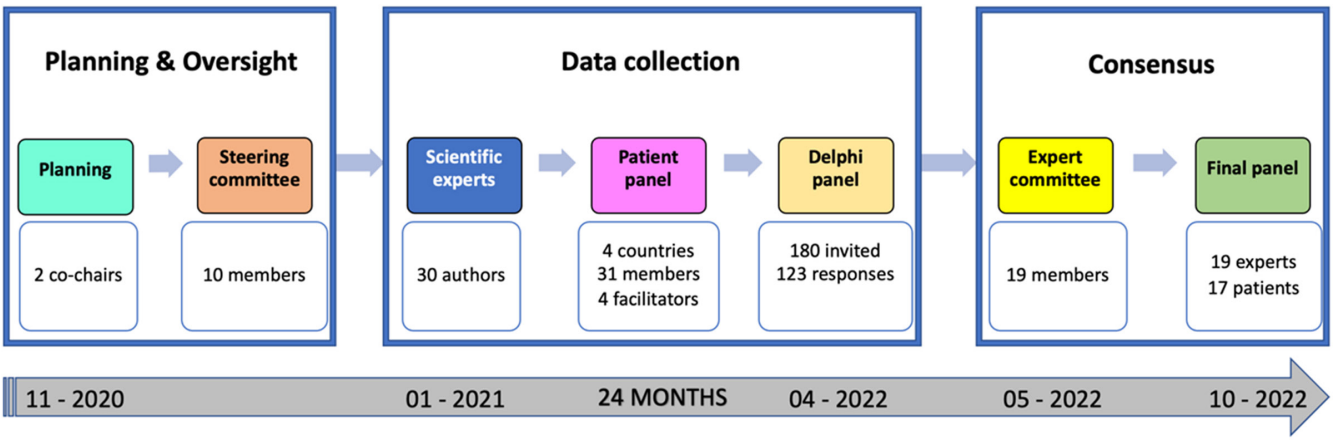

FIGURE 1 Schematic representation of the different phases and levels of stakeholder representation over the 24 months of the Implant Dentistry Core Outcome Set and Measurements project.

2020. The five systematic reviews covered the following topics: (i) single and partial tooth replacement (Sailer et al., 2022), (ii) rehabilitation of full-arch edentulism (Messias et al., 2022), (iii) prevention and treatment of peri-implant mucositis and peri-implantitis (Derks et al., 2022), (iv) soft-tissue augmentation (STA; Avila-Ortiz et al., 2022) and (v) bone augmentation (BA) trials (Shi, Montero, et al., 2022). All protocols were registered in PROSPERO.

2.4 | People with lived experience

To gain an independent perspective of outcomes that matter to patients, 31 people with lived experience (PWLE) participated in four focus groups representing low-, middle- (China and Malaysia) and high-income countries (Spain and the United Kingdom; Needleman et al., 2023). To avoid biased responses, participants were not provided with knowledge of outcomes collected in implant dentistry trials. Focus groups were conducted with a standardized methodology by trained facilitators and identified 34 candidate outcomes.

2.5 | Delphi project

The outcomes identified in the systematic reviews and the patient focus groups were incorporated into an exercise using the Delphi methodology for gathering information from experts and other stakeholders (clinical trials specialists, methodologists, clinicians, PWLE and industry representatives; Sanz et al., 2023). Questionnaires were developed using these outcomes, which were completed in two rounds and incorporated individual feedback, group judgement and a final discussion to achieve the consensus through a structured, unbiased assessment by multiple stakeholders. The DelphiManager software, developed and maintained by the COMET initiative, was used to produce and later analyse the e-Delphi questionnaire. Participants were asked to score each outcome on a 9-point Likert scale and were offered the opportunity to add outcomes and comments as described (Williamson et al., 2017). One-hundred eighty stakeholders were invited, of whom 123 participated in the first and second rounds. Experts ($N = 19$) and PWLE representatives ($N = 7$) participated in the third Delphi round, which used three filters to reduce the number of outcomes from 111 to 14. The first filter removed outcomes that did not receive a score of 7–9 (on the 9-point scale, with 1 = least important and 9 = most essential to include) by at least 70% of respondents or that received a score of 1–3 from 15% of respondents in the Delphi survey. The second filter excluded aspects of the PICO questions related to reporting on patient/population, intervention or comparison rather than outcomes. The third filter aggregated multiple ways to measure the same feature in a single outcome. At the end of the third round, experts and PWLE representatives were asked to anonymously rate each outcome as (i) essential for inclusion in the core set, (ii) possible to be dropped or (iii) do not know. Detailed methods and results have been reported elsewhere (Sanz et al., 2023).

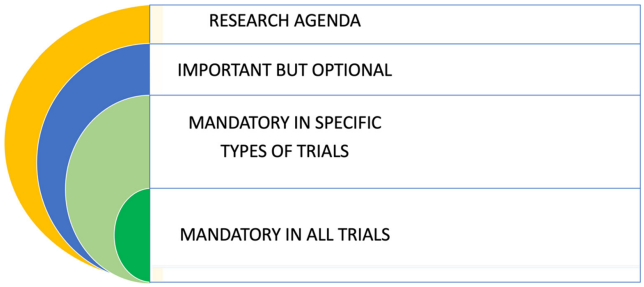

FIGURE 2 Implant Dentistry Core Outcome Set and Measurements (ID-COSM) 'onion'. Illustration of the ID-COSM 'onion' depicting the different layers in classifying outcomes: mandatory outcomes in all trials (core set to be reported in all clinical studies), outcomes mandatory in specific types of trials (expanded core set with additional mandatory outcomes), outcomes that are considered important but optional and outcomes that belong to the research agenda. The latter category comprises areas that are currently under investigation and may provide outcomes for inclusion in the core set once adequate development and validation has been completed.

2.6 | Consensus process

Experts met in person on 15 June 2022, for a 1-day workshop in Copenhagen. Prior to the workshop, participants were trained in several online meetings: (i) in best practice approaches to identify outcome domain areas covering benefits and harms according to the OMERACT approach (Beaton et al., 2021) and (ii) in the development and use of the OMERACT 'onion' concept to classify outcomes as mandatory in all trials, mandatory in specific circumstances and important but optional. They also received a summary of the Delphi results. At the meeting, experts organized outcome domains according to a mindmap and agreed upon the definition and use of a specific tool—the ID-COSM onion (Figure 2)—and the format of specific outcome definition tables modified from the OMERACT manual (Table 1). The ID-COSM onion classifies relevant outcomes into three layers: (1a) mandatory in all trials, (1b) mandatory in specific types of trials, (2) important but optional and (3) research agenda items.

After the Copenhagen meeting, expert groups were assigned to draft the Outcome Domain and Measurement Definition Tables and specific ID-COSM onions for the multiple applications covered in the five systematic reviews. Definitions and drafts were discussed, and changes were agreed upon at an online expert meeting on 21 September 2022, which also included the decision to consolidate COSs for single and partial tooth replacement, full-arch edentulism and prevention and treatment of peri-implant mucositis and peri-implantitis. The group agreed that specialized outcome sets were necessary to capture outcomes of STA and BA trials. Based on the result, working groups were tasked with the identification/definition of appropriate measurements to accurately reflect the core outcomes of interest. The identified measures were refined and agreed upon in an additional online

expert meeting held on 17 October 2022. Lastly, core outcomes and measurements were discussed in a final online meeting with experts ($N = 19$) and PWLE ($N = 17$) and formally voted on using an anonymous online tool (Polls App for Teams, Microsoft, USA) on 31 October 2022. The strength of consensus was evaluated using the GRADE approach (German Association of the Scientific Medical Societies [AWMF], 2012). Throughout the process, also considering disruptions due to COVID-19, recordings and online power point presentations were made available to members of the panel who could not join a specific meeting.

3 | CONSENSUS RESULTS

3.1 | Core outcome areas and domains—Implant dentistry trials

Outcomes identified in the Delphi survey and filtered through the third Delphi round ($N = 13$) were organized into four core domain areas and aligned with a modification of the theoretical framework developed by the OMERACT group to organize COSs: (i) pathophysiology, (ii) lifespan of the device/restoration, (iii) life impact and (iv) access to care. In each core area, outcomes were grouped to reflect benefits and harms. Figure 3 shows the mindmap of core outcome areas and domains agreed upon by experts at the Copenhagen meeting. Regarding pathophysiology, benefits were captured in terms of improved function and comprised (i) mastication, (ii) smiling/aesthetics, (iii) speech and (iv) denture retention. The main outcomes related to harms included surgical morbidity and complications and alterations of the tissue health status reflected by case diagnosis (health, peri-implant mucositis and peri-implantitis) and marginal bone level/loss. To capture the long-term benefits (lifespan) of tooth replacement with implants, complication-free survival was considered the most informative parameter. In contrast, technical complications and implant and prosthesis loss were used to describe harms. Life impact was identified as a core area, with benefits captured by overall satisfaction with treatment and changes in quality of life, while harms were described by effort for treatment, oral hygiene and professional maintenance. Access to care was evaluated using health economic aspects including cost effectiveness, affordability and the level of professional competence/experience necessary to ensure a good outcome.

3.2 | Definition of core outcome domains and measurements—Implant dentistry trials

To avoid ambiguity, the expert group defined the scope of each outcome domain in the different core areas using the template shown in Table 1.

The commissioned systematic reviews were used as the primary knowledge base to identify measurements that could discriminate the outcome domains of interest. These were complemented by a targeted evidence search, if necessary. The evidence generally needed more uniform and validated measures to precisely discriminate the outcomes of interest. In particular, the consensus identified the existence of a large disparity in terms of the availability of validated tools to measure the different outcome domains. On one side of the spectrum, the assessment of tissue health status was performed using case definitions agreed upon in an international consensus conference (Berglundh et al., 2018). On the other, outcome domains with newly expanded scope, thanks to patient participation in this initiative, required developing specific tools. The consensus group decided to maintain such outcomes within the COS to emphasize their importance and the need to perform targeted research to develop and validate the necessary instruments. Specific assessment approaches were included in the domain definition and measurement tables (see below). Frequently, the selection of appropriate measurements is reported as an example. Investigators carefully considered each outcome's options to identify the best measurement instrument. The agreed description of each domain with its measurements is listed below.

3.2.1 | Pathophysiology benefits: Function

This domain's scope is assessing the functional benefit(s) of tooth replacement with implants. Based on the specific condition (population in PICO), the functional benefits include (i) masticatory function, (ii) phonetics/speech, (iii) aesthetics of the smile/

TABLE 1 Domain and measurement definition table template.

Core area	Pathophysiology/life impact/lifespan/access to care.
Broad domain	General term of broad domain (e.g., pain impact).
Target domain	The name given to this more specific domain (e.g., impact of pain in all realms of life): this is what will be measured.
Working definition of target domain	Definition of the scope of the domain: what are the features that should be captured by the measurement instruments.
Measurements	Input what needs to be measured and how to capture it (valid measurement tools).
Qualitative or literature support	Insert literature reference on outcome and measurement systems. Insert input from patients/public focus group.
Sources of variability in score	Identify/think through sources of variability or contextual factors.

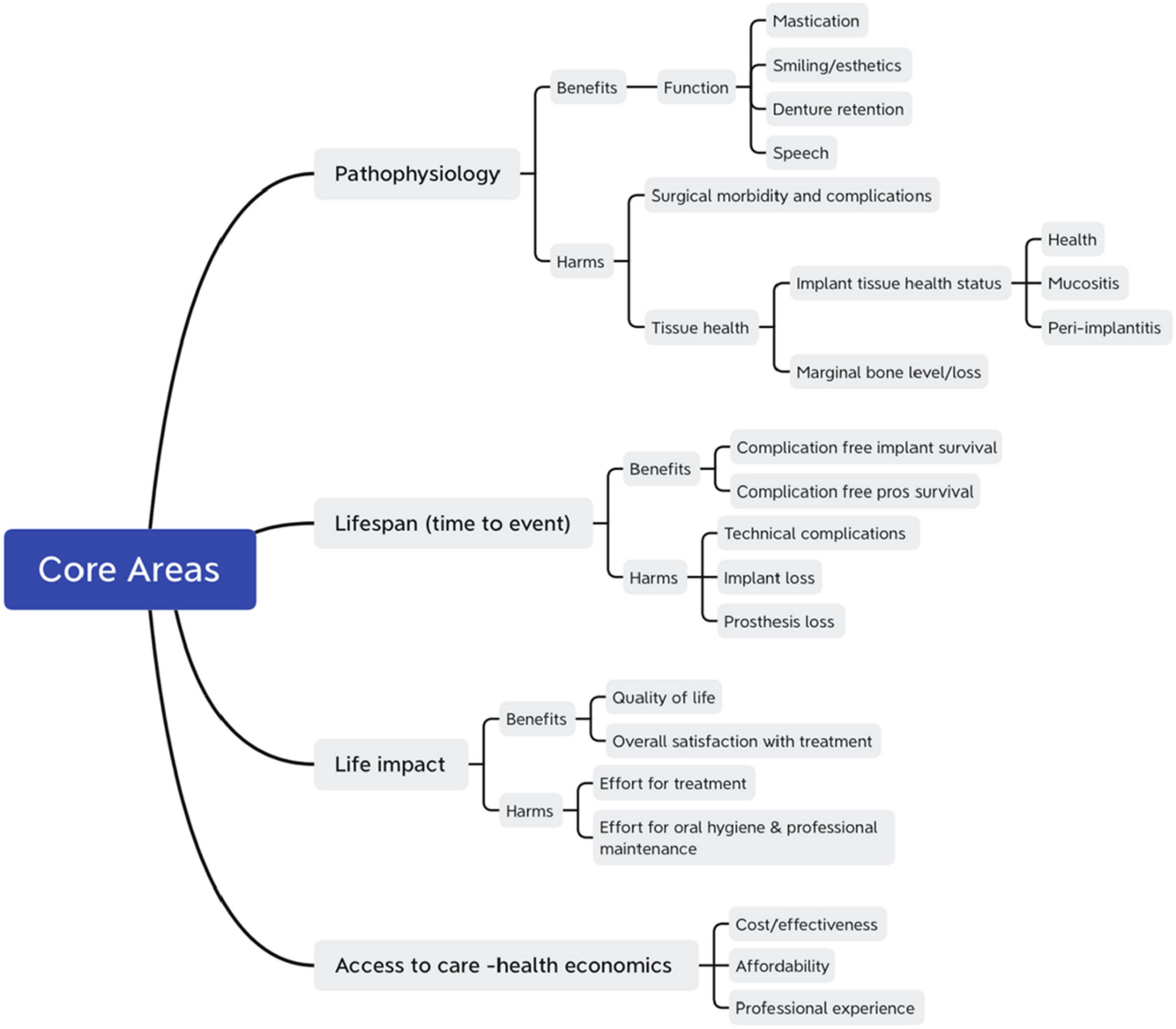

FIGURE 3 Implant Dentistry Core Outcome Set and Measurements core outcome areas and domains. Mindmap of the core outcomes areas and core outcome domains that should be captured in implant dentistry clinical trials. Each area needs to capture both benefits and harms.

ability to relate with others/self-worth and/or (iv) retention of a denture (Messias et al., 2022; Sailer et al., 2022). This domain includes both patient-reported and professionally assessed outcome measures:

A. masticatory function (masticatory test, e.g., Schimmel test; Schimmel et al., 2015);
B. phonetics/speech (phonetic exam), or VAS (0–100), PROM;
C. aesthetics of the smile/ability to relate with others/self-worth (visual analogue scale [VAS] 0–100), Pink and White Esthetic Score, PES/WES (Belser et al., 2009; Fürhauser et al., 2005);
D. retention of a denture (yes/no) or qualitative evaluation.

3.2.2 | Pathophysiology harms: Surgical morbidity and complications

This domain comprises early intervention-related adverse effects. It is defined as all harms and adverse events arising from surgical implant placement. These include (1) complications from the surgical placement of dental implants (e.g., failure to osseointegrate or early implant loss; injuries to adjacent structures; surgical wound failure, infection, swelling, post-operative pain and so on; Lang et al., 2007; Tonetti et al., 2004, 2018) and (2) complications associated with the temporary or definitive prostheses upon immediate implant loading after surgical placement.

The presence/absence of surgical complications encompasses both patient-reported outcomes and objective assessment. Evaluation of surgical complications should include the following:

A. *The number of days of total or partially impaired activity*: Total impaired activity: days that, in the patient's opinion, they could not perform their ordinary life activity, including work and partially impaired activity: days that, according to the patient, they could only partially perform their everyday life activity, including work.
B. *Post-operative pain*: Patient-reported outcome: 100-mm VAS or 5-point Likert scale; Use of pain control medications (number of tablets).
C. *Post-operative oedema/swelling*: Clinician-reported rating: 0 = no visible oedema; 1 = slight oedema (intra-oral swelling in the surgical zone); 2 = moderate oedema (extra-oral swelling in the surgical area); 3 = severe oedema (extra-oral swelling extending the surgical site) and/or visible haematoma and ecchymosis.
D. *Surgical implant placement complications (reported dichotomously)*: (i) Intra-operative haemorrhage, (ii) injuries to adjacent structures (including teeth, nerves, maxillary sinus), (iii) injuries to nerves (self-reported sensory impairment), (iv) injuries to adjacent teeth (self-reported sensitivity/pain and/or radiographic evaluation) and (v) implant displacement over the apical anatomic limit (maxillary sinus, sublingual space, submandibular space, etc.).
E. *Post-operative implant placement complications (reported dichotomously)*: (i) Loss of osseointegration (or failure to achieve osseointegration) or early implant failure (early implant loss), (ii) post-operative haemorrhage, (iii) wound dehiscence primary/secondary (Wachtel et al., 2003) and (iv) wound/graft infection.
F. *Post-operative complications related to prosthesis insertion (temporary or definitive) in immediate loading/temporisation cases*: Peri-implant soft tissue inflammation due to (i) poor fit, (ii) loss of retention of the prosthesis (screw loosening, partial decementation), (iii) presence of remnants of submucosal luting cement following cementation of an implant-supported prosthesis and (iv) inability of the patient to obtain access to remove plaque from the prosthesis.

3.2.3 | Pathophysiology harms: Peri-implant marginal tissue health status

Assessment of peri-implant tissue health status defines the presence of peri-implant mucositis, the presence of peri-implantitis according to established case definitions (2017 Workshop) and peri-implant health defined by the absence of either condition (Berglundh et al., 2018; Derks et al., 2022). These should include an assessment of the following parameters and specific reporting as follows:

A. *Bleeding on probing (BOP)/suppuration on probing (SOP)*. Tool: 0.5-mm diameter periodontal probe at 20–25 g. Assess: circumferentially. Measure in a dychotomous fashion (yes/no) and record at four or six sites per implant. Report the number/proportion of implants presenting with complete absence of BOP/SOP; the number/proportion of implants with limited extent of BOP (≤1 spot/implant—the presence of a single spot, not line or profuse bleeding—of BOP is considered acceptable), and the number/proportion of implants with extensive BOP (≥2 spots/implant or ≥1 site/implant with a line or profuse bleeding) and the number/proportion of implants with SOP.
B. *Probing pocket depth (PPD)*. Tool: 0.5-mm diameter periodontal probe at 20–25 g. Assess: circumferentially. Measure in millimeters and record at four or six sites per implant. Report mean of all sites, deepest site per implant and the number/proportion of implants with PPD ≤ 5 mm.
C. *Marginal bone level (MBL)*. Tool: intra-oral radiograph using the parallel technique with a standard holder. Assess and record: mesial and distal. Measure in millimeters from the implant platform. Also, assess and report examiner reproducibility and measurement error.
D. *In studies with repeated assessments, assess and record changes over time for the parameters mentioned above*. Report mean changes and number/proportion of implants presenting with changes of different magnitude (e.g., MBL change exceeding measurement error, MBL gain/loss >2 mm).
E. *Composite outcome*. Concomitant absence of BOP (≤1 spot/implant), SOP, shallow PPD (≤5 mm) and absence of MBL loss. Report the number/proportion of implants/patients. Report the number/proportion of implants/patients with health/peri-implant mucositis/peri-implantitis following the case definition.

3.2.4 | Lifespan benefits: Complication-free survival

It is defined as the time from completion of treatment (delivery of prosthesis) until the patient experiences the first complication requiring intervention. It is reported as a time-to-event analysis (months/years). The type and time of complication (event) should be fully reported in tabular format. It is understood that multiple Kaplan–Meier analyses will be required to accurately capture the spectrum of complications. For example, these will include biological complications (peri-implant mucositis, peri-implantitis), technical complications and implant loss (Karlsson et al., 2018, 2020). To capture multiple events occurring in the same case, an additional recurrence analysis may be considered (Cortellini et al., 2017, 2020; Shi et al., 2021). In cases with multiple implants, separate analyses should be performed for implants and prostheses.

3.2.5 | Lifespan harms: Technical or intervention-related complications, implant/prosthesis loss

Technical complications and intervention-related adverse events occur after the insertion of the definitive prosthesis. This domain comprises adverse device events (implant, abutment and prosthetic

components), screw loosening, de-cementation, fracture of prosthetic materials and so on, and should follow standard reporting for medical devices.

It is reported as the presence/absence of an adverse event as described in the working definition. It is expressed dichotomously or by validated rating scales (e.g., USPHS criteria; Naenni et al., 2015; Pol et al., 2022).

- Implant/prosthesis loss.
- Fixed prostheses: chipping, framework fracture, veneering fracture, abutment fracture, screw fracture, screw loosening, loss of retention, de-cementation.
- Removable prostheses: fracture or dislodgement of matrix or bar, loss of retention of components, fracture of the prosthesis, relining/rebase, fracture/detachment of acrylic teeth, loosening of components (matrix, bar), wear of matrix, wear of acrylic teeth, replacement of acrylic teeth and discolouration.

They can be described as either minor (can be corrected in one appointment) or major (requires more than one appointment).

3.2.6 | Life impact benefits: Quality of life

Oral-health-related quality of life should be self-reported with a standard validated instrument sensitive to the specific condition. Examples of validated instruments include OHIP-49 (Slade & Spencer, 1994), OHIP-14 (Slade, 1997), OHIP-20/OHIP-EDENT (Allen & Locker, 2002), Dental Impact on the Daily Living questionnaire (Leao & Sheiham, 1996) and GOHAI (Atchison & Dolan, 1990). For some conditions, assessment of quality of life may require custom measures/instruments, which are yet to be validated.

3.2.7 | Life impact benefits: Overall satisfaction with treatment

This domain covers the overall level of patient satisfaction with the treatment received and comfort; it is a patient-reported outcome. Measures include patient-reported outcomes with a 100-mm VAS with defined questions and anchors (e.g., not at all satisfied to perfectly satisfied) or a 5-point Likert scale. In some conditions, validated, condition-specific rating scales should be considered. Examples of validated standard instruments include the McGill Denture Satisfaction Instrument (Awad & Feine, 1998; de Grandmont et al., 1994; Feine et al., 1994), the Denture Satisfaction Questionnaire (Allen & McMillan, 2002) and the Patient Satisfaction Questionnaire (Brennan et al., 2010; de Bruyn et al., 1997; Komagamine et al., 2012, 2014; Layton & Walton, 2011; Vermylen et al., 2003).

3.2.8 | Life impact harms: Effort for treatment and maintenance

This domain covers the effort for treatment and maintenance from a patient perspective. The overall effort needed for treatment includes assessment of the duration (beginning to end) and the total time effort (hours, number of appointments). It also includes the overall effort needed to maintain the result over time in terms of daily care (self-performed oral hygiene) and professional visits (supportive care). Examples of measurements include the following:

- Duration of treatment (months from beginning to end and number of appointments);
- Effort for maintenance in daily care (number and complexity of self-performed oral hygiene sessions and related duration, PROM–VAS 0–100 e.g., 'How difficult is it for you to clean your implant prosthesis?');
- Professional visits for supportive peri-implant care (number of professional visits/year).

3.2.9 | Access to care: Cost effectiveness

Assessing this outcome requires an economic analysis comparing the relative cost and outcomes (effects) of different courses of action. One relies on the ratio of costs to gains in health. Health gains include improvement in clinical or professionally measured outcomes (such as aesthetics and function), quality-adjusted life years or quality-adjusted tooth/implant years. A cost effectiveness analysis requires the assessment of direct plus indirect costs of treatment (time required to receive the treatment, including the absence from work and transportation and maintenance/treatment of complications) in relation to the benefit of treatment, that is, patient satisfaction with and longevity of treatment.

3.2.10 | Access to care: Affordability

Treatment affordability is an economic analysis comparing the relative cost and household resources. One relies on the ratio of costs to total household resources. It is measured as direct and indirect costs of treatment and supportive care in relation to the median income of the country/region. It has not been studied in implant dentistry clinical trials, but was considered essential among the relevant outcomes identified by the PWLE focus groups.

3.2.11 | Access to care: Professional experience/expertise

This domain covers the definition of the level of competence required for delivering an adequate level of care for a specific implant

dentistry procedure. It relates to the level of care: primary care, specialist care and tertiary care. It comprises an assessment of the qualifications of the clinician: for example, clinician's specialist qualification (yes or no), the number of years of clinical practice in implant dentistry and the number of implant-related procedures provided annually by the clinician. It parallels the data required by the CONSORT extension for non-pharmacological interventions. It has not been studied in implant dentistry clinical trials but was considered essential among the relevant outcomes identified by the PWLE focus groups.

3.3 | COS for implant dentistry clinical trials—ID-COSM

Work by the expert group identified 11 core outcome domains (5 mandatory in all trials and 6 mandatory in specific circumstances/trial types) for use in implant dentistry clinical trials. The clinical trials evaluated to identify these core outcome domains encompassed a wide area of research involving implant treatment, including all surgical and restorative interventions associated with dental implant placement as well as the management of complications and diseases associated with dental implants. Trials evaluating STA/BA procedures in which dental implants were not placed were not included.

The agreed outcome domains are illustrated in Figure 4. The five outcome domains considered mandatory in all trials comprise the assessment of (i) surgical morbidity and complications until definitive/final prosthesis delivery, (ii) peri-implant tissue health status, (iii) intervention-related adverse events, (iv) complication-free survival and (v) overall patient satisfaction and comfort. The definition of each outcome domain and its measurement instruments have been reported in the previous section.

Formal voting on the final set of ID-COSM core outcomes and measurements among experts and patients revealed unanimous consensus.

Six outcome domains were considered mandatory in specific circumstances (types of trials or trials dealing with specific populations). Among these outcomes are the functional benefits of implant dentistry; these span from the improvement of mastication to improvements in aesthetics, smile, sense of self-worth, social interaction, speech and/or ability to retain a denture. The choice of capturing one or more of these functions depends upon the population/condition under study and the specifics of the intervention and comparison. Other aspects that should be considered for inclusion in a specific trial include (i) measures of the effort required for treatment and maintenance of the implant and prosthesis (encompassing patient self-care and professional needs), (ii) impact on measures of quality of life and (iii) cost effectiveness assessments in trials where it is possible to estimate health economics. The panel of experts also agreed that in trials in which the intervention includes STA and/or BA, specific outcomes are also mandatory and that specialized COSs need to be applied to specifically enrich the set of mandatory outcome domains (refer to the bone augmentation [BA-COSM] and the soft-tissue augmentation [STA-COSM] COSs, Figures 5b and 6b).

3.4 | Definition of specialized core outcome domains—Bone augmentation trials (BA-COSM)

Figure 5a shows the mindmap of the specialized outcome domains identified for BA trials. The panel of experts recognized that BA could be part of the interventions in implant dentistry clinical trials or be assessed in specialized trials that do not include implant placement. In this context, the bone augmentation core outcome set and

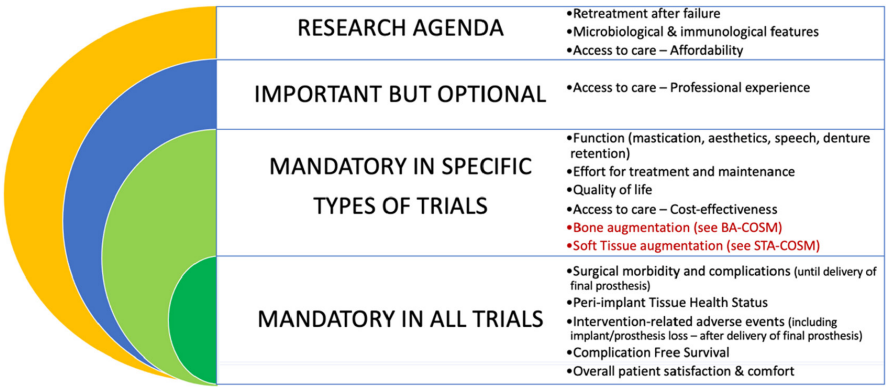

FIGURE 4 Core outcome set for implant dentistry trials: Implant Dentistry Core Outcome Set and Measurements (ID-COSM) implant dentistry. Consensus of the core outcome domains inserted in the ID-COSM implant dentistry 'onion'. Five outcomes are considered mandatory in all trials, and six outcomes are considered mandatory in specific types of trials. Among the latter are the key pathophysiological benefits of dental implant treatment: improving function. Appropriate functional benefit(s) should be selected based on the specific condition/population being treated. In red are specific outcomes mandatory for trials where the intervention involves bone (BA-COSM) or soft-tissue augmentation (STA-COSM). For specifics about these outcomes, the reader is referred to Figures 5 and 6. Examples of the specific measures needed to capture ID-COSM implant dentistry outcomes are illustrated in the text.

measurements (BA-COSM) domains can complement the general ID-COSM domains or be a stand-alone outcome set if implants are not placed within the trial.

Specific assessment approaches were included in the domain definition and measurement tables (see below). Frequently, the selection of appropriate measurements is reported as an example. Investigators shall carefully consider options while the necessary outcome research is conducted. The agreed description of each domain with its measurements follows.

3.4.1 | Pathophysiology benefits: Bone dimensional changes

This domain area aims to identify changes in bone dimension (amount and rate of change) captured by linear or volumetric measurements to enable implant insertion in a prosthetically guided position with long-term complication-free survival of dental implants. Measurement examples include the following:

A. *Clinical examination using a periodontal probe or a calliper with anatomic landmarks/stent as reference* (Schwarz et al., 2018; Thoma et al., 2018);
B. *3D radiographic measurement*: (a) superimposition of cone-beam computer tomograms (CBCT) (César Neto et al., 2020), (b) measurement in CBCT with anatomy markers as references (Abd-Elrahman et al., 2020; Chiapasco et al., 2021) and (c) volumetric change (Li et al., 2019);
C. *2D radiographic measurement of vertical changes*: (a) measurement on panoramic radiographs with anatomy markers as references (Rammelsberg et al., 2015) and (b) intra-oral radiographs using the parallel cone technique with a standard holder.

3.4.2 | Pathophysiology benefits: Ability to place an implant

This domain area reports on the achievement of an adequate alveolar ridge for placing a properly dimensioned dental implant in the correct, prosthetically guided position with or without the need for additional grafting. The criteria are based on the following:

A. *In staged BA procedures* (alveolar ridge preservation, staged horizontal and/or vertical BA, STA), the ability or not to place the implant in a prosthetically guided implant position with the endosteal portion of the implant completely in bone with more than 1–1.5 mm thickness on the buccal and oral aspect. Investigators should also report the need for additional BA based on the previous objective.
B. *In simultaneous approaches* (simultaneous horizontal and/or vertical BA), the need of additional BA at re-entry if the previously exposed implant surface has not been completely surrounded by bone.

3.4.3 | Pathophysiology benefits: Histology

This domain area reports on the biological healing characteristics of BA procedures. It comprises histology and functional tissue analyses. Histology reports on the fraction of newly formed bone, the soft tissue component (connective tissue/marrow spaces) and residual graft particles. Micro-CT, immunohistochemistry (Keil et al., 2021) and gene expression analyses (de Freitas et al., 2016) are frequently used to characterize the regenerated bone.

3.4.4 | Pathophysiology harms: Surgical complications and adverse events

This domain area reports intervention-related surgical morbidity and adverse effects. It includes all harms and adverse events arising from BA procedures. It comprises complications associated with the placement of graft or BA devices (e.g., graft/device exposure, infection), injuries to adjacent structures, surgical wound failure, infection, swelling and post-operative pain.

Presence/absence of surgical complications encompasses both patient-reported outcomes and objective assessment. Description of an adverse event is defined in the working definition. Evaluation of surgical complications must include the following:

A. *Number of days of total or partially impaired activity*: Total impaired activity: days that, in the patient's opinion, he/she could not perform his/her ordinary life activity, including work; Partially impaired activity: days that, according to the patient, he/she could only partially perform his/her ordinary life activity, including work. Report time to recovery.
B. *Post-operative pain*: Patient-reported outcome: 100-mm VAS or 5-point Likert scale—Use of pain control medications.
C. *Post-operative oedema/swelling*: Clinician-reported rating: 0 = no visible oedema; 1 = slight oedema (intraoral swelling in the surgical zone); 2 = moderate oedema (extraoral swelling in the surgical zone) and 3 = severe oedema (extraoral swelling extending the surgical zone) and/or visible haematoma and ecchymosis.
D. *Post-operative complications (reported dichotomously)*: (i) Post-operative haemorrhage, (ii) wound dehiscence primary/secondary and (iii) wound/graft/device infection.
E. *Wound failure*: Early wound healing index (Wachtel et al., 2003). Modified wound healing index.

3.4.5 | Lifespan: Bone stability

This domain area reports the stability of augmented alveolar bone volumes around an adequately dimensioned dental implant. Measurement examples include the following:

A. (Changes in) bone thickness in buccal and lingual surfaces assessed on CBCT

B. Percentage of resorbed bone volume versus initial (or augmented total) bone volume assessed on CBCT
C. Marginal bone level changes assessed on intra-oral radiographs or panoramic radiographs;
D. Percentage of resorbed bone height versus initial (or augmented total) bone height assessed on panoramic radiographs.

Figure 5b shows the core outcome domains for BA trials identified by the experts and approved in the consensus. Formal voting on the final set of BA-COSM core outcomes and measurements among experts and patients obtained unanimous consensus.

Among the mandatory outcomes in all BA trials, the consensus identified (i) assessment of surgical complications and adverse events, (ii) dimensional bone changes and (iii) the ability to place the implant(s) in a prosthetically guided position. In specific types of trials, assessment of peri-implant bone stability and mid-facial mucosal recession were also considered mandatory (for this outcome domain, readers are referred to the STA-COSM). Finally, in BA trials involving implant placement, it is critical to refer to the general ID-COSM outcome set and include the relevant mandatory outcomes.

3.5 | Definition of specialized core outcome domains—Soft-tissue augmentation trials (STA-COSM)

Figure 6a shows the mindmap of the specialized outcome domains identified for STA. The consensus recognized that STA could be part of the interventions in implant dentistry clinical trials or be assessed in specialized trials that do not include implant placement. This area of research also includes the correction of soft-tissue deformities around functioning dental implants. In this context, the soft-tissue augmentation core outcome set and measurements (STA-COSM) domains can complement the general ID-COSM domains or be a stand-alone outcome set if implants are not placed within the trial.

Specific assessment approaches were included in the domain definition and measurement tables (see below). Frequently, the selection of appropriate measurements is reported as an example. Investigators shall carefully consider options while the necessary outcome research is conducted. The agreed description of each domain with its measurements follows.

3.5.1 | Pathophysiology benefits: Soft-tissue dimensions

This domain area aims to identify dimensional changes in the peri-implant mucosa in terms of width, thickness and height. It captures linear and profilometric changes in peri-implant soft-tissue dimensions over time following therapeutic intervention to achieve a desired clinical outcome (keratinised mucosa width, mucosal thickness and/or supracrestal tissue height gain) often to facilitate oral hygiene practice, to protect the underlying bone and to reduce the risk of peri-implant disease onset. Examples of relevant measurements are as follows:

A. Keratinized mucosa width changes using a calibrated periodontal probe (Golmayo et al., 2021)
B. Mucosal thickness changes via transmucosal horizontal probing using a piercing instrument (e.g., endodontic spreader) or with digital imaging analysis after superimposition of standard tessellation language (STL) files or other advanced imaging methods (e.g., ultrasonography; Artzi et al., 2022; Chan et al., 2018; Couso-Queiruga et al., 2021; Hutton et al., 2018).
C. Supracrestal tissue height changes via transmucosal vertical probing using a piercing instrument or with digital imaging analysis after superimposition of STL files or other advanced imaging methods (e.g., ultrasonography; Chan et al., 2018; Eghbali et al., 2016; Puisys & Linkevicius, 2015; Thoma et al., 2016; Zeltner et al., 2017).

3.5.2 | Pathophysiology benefits: Objective aesthetic assessment

This domain area includes the aesthetic assessment of the peri-implant mucosa by the investigator(s) following augmentation. It is performed using a standardized method (e.g., Pink Aesthetic Score [PES], Fürhauser et al., 2005) via direct or indirect assessment (Cooper et al., 2021; Cosyn et al., 2021).

3.5.3 | Pathophysiology benefits: Mid-facial mucosal margin position

This domain area evaluates the position of the mid-facial mucosal margin. It reflects the ability to conceal the implant hardware below the tissue margin and, therefore, is related to soft-tissue aesthetics. It measures the mid-facial mucosal margin position relative to a reproducible intra-oral landmark (e.g., restorative interface, incisal edge) or a custom stent directly with a calibrated periodontal probe or indirectly with digital imaging assessments (e.g., standardized photographs or surface scans; Eghbali et al., 2018; Frizzera et al., 2019). Repeated measures provide estimates of stability/changes over time.

3.5.4 | Pathophysiology benefits: Peri-implant soft-tissue volume

This domain area evaluates changes in peri-implant soft-tissue volume over time following augmentation procedures. Peri-implant soft-tissue volume changes can be measured using STL files obtained after intra-oral scanning or extra-oral scanning of models or other advanced imaging methods (e.g., STL and CBCT file superimposition or ultrasonography) using dedicated software (Eghbali et al., 2016; Naenni et al., 2021; Tavelli et al., 2021; Zeltner et al., 2017).

3.5.5 | Pathophysiology benefits: Interproximal soft-tissue height

This domain aims to assess changes in peri-implant interproximal soft-tissue height dimensions over time following therapeutic intervention with augmentation purposes. Dimensional changes can be measured with an index (e.g., Jemt papilla score; Jemt, 1997), measured directly with a calibrated periodontal probe or indirectly with digital imaging analysis (e.g., standardized photographs or surface scans; Thoma et al., 2020).

3.5.6 | Pathophysiology harms: Surgical morbidity and adverse events

This domain covers all harms and adverse events arising from STA. It comprises complications associated with the harvesting and placement of graft or STA devices (e.g., graft/device exposure, infection), injuries to adjacent structures, surgical wound dehiscence, post-operative infection, swelling or pain.

The presence/absence of surgical complications encompasses both patient-reported outcomes and investigator assessment. The description of an adverse event is defined in the working definition. Evaluation of surgical complications must include the following:

A. *The number of days of total or partially impaired activity*: Total impaired activity: days that, in the patient's opinion, he/she could not perform his/her ordinary life activity, including work; Partially impaired activity: days that, according to the patient, he/she could only partially perform his/her ordinary life activity, including work.
B. *Post-operative pain*: Patient-reported outcome: 100-mm VAS or 5-point Likert scale—Use of pain control medications.
C. *Intra-operative complications (reported dichotomously)*: (i) Intra-operative haemorrhage, (ii) injuries to adjacent structures (including bone, nerves, teeth, other), (iii) If injuries to nerves occur, self-reported sensory impairment and (iv) if injuries to adjacent teeth occur, self-reported sensitivity/pain and/or radiographic evaluation.
D. *Post-operative complications (reported dichotomously)*: Post-operative haemorrhage, wound dehiscence primary/secondary, wound/graft/device infection.
E. *Wound healing alterations*: Early wound healing index or modified wound healing index (Wachtel et al., 2003).

3.5.7 | Life impact benefit: Aesthetic and overall patient satisfaction

This domain covers patient-reported aesthetic outcomes and general satisfaction upon completion of therapy or at different follow-up intervals. They can be measured as follows:

A. *Aesthetic satisfaction*: 100-mm VAS or 5-point Likert scale
B. *Overall satisfaction*: 100-mm VAS or 5-point Likert scale.

3.5.8 | Life impact benefit: Quality of life

This domain reports the patient-reported impact of peri-implant STA therapy on their quality of life. It is measured with oral-health-related quality of life instruments (e.g., OHIP-14). Condition-specific instruments may be required for adequate sensitivity.

The specialized core outcomes identified by the experts and approved in the consensus in the STA-COSM set are shown in Figure 6b. They cover conditions in which STA is performed before, during or after implant placement. Formal voting on the final set of core outcomes and measurements among experts and patients revealed unanimous consensus.

Mandatory outcomes for trials involving STA included the assessment of (i) surgical morbidity and adverse events, (ii) peri-implant mucosa dimensions, (iii) objective professional aesthetic assessments, (iv) subjective aesthetic assessments (patient-reported and professional evaluation) and (v) peri-implant soft-tissue health status following the ID-COSM criteria. In specific trials, mandatory outcomes may also comprise (i) mid-facial mucosal margin position, (ii) peri-implant soft-tissue volume, (iii) interproximal soft-tissue height (papilla height), (iv) quality of life, (v) health economics and (vi) relevant ID-COSM and/or BA-COSM outcomes.

4 | DISCUSSION

The objective of identifying a COS is to enrich clinical trials by providing a full picture of the benefits and harms of different interventions across all relevant areas and domains in the particular field of investigation. Importantly, it is a voluntary set of guidelines aimed at improving the relevance of clinical research. It is critical to emphasize that the current initiative, which focuses on clinical trials in implant dentistry, does not aim to standardize the primary outcome of individual trials. This selection should continue to be guided by the specific hypotheses of each trial. While the primary outcome will often be included in the mandatory outcomes in the ID-COSM set, investigators are free to add additional outcomes to capture the specific aims and benefits tested in their respective studies. However, the COS is the minimum set of outcomes that should be consistently included across all reported trials.

The end product of this process is the definition of one general core set of outcomes (ID-COSM) and two specialized sets of outcomes applicable to BA and STA trials (BA-COSM and STA-COSM). The authors of this consensus debated the possibility of distilling outcomes into a single set. Still, they agreed that a single set would not adequately guide authors towards selecting core outcomes in many trials. The current structure refers investigators to the specialized outcome sets whenever BA or STA is incorporated into an implant dentistry trial. In particular instances, research may focus on developing better STA and BA approaches and, on some occasions, may not involve the actual placement of dental implants within the course of the trial. In such trials, investigators should initiate the outcome selection from the specialized tools and enrich them with outcomes in the general ID-COSM domains, as appropriate.

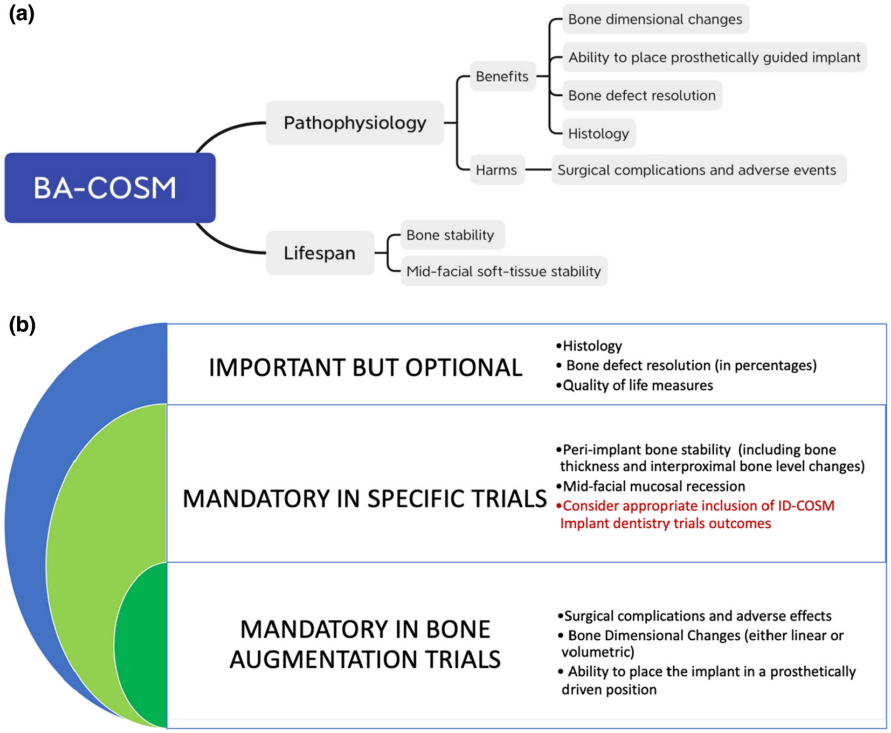

FIGURE 5 (a) Bone augmentation core outcome set and measurements (BA-COSM) core outcome areas and domains for bone augmentation. Mindmap of the core outcomes areas and core outcome domains that should be captured in bone augmentation clinical trials. (b) Core outcome set for bone augmentation trials: BA-COSM. Consensus on the core outcome domains inserted in the BA-COSM 'onion'. Three outcomes are considered mandatory in all trials, and three outcomes are considered mandatory in specific types of trials. In trials involving dental implants, the reader is referred to the need to include the general Implant Dentistry Core Outcome Set and Measurements core outcome set (highlighted in red) and Figure 4. Examples of the specific measures needed to capture BA-COSM outcomes are detailed in the text.

This is the first systematic attempt to identify a COS for inclusion in implant dentistry research. Identification of COSs in other areas of medicine has been an ongoing process of maturation and improvement over several decades. This initial attempt in the field of implant dentistry will likely have shortcomings that require future modifications. Members of the steering committee and expert panels recognized the need to learn from best practice approaches and realized that the present document has limitations. They, nevertheless, recognized that introducing COSs has great potential to improve clinical research in implant dentistry and clinical practice. A key strength of this project has been its inspiration by best practice approaches in applying a rigorous, inclusive and transparent process. Scientific evidence of outcomes used in clinical research in the last 10 years has been combined with an unbiased perspective provided by patients (PWLE) focus groups in the data collection step of the process. A broad collection of outcomes was compiled and subjected to a rigorous three-round Delphi survey to identify essential outcomes using recognized a priori criteria to distil many outcomes into a manageable number of domains. Furthermore, the Delphi process was used to reach a wide constituency of stakeholders within the profession, patient population and industry. Organizing outcome domains into a theoretical framework is also a strength of the process.

An important limitation is a need for more valid and agreed-upon outcome measures to capture the multiple dimensions of benefits and harms of implant therapy. This is an area of priority for future development.

It is recognized that many studies are currently going on and that such studies may have included only some mandatory domains in their protocols. For these trials, the study outcomes should be reported following the logical structure of the core areas and essential domains identified in this project (see Figures 3–6). Missing mandatory outcomes should be highlighted in the description of trial materials and methods.

Protocols for future trials should carefully consider the ID-COSM, BA-COSM and STA-COSM mandatory domains (mandatory in all trials and mandatory in specific circumstances) as the current best practice approach. It is strongly suggested that the trial protocol refers to the core sets identified in this consensus report in the materials and methods section. The omission of a specific domain(s) should be explicitly acknowledged as a study limitation in the final publication(s). Limitations in terms of the validity of the instruments to accurately measure some of the outcomes are recognized. Nevertheless, implementing most of the domains included in the sets appears highly feasible.

The proposed COSs for implant dentistry research should be periodically amended. An apparent challenge is a need for validated

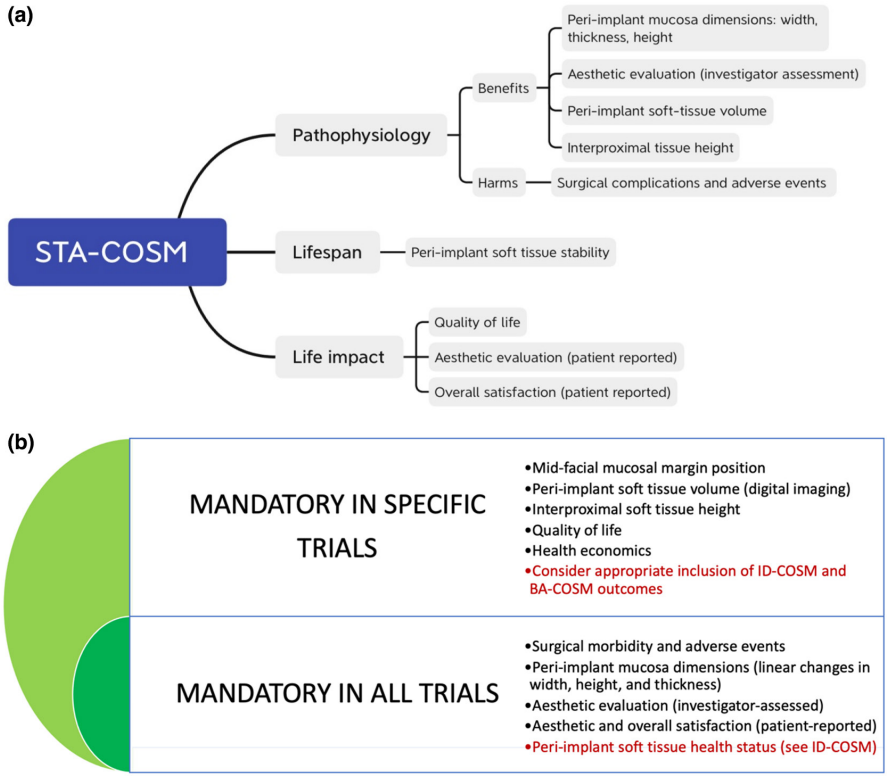

FIGURE 6 (a) Soft-tissue augmentation core outcome set and measurements (STA-COSM) core outcome areas and domains for soft-tissue augmentation. Mindmap of the core outcomes areas and core outcome domains that should be captured in soft-tissue augmentation clinical trials. (b) Core outcome set for soft tissue augmentation trials: STA-COSM. Consensus of the core outcome domains inserted in the STA-COSM 'onion'. Five outcomes are considered mandatory in all trials, and six outcomes are considered mandatory in specific types of trials. For the outcomes necessary to capture the peri-implant soft-tissue health status, readers are referred to the appropriate section of the general Implant Dentistry Core Outcome Set and Measurements (ID-COSM). In trials involving dental implants and to the need to include the general ID-COSM core outcome set (COS) (Figure 4). If bone augmentation is part of the trial, the reader is referred to the BA-COSM (Figure 5). Outcomes highlighted in red indicate that they are part of another COS. Examples of the specific measures needed to capture STA-COSM soft-tissue augmentation outcomes are detailed in the text.

outcome measures/instruments to capture some mandatory domains, which are continuously refined as contemporary methodologies are being developed. Nevertheless, and because of the challenges with the present sets, implant dentistry outcome research should be encouraged.

5 | CONCLUSIONS

The ID-COSM initiative agreed upon the core areas and domains to capture benefits and harms in implant dentistry and STA/BA clinical trials. It also identified a limited set of mandatory outcomes that should be assessed in all trials as well as additional mandatory outcomes that should be assessed under specific circumstances. It is recognized that evidence to support the use of specific measurement instruments is sometimes lacking and that outcome research in implant dentistry should be encouraged. Nevertheless, the panel of experts agreed that ID-COSM, BA-COSM and STA-COSM should be implemented in the protocol of future clinical studies and utilized in the reporting of ongoing studies in implant dentistry.

AUTHOR CONTRIBUTIONS

Maurizio S. Tonetti conceived the work and drafted the final report based on the discussions and consensus development meetings. Maurizio S. Tonetti and Mariano Sanz co-chaired the process. Tord Berglundh, Elena Figuero, Lisa Heitz-Mayfield, Hongchang Lai, Ronald Jung, Ian Needleman, Panos N. Papapanou, Mariano Sanz, Frank Schwarz and Maurizio Tonetti participated as members of the steering committee. Gustavo Avila-Ortiz, Francesco Cairo, Jan Derks, Filippo Graziani, Fernando Guerra, Irena Sailer, Ignacio Sanz-Sanchez, Junyu Shi and Daniel Thoma participated in the experts' committee together with the co-chairs and the steering committee. Mariano Sanz led the Delphi survey and Ian Needleman the patient involvement part of the project. All co-authors participated in all stages of the consensus development process and critically reviewed the manuscript.

ACKNOWLEDGEMENTS

We are grateful for the input from the many stakeholders who participated in the Delphi phase of this consensus process. Particular thanks are due to the contributions of the people with a living experience of dental implant treatment who kindly volunteered their

time. Lastly, the excellent work of all co-authors of the systematic reviews commissioned for this process is gratefully acknowledged.

FUNDING INFORMATION

This consensus development conference was supported by the National Natural Science Foundation of China (grant 82171005). Additional funding was provided by the Science and Technology Commission of Shanghai Municipality (19411950100), Shanghai Innovative Research Team Award of High-Level University (SHSMU-ZDCX202125000), the National Clinical Research Center for Oral Diseases, the Clinical Research Program of Ninth People's Hospital affiliated with Shanghai Jiao Tong University School of Medicine (JYLJ201909) and the European Research Group on Periodontology, Switzerland. Funders had no impact on the content of this initiative.

CONFLICT OF INTEREST STATEMENT

Maurizio S. Tonetti received grant support and/or personal fees from Geistlich Pharma AG, Straumann AG, Nobel Biocare, Procter and Gamble and Sunstar SA, unrelated to the present work. Mariano Sanz received grant support and/or personal fees from Straumann, Nobel Biocare, Sweden and Martina, Dentsply Implants, TiCare Implants, Klockner Implants, Dentaid, Sunstar, Geistlich Pharma, Osteology Foundation, Oral Reconstruction Foundation and ITI Foundation, unrelated to the present work. Francesco Cairo received grant support and/or personal fees from Geistlich Pharma AG and Straumann AG, unrelated to the present work. Daniel Thoma reports grants from Geistlich Pharma AG, Sunstar SA, Institute Straumann, Dentsply Sirona and Dentium, unrelated to the present work. Gustavo Avila-Ortiz received grant support and/or honoraria from Geistlich Pharma AG, Osteogenics Biomedical and Dentsply Implants, unrelated to the present work. Gustavo Avila-Ortiz receives a honorarium as Associate Editor of the *Journal of Periodontology* and *Clinical Advances in Periodontology*. Lisa Heitz-Mayfield received grant support from the Osteology Foundation, International Team for Implantology Foundation and honoraria from Geistlich Pharma AG, Straumann AG, unrelated to the present work. Lisa Heitz-Mayfield receives an honorarium as Editor-in-Chief of *Clinical Oral Implants Research*. Elena Figuero received grant support from the Dentaid, Lacer and the University of Bristol through contracts from the University, payment for lectures for Oral-B, Colgate, Johnson & Johnson, Spanish Society of Periodontology, Irish Society of Periodontolgy, French Society for Dentistry and Ukranian Association of Periodontoloy, unrelated to the present work. Elena Figuero receives an honorarium as Associate Editor of the *Journal of Clinical Periodontology*. Ronald Jung received grant support and/or personal fees from Geistlich Pharma AG, Straumann AG, Camlog Biotechnologies GmbH, VITA Zahnfabrik, TRI Implants, unrelated to the present work. Ian Needleman is an Editor with *Cochrane Oral Health*. Frank Schwarz received research grants from Geistlich Pharma AG, Institut Straumann AG, Camlog Biomaterials and Dentsply, unrelated to the present work. Ignacio Sanz-Sanchez received personal fees from EMS, Colgate, Inibsa, Mozograu, Klockner, Dentsply, Oral-B, Nobel-Biocare, Osteocom, SEPA Foundation and Oral Reconstruction Foundation, unrelated to the present work. Jan Derks received grant support and/or personal fees from Dentsply Sirona Implants, Straumann AG, Osteology Foundation, Eklund Foundation and Electro Medical Systems, unrelated to the present work. Tord Berglundh received grant support and/or personal fees from Dentsply Sirona Implants and Osteology Foundation, unrelated to the present work. Filippo Graziani received grant support and/or honoraria from Straumann, Procter and Gamble, Sunstar, Curasept and Haleon, unrelated to the present work.

DATA AVAILABILITY STATEMENT

The data supporting this study's findings are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

There are no ethics issues related to this manuscript.

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How to cite this article: Tonetti, M. S., Sanz, M., Avila-Ortiz, G., Berglundh, T., Cairo, F., Derks, J., Figuero, E., Graziani, F., Guerra, F., Heitz-Mayfield, L., Jung, R. E., Lai, H., Needleman, I., Papapanou, P. N., Sailer, I., Sanz-Sanchez, I., Schwarz, F., Shi, J., & Thoma, D. (2023). Relevant domains, core outcome sets and measurements for implant dentistry clinical trials: The Implant Dentistry Core Outcome Set and Measurement (ID-COSM) international consensus report. *Clinical Oral Implants Research*, *34*(Suppl. 25), 4–21. https://doi.org/10.1111/clr.14074