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Multi-stakeholder contribution to the identification of a core outcome set and measurements in implant dentistry (ID-COSM initiative) using the Delphi methodology

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Abstract

Aim: To obtain input from multiple stakeholders and generate agreement on essential outcomes in implant dentistry using the Delphi methodology and incorporate them into an international consensus defining a core outcome set.

Materials and Methods: Candidate outcomes in implant dentistry were generated from scientific evidence through five commissioned systematic reviews and from people with lived experience in dental implants (PWLE) through four international focus groups. A steering committee identified stakeholders among representatives from dental professionals, industry-related experts and PWLE. Participants underwent a three-round Delphi survey using a multi-stakeholder approach; they assessed candidate outcomes and additional outcomes identified in the first Delphi round. The process followed the COMET methodology.

Results: From the 665 potential outcomes identified in the systematic reviews and 89 in the PWLE focus group, the steering committee selected 100 and organized them into 13 categories, to be included in the first-round questionnaire as candidate outcomes. A total of 99 dental experts, 7 dental-industry-related experts and 17 PWLE participated in the first round, and 11 additional outcomes were added to the second round. There was no attrition between the first and second rounds, where 61 (54.9%) outcomes exceeded the pre-established threshold of agreement. PWLE and experts participated in the third round that applied "a priori" standard filters to distil a list of candidate essential outcomes.

Conclusion: This Delphi study utilized a standardized, transparent and inclusive methodology and preliminarily validated 13 essential outcomes organized into four core areas. These results informed the final stage of the ID-COSM consensus.

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

1 | INTRODUCTION

A core outcome set (COS) is a widely agreed, standardized set of outcomes that should be recommended for its use in all clinical trials in specific areas of health or health care (COMET initiative—www.comet-initiative.org). Accordingly, COS in dentistry should be developed to facilitate the comparison, combination and critical appraisal of results derived from clinical research. In parallel, efforts should continue to explore additional outcomes and improved ways to measure them.

Although it is recognized that adequate selection of the right outcome domains and outcomes is an essential aspect in the design of randomized controlled clinical trials (RCTs), it has, so far, received insufficient attention. Furthermore, potential bias when interpreting outcomes from published clinical trials is derived from their heterogeneity within RCTs, possible outcome reporting bias (defined as the results-based selection for publication of a subset of the original measured outcome variables) and insufficient attention to patient-reported outcomes and opinions (Kirkham et al., 2019; Williamson et al., 2012). In light of these problems, clinical research in many areas of health care is progressively moving towards adopting a more structured approach towards COS development, making an effort to include public representation, and developing a set of core outcomes following a structured process (Williamson et al., 2017). However, the validity of the developed COS depends not only on the use of an adequate methodology but also on the fulfilment of a clear and transparent reporting of the processes adopted (Kirkham et al., 2015; Kirkham et al., 2017). As an example of such a process, the OMERACT (Outcome Measures in Rheumatology; https://omeract.org) collaboration has extensively worked on developing a COS in this area and defining the set of measurements recommended for each outcome using a data-driven, iterative consensus process involving relevant stakeholder groups. Since no COS is currently available in dentistry, the international initiative named "the Implant Dentistry Core Outcome Sets and Measurements initiative" (ID-COSM initiative) was developed to achieve a consensus in a core set of outcomes to be implemented in future research on implant dentistry.

A first step of this initiative was searching for an iterative consensus process. Here, the Delphi process, which uses structured communication, individual feedback, group judgement and discussion to deal with complex problems, has proven to be a valuable tool to achieve the consensus of a structured group of individuals (Linstone & Turoff, 1975). The RAND Corporation developed this methodology in the 1950s through a series of studies conducted to achieve the most reliable agreement by a group of experts (Dalkey & Helmer, 1963). This methodology usually builds up the agreement by allowing the experts and stakeholders to answer structured questionnaires in two or more "rounds", where the results of the previous rounds are provided as feedback to allow for multiple iterations with controlled opinion feedback (Woudenberg, 1991). It has the advantage of anonymity, thus avoiding the effect of dominant individuals, and the use of electronic communication allows the involvement of geographically distant panellists (Sinha et al., 2011).

By answering the structured questionnaires and, at the same time, considering the views of the other participants before re-rating each question in the second round, panellists could modify their responses based on the feedback from the previous rounds. Finally, the resulting data from the questionnaires is further discussed by a group of selected experts until achieving a formal result developed by agreement. Despite concerns regarding its validity and reproducibility, due to the possible attrition during the process, it remains one of the most widely used methods for reaching expert-level agreement (Acharya et al., 2021; Lam et al., 2021).

The previous applications of the Delphi methodology in dentistry did not use a standardized methodology and a priori criteria for the development of the questions or the analysis of the results (Madianos et al. 2016; Alarcón, Sanz-Sánchez, López-Pacheco, et al., 2021; Alarcón, Sanz-Sánchez, Shibli, et al., 2021; Sanz et al., 2019). In the field of outcome research, the Delphi methodology has been applied following strict scientific criteria in order to further limit bias. These developments have been formalized in the standards for development of core outcome sets COS-STAD (Kirkham et al., 2016) and in a specific software ensuring high levels of quality control in the delivery of the Delphi survey.

The present study reports the methods and the results of the Delphi process used to achieve a multi-stakeholder agreement in a core set of outcomes in implant dentistry. The validated results will be used as part of the ID-COSM initiative "the Implant Dentistry Core Outcome Sets and Measurements" using the methodologies to develop Core Outcome Measures in Effectiveness Trials (COMET—www.comet- initiative.org, OMERACT—www.omeract.org).

Clinical Relevance

Scientific rationale for the study: A standardized set of outcome measures in implant dentistry clinical trials is needed. These should be adopted by a broad consensus of relevant stakeholders, including patients.

Principle findings: The results of this Delphi project using a multi-stakeholder participation strategy preliminarily validated 13 essential outcomes organized into four core areas. These will provide the basis for developing a core outcome set (COS) on implant dentistry in the final stage of the ID-COSM initiative project.

Practical implications: Adopting the ID-COSM set of mandatory outcome domains will contribute to improve the evidence base of implant dentistry and lead to better informed care.

2 | MATERIALS AND METHODS

This study reports the selection of a potential core set of outcomes in implant dentistry by a significant degree of agreement using the Delphi methodology through a three-round multi-stakeholder process.

2.1 | Candidate outcomes

As a first step, potential candidate outcomes in implant dentistry were selected from two sources: (1) scientific data and (2) patient focus groups.

Outcomes and measurements reported in the previous 10 years of clinical research in implant dentistry (2011–2021) were retrieved from five commissioned systematic reviews using a broad, inclusive and scientific perspective. An international team of research experts in the field conducted these reviews. Eligible studies were randomized clinical trials (RCTs), non-randomized clinical trials (n-RCTs), prospective or retrospective cohort studies and descriptive prospective or retrospective studies (single cohort) identified from three electronic databases: (1) MEDLINE via PubMed; (2) Cochrane Library (including Cochrane Database for Systematic Reviews and Cochrane CENTRAL register for Clinical Trials); and (3) Embase. All the protocols of the systematic reviews were previously registered in the PROSPERO and followed the PRISMA guidelines (Page et al., 2021). These systematic reviews covered five broad areas of clinical research in implant dentistry:

- Single and partial tooth replacement with fixed dental prostheses supported by dental implants (Sailer et al., 2022);
- Rehabilitation of full-arch edentulism with fixed or removable dentures retained by root form dental implants (Messias et al., 2022);
- Bone preservation or augmentation simultaneous with or before dental implant placement (Shi et al., 2022);
- Soft tissue preservation/augmentation (Avila-Ortiz et al., 2022);
- Prevention and management of peri-implant mucositis and peri-implantitis (Derks et al., 2022).

The patient's perspective on clinical research outcomes in implant dentistry may differ from those of clinicians and researchers because it includes different perceptions based on living with the condition, in this case, having undertaken a dental implant intervention. Therefore, involving people with lived experience (PWLE) has become a key standard of quality for COSM development because informed clinical decisions should be based not only on the outcomes measured in clinical trials but also on those relevant to patients (Sinha et al., 2011). In the present ID-COSM initiative, 31 PWLE participated in four focus groups representing low-middle- (9 PWLE from China and 8 from Malaysia) and high-income countries (7 PWLE from Spain and 7 from the United Kingdom) to identify outcomes they found relevant and important in relation to their dental implant experience. Briefly, each focus group was led by a moderator who stressed that the purpose was to identify outcomes for future research in dental implants that were relevant to PWLE. PWLE were able to express their views in their native languages with a dental professional moderator from each region. Outcomes were organized into five main categories: (1) decision making regarding the choice of implant therapy; (2) dental implant treatment; (3) living with dental implants; (4) the most important thing you believe implant researchers should measure; and (5) any other aspect of dental implants not previously considered. PWLE were asked to speak freely, and their information was processed anonymously; their answers were recorded in electronic format by the moderator for further analysis and synthesis. The details of this process have been published in a separate report (Needleman et al. 2023).

2.2 | Steering committee

To guide the ID-COSM initiative, a steering committee was formed consisting of two principal investigators (Maurizio Tonetti, Mariano Sanz), the scientific committee (Tord Berglundh, Ronald Jung, Hongchang Lai, Lisa Heitz-Mayfield, Panos N. Papapanou, Frank Schwarz) and two methodological consultants (Ian Needleman, Elena Figuero).

This committee, especially the principal investigators (PIs) (MT and MS) and one methodological consultant (IN), rationalized, consolidated and, hence, reduced the list of outcomes and measurements derived from the systematic reviews and PWLE focus groups by eliminating duplicates or redundancies, and developed a final list of candidate outcomes to be included in the Delphi questionnaires.

The outcomes from the scientific data were organized into the following categories: (1) implant performance; (2) implant-supported restoration performance; (3) functional and aesthetic domain; (4) surgical domain; (5) peri-implant tissue health; (6) patient satisfaction; (7) prognostic indicator/treatment modifiers; and (8) economic domain. Similarly, the outcomes from the PWLE data were organized into the following categories: (1) patient information before treatment; (2) implant treatment; (3) living with dental implants; (4) having dental implants; and (5) other outcomes.

2.3 | Stakeholders

A Delphi panel was selected to ensure a broad multi-stakeholder representation and comprised the following groups:

1. Patients. This group was formed by most of the PWLE who participated in the four previously referred focus groups.
2. Dental professionals. This group was formed by dental experts selected from a wide representation of expertise (including academicians, clinicians and methodologists) and geographical distribution.

3. Industry-related experts. Clinical research directors/professionals of leading companies in the field of implant dentistry and regenerative biomaterials comprised this group.

This panel participated in the two consecutive rounds by answering the questionnaires and scoring the selected outcomes.

2.4 | Online Delphi questionnaires

We used the scientifically validated software to develop Delphi questionnaires by the COMET initiative (DelphiManager, University of Liverpool, UK), which is a web-based system designed to facilitate the organization and management of Delphi questionnaires, where the list of candidate outcomes is compiled within the previously cited categories for defined stakeholders (in this case dental professionals, industry-related experts and PWLE participants). The questionnaire was organized into columns detailing the name of the outcome, help text describing each outcome in detail and the category to which the outcome belongs (Suppl 1). Selected participants were invited via email containing a hyperlink to the web-based Delphi survey containing the appropriate instructions, information and dates for each round. The invitation also assured potential panellists that their participation would be anonymous and that they could exit the process anytime. Delphi survey was only available in English, although PDF help text was also available in Spanish and Chinese for PWLE in need of translation. Those agreeing to participate signed an electronic informed consent, considering that DelphiManager software is compliant with the General Data Protection Regulation (GRPR). Ethical approval was not required.

Round 1 questionnaire also included space for filling in demographic data, including the country of residence and stakeholder group. In addition, dental professionals and industry-related experts should fill in information on their work setting and dental speciality (periodontology, prosthodontics, oral surgery or others for dental professionals, and research and development or management for industry-related experts). PWLE should provide information on when their implants were placed (within last year, between 1 and 5 years, more than 5 years ago) and the number of implants (1–3 implants, more than 3 implants, complete upper or lower jaw). The rest of the questionnaire was structured in two sections, one with outcomes relevant to dental professionals and industry-related experts, and the other with those relevant to PWLE (Suppl 2 depicts the round 1 questionnaire). Even though all panellists could see all the outcomes, the software recommended filling and rating the outcomes from their respective sections. The rating provided a choice on a 1–9 Likert scale (with 9 being the most important outcome, judged as essential for inclusion in a core outcome set). Scoring also included the use of the 'unable to rate' option, and it was possible to add comments or clarifications to each outcome. Suggestions for additional outcomes for the second round were also possible.

In round 2, participants were asked to fill and re-score the same questionnaire and, additionally, those outcomes that the steering committee had previously validated from those proposed by the panellists during round 1. When filling out this questionnaire, participants were shown the results from round 1 and a reminder of their previous rating for each outcome.

2.5 | Agreement definition

Participants' agreement was reached when the analysis of the results from round 2 satisfied both criteria: ≥70% scores of 7–9 and ≤15% scorings of 1–3.

Round 3 consisted of a direct meeting of experts ($N = 19$) and PWLE ($N = 7$) to review the results, exclude those variables not meeting the threshold for agreement and further discuss those not being real outcomes. The selection of the final list of essential outcomes was made by formal voting by the representatives of the two groups of stakeholders and specifically asking if the outcomes meeting the agreement definition were considered to be essential or could be dropped.

2.6 | Data analysis

2.6.1 | Quantitative analysis

Data from outcomes scored by dental professionals and industry-related experts were analysed together, while data from PWLE were analysed separately. The degree of agreement was calculated for each outcome. The results of each outcome were reported as mean score (and standard deviation), median score (and interquartile range) and the proportion of participants that exceeded the agreement definition threshold. Comparisons of these percentages between rounds, dental professionals and industry-related experts were assessed using the Chi-square test. Similarly, comparisons of median values for each outcome between dental professionals and industry-related experts were assessed with the Mann–Whitney test. In case of attrition between rounds 1 and 2, attrition bias was measured by comparing the scores of those panellists participating in the first round but not in the second, with those participating in both rounds.

All analyses used SPSS (IBM SPSS Statistics for Mac, Version 26, Armonk, NY), and Excel (version 16.67; Microsoft Corporation, Redmond, WA). Statistical significance was set at $p < .05$.

2.6.2 | Qualitative analysis

After preliminary grouping by themes and sub-themes, the open comments generated in both rounds were analysed by the steering committee, who decided whether to include additional outcomes for the second round.

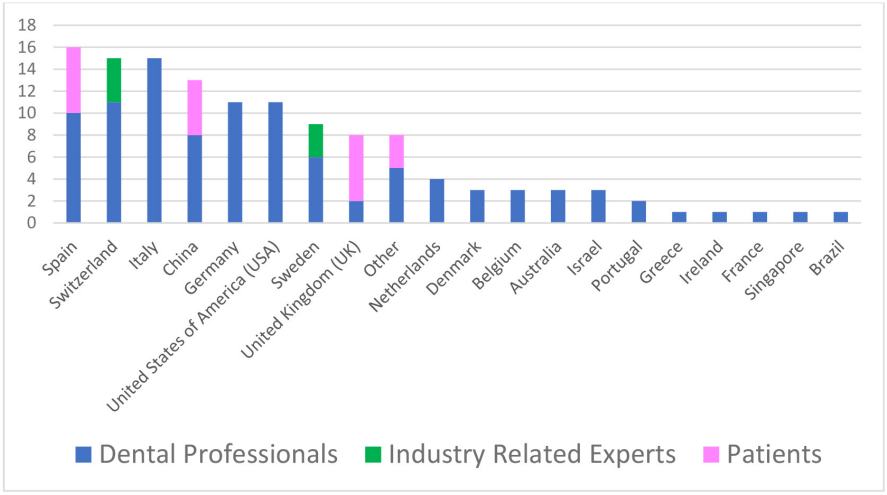

FIGURE 1 Country of residence of stakeholders participating in the Delphi project.

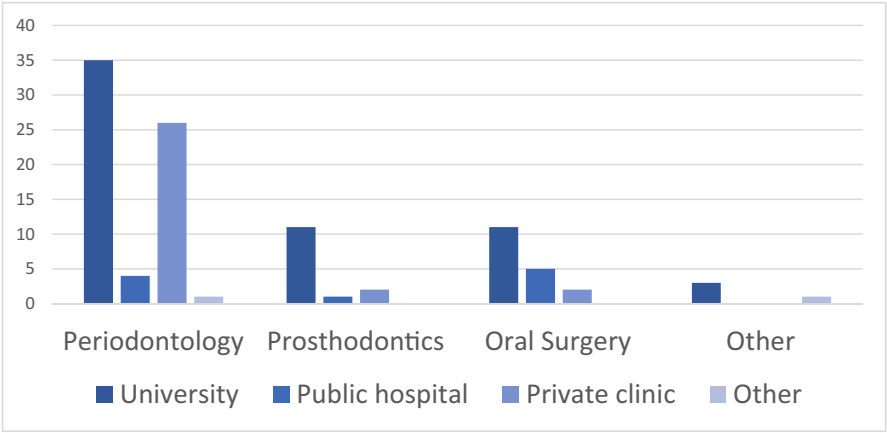

FIGURE 2 Relative frequency of professional profiles of dental professionals participating in the Delphi project.

3 | RESULTS

The five systematic reviews identified 665 potential outcomes. After the above-referred selection process, a final list of 66 candidate outcomes was included in the Delphi questionnaire. These were organized within the eight pre-established categories and sent to dental professionals and industry-related experts for scoring. The PWLE identified 89 potential topics with substantial overlap and duplications. After appropriate filtering, a list of 34 candidate outcomes was selected, distributed into five categories, and included in the Delphi questionnaires to be scored by the PWLE stakeholder group. Finally, a total of 100 outcomes organized into 13 categories were included in the questionnaire for the first Delphi round (Suppl 2).

The Delphi survey round 1 was conducted between 26 March 2022 and 11 April 2022, and 180 stakeholders were invited to participate (142 dental experts, 11 dental industry-related experts and 26 PWLE). From these, 129 registered on the DelphiManager software, and 123 completed round 1 questionnaire once they filled the appropriate consent form. In round 2, 124 panellists completed the round, resulting in a retention rate across rounds of 100% (no attrition). Thus, 6 and 5 out of 129 registered panellists did not complete round 1 and 2 surveys, respectively. The distribution among stakeholders consisted of 100 dental professionals (80.6%), 7 industry-related experts (5.6%) and 17 PWLE (13.7%). The mean age of participants (SD) was 53.9 (10), 48.8 (8.3) and 55.2 (14.5) for dental professionals, industry-related experts and PWLE, respectively. The number of participants per geographical distribution is presented in Figure 1, and the professional profile of the dental experts is depicted in Figure 2. Industry-related experts were mainly involved in areas of research and development (71.4%), and the remaining in management (28.6%). PWLE reported that their implants had been placed within the last year (20%), between 1 and 5 years (40%) and more than 5 years earlier (40%). In relation to the number of dental implants per patient, 60% reported having 1–3 dental implants, 35% more than 3 implants, and 5% a complete upper or lower jaw.

After round 1, there were 28 further suggestions as potential new outcomes. Once the steering committee did the appropriate filtering, 11 new outcomes were added to the second round questionnaire, for a total of 111 candidate outcomes. Round 2 was conducted between 14 April 2022 and 30 April 2022. The median values for outcomes scored by dental professionals and industry-related experts according to the pre-set categories in the second round are shown in Figure 3. The following outcomes were scored significantly higher by dental professionals, compared to industry-related experts: prosthesis design for oral hygiene, indirect patient costs and economic total cost of recurrence. Conversely, industry-related

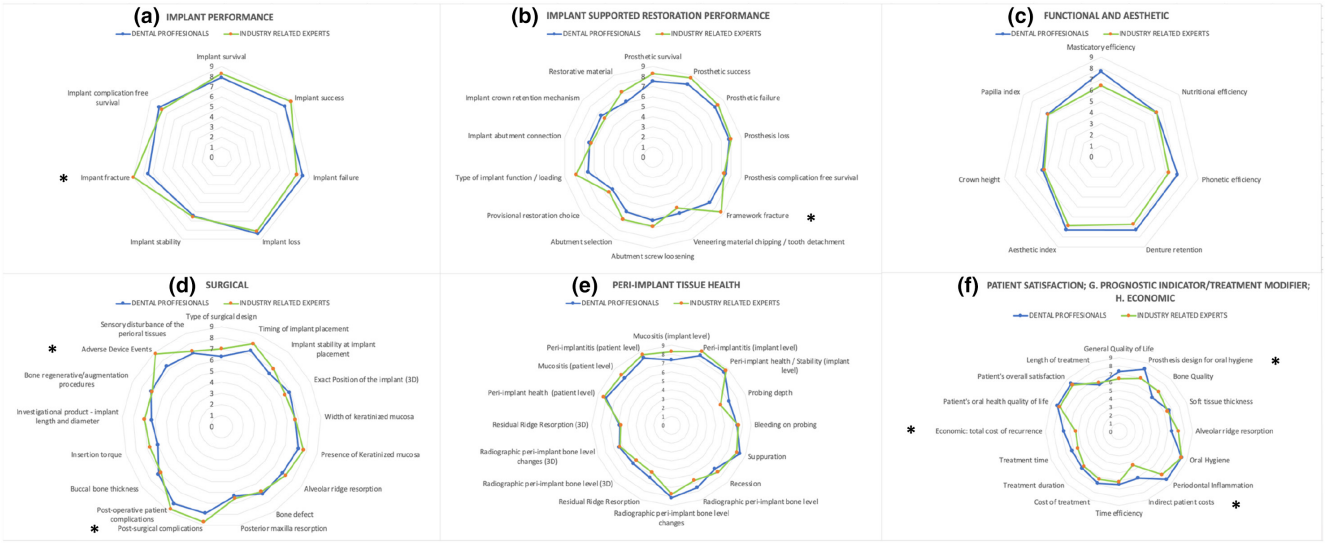

FIGURE 3 Scoring by dental professionals and industry-related experts of 77 candidate outcomes after the second round, distributed in categories. *$p < .05$ for differences among dental professionals and industry-related experts.

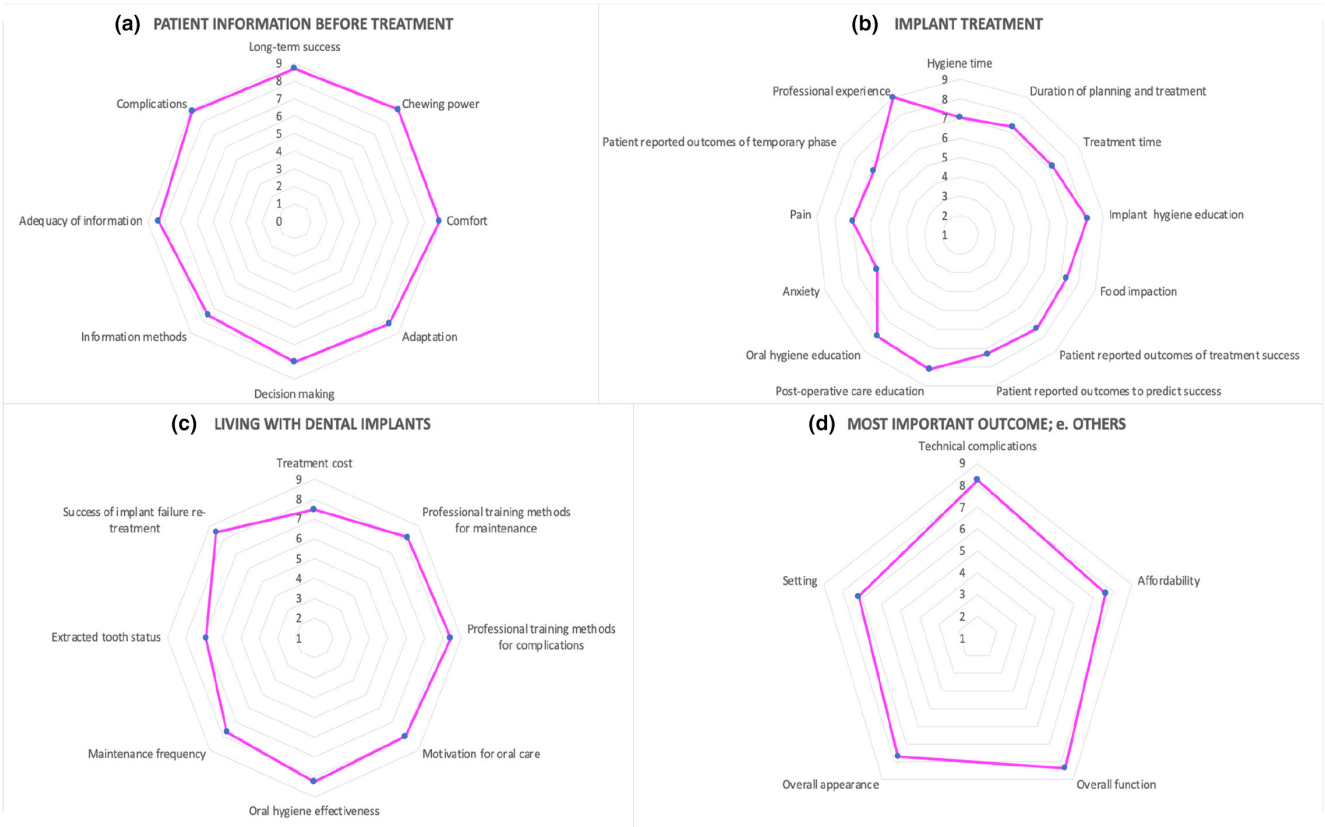

FIGURE 4 Scoring by people with lived experience in dental implants of 34 candidate outcomes after the second round, distributed into categories.

experts scored significantly higher on the following outcomes: implant fracture, framework fracture, adverse device events and post-surgical complications. The respective median values for outcomes scored by PWLE are depicted in Figure 4.

Table 1 shows the candidate outcomes reaching the minimum agreement (≥70% scores 7–9 and ≤15% scores 1–3) in the second round, resulting in 39 candidate outcomes (50.6%) by dental professionals and industry-related experts.

TABLE 1 Candidate outcomes reaching the minimum agreement threshold (at ≥70% scores of 7–9 and ≤15% scorings of 1–3). Mann–Whitney test for comparisons between dental professionals and industry-related experts, $^{*}p < .05$.

Categories	*n*	Outcome	Dental + industry	Dental professionals	Industry experts	*p*-value
Implant performance	1	Implant survival	87.90%	88.00%	85.70%	NS
	2	Implant success	89.70%	89.00%	100.00%	NS
	3	Implant failure	92.50%	93.00%	85.70%	NS
	4	Implant loss	94.40%	95.00%	85.70%	NS
	5	Implant stability	53.30%	52.20%	57.10%	NS
	6	Implant fracture	75.70%	74.00%	100.00%	0.015
	7	Implant complication-free survival	84.10%	82.00%	71.40%	NS
Implant-supported restoration performance	1	Prosthetic survival	82.20%	81.00%	100.00%	NS
	2	Prosthetic success	86.00%	85.00%	100.00%	NS
	3	Prosthetic failure	85.00%	85.00%	85.70%	NS
	4	Prosthesis loss	84.10%	84.00%	85.70%	NS
	5	Prosthesis complication-free survival	76.60%	78.00%	57.10%	NS
	6	Framework fracture	74.50%	72.70%	100.00%	0.013
	7	Veneering material chipping/tooth detachment	40.60%	42.40%	14.30%	NS
	8	Abutment screw loosening	50.50%	50.00%	57.10%	NS
	9	Abutment selection	47.60%	45.90%	71.40%	NS
	10	Provisional restoration choice	22.60%	22.20%	28.60%	NS
	11	Type of implant function/loading	61.70%	61.00%	71.40%	NS
	12	Implant abutment connection (Added 2 round)	55.80%	56.70%	42.90%	NS
	13	Implant crown retention mechanism (Added 2 round)	57.70%	57.70%	57.10%	NS
	14	Restorative material (Added 2 round)	43.10%	42.70%	50.00%	NS
Functional and aesthetic domain	1	Masticatory efficiency	81.10%	83.00%	50.00%	NS
	2	Nutritional efficiency	46.70%	47.00%	66.70%	NS
	3	Phonetic efficiency	72.90%	73.00%	71.40%	NS
	4	Denture retention	78.30%	81.00%	33.30%	NS
	5	Aesthetic index	77.60%	78.00%	71.40%	NS
	6	Crown height	24.80%	26.50%	21.40%	NS
	7	Papilla index	50.00%	49.50%	57.10%	NS
Surgical domain	1	Type of surgical design	43.90%	44.00%	42.90%	NS
	2	Timing of implant placement	72.90%	72.00%	85.70%	NS
	3	Implant stability at implant placement	60.70%	60.00%	71.40%	NS
	4	Exact position of the implant (3D)	58.90%	59.00%	57.10%	NS
	5	Width of keratinized mucosa	56.10%	56.00%	57.10%	NS
	6	Presence of keratinized mucosa	74.80%	74.00%	85.70%	NS
	7	Alveolar ridge resorption	67.30%	66.00%	85.70%	NS
	8	Bone defect	72.40%	73.70%	50.00%	NS
	9	Posterior maxilla resorption	48.10%	47.50%	57.10%	NS
	10	Post-surgical complications	90.70%	90.00%	10.00%	0.043
	11	Post-operative patient complications	89.70%	89.00%	100.00%	NS
	12	Buccal bone thickness (Added 2 round)	72.00%	72.00%	71.40%	NS
	13	Insertion torque (Added 2 round)	44.90%	44.00%	57.10%	NS
	14	Investigational product - implant length and diameter (Added 2 round)	59.80%	58.00%	85.70%	NS
	15	Bone regenerative/augmentation procedures (Added 2 round)	70.10%	70.00%	71.40%	NS
	16	Adverse device events (Added 2 round)	71.20%	69.10%	100.00%	0.008
	17	Sensory disturbance of the perioral tissues (Added 2 round)	67.00%	68.00%	50.00%	NS

TABLE 1 (Continued)

Categories	n	Outcome	Dental + industry	Dental professionals	Industry experts	p-value
Peri-implant tissue health	1	Mucositis (implant level)	79.40%	78.00%	100.00%	NS
	2	Peri-implantitis (implant level)	96.30%	96.00%	100.00%	NS
	3	Peri-implant health/stability (implant level)	99.10%	99.00%	100.00%	NS
	4	Probing depth	65.40%	68.00%	28.60%	NS
	5	Bleeding on probing	75.70%	76.00%	71.40%	NS
	6	Suppuration	93.30%	95.00%	60.00%	NS
	7	Recession	57.00%	55.00%	85.70%	NS
	8	Radiographic peri-implant bone level	76.60%	78.00%	57.10%	NS
	9	Radiographic peri-implant bone level changes	88.80%	91.00%	57.10%	NS
	10	Residual ridge Resorption	46.20%	47.50%	28.60%	NS
	11	Radiographic peri-implant bone level (3D)	41.50%	41.40%	42.90%	NS
	12	Radiographic peri-implant bone level changes (3D)	49.10%	49.50%	42.90%	NS
	13	Residual Ridge Resorption (3D)	38.30%	39.00%	28.60%	NS
	14	Peri-implant health (patient level)	87.70%	86.90%	100.00%	NS
	15	Mucositis (patient level)	76.40%	74.70%	100.00%	NS
	16	Peri-implantitis (patient level)	87.70%	86.90%	100.00%	NS
Patient satisfaction	1	Patient's oral health quality of life	90.70%	91.00%	85.70%	NS
	2	Patient's overall satisfaction	90.70%	91.00%	85.70%	NS
	3	Length of treatment	40.20%	41.00%	28.60%	NS
Prognostic indicator/ treatment modifier	1	General Quality of Life (Added 2 round)	69.50%	71.40%	42.90%	NS
	2	Prosthesis design for oral hygiene	87.90%	91.00%	42.90%	0.039
	3	Bone Quality	35.50%	35.00%	42.90%	NS
	4	Soft tissue thickness	56.10%	57.00%	42.90%	NS
	5	Alveolar ridge resorption	47.20%	46.50%	57.10%	NS
	6	Oral Hygiene	89.70%	90.00%	85.70%	NS
	7	Periodontal Inflammation	92.50%	93.00%	85.70%	NS
Economic domain	1	Indirect patient costs	36.80%	39.40%	0.0%	0.041
	2	Time efficiency	45.30%	46.50%	28.60%	NS
	3	Cost of treatment	55.70%	56.60%	42.90%	NS
	4	Treatment duration	42.50%	43.40%	28.60%	NS
	5	Treatment time	36.80%	38.40%	14.30%	NS
	6	Economic: total cost of recurrence (Added 2 round)	55.20%	57.10%	28,60%	0.043

Results of this second round were as follows:

- Dental professionals did not score a single outcome reaching 100% agreement of the minimum agreement threshold. Still, those with mean values ≥8 were (Figure 3) implant success, implant failure, implant loss, prosthetic success, post-operative patient complications, peri-implantitis (implant level), peri-implant health/stability (implant level), suppuration, radiographic peri-implant bone level changes, peri-implant health (patient level), peri-implantitis (patient level), patient's oral health quality of life, patient's overall satisfaction, prosthesis design for oral hygiene, oral hygiene and periodontal inflammation.
- Industry-related experts unanimously assigned the maximum score to 14 (18%) outcomes: implant success, implant fracture, prosthetic survival, prosthetic success, framework fracture, post-surgical complications, post-operative patient complications, adverse device events, mucositis (implant level), peri-implantitis (implant level), peri-implant health stability (implant level), peri-implant health (patient level), mucositis (patient level) and peri-implantitis (patient level).
- The PWLE group scored 22 (out of 34) outcomes above the minimum agreement threshold (Table 2), and 4 were unanimously assigned the maximum percentage: chewing power, comfort, complications and professional experience.

In round 3/final Delphi, experts ($N = 19$) and PWLE representatives ($N = 7$) reviewed the results and further analysed the 61 (out of 111) outcomes that exceeded the established agreement threshold. This discussion led to the establishment of a core set of outcomes by using three filters. The first filter removed outcomes that did not

TABLE 2 Candidate outcomes scored by PWLE (people with lived experience) reaching the minimum agreement threshold (at ≥70% scores of 7–9 and ≤15% scorings of 1–3).

Domain	*n*	Outcome	Consensus achieved PWLE
Patient information before treatment	1	Long-term success	93.3%
	2	Chewing power	100%
	3	Comfort	100%
	4	Adaptation	86.7%
	5	Decision making	80%
	6	Information methods	60%
	7	Adequacy of information	78.6%
	8	Complications	100%
Implant treatment	1	Hygiene time	58.8%
	2	Duration of planning and treatment	58.8%
	3	Treatment time	64.7%
	4	Implant hygiene education	82.4%
	5	Food impaction	64.7%
	6	Patient-reported outcomes of treatment success	64.7%
	7	Patient-reported outcomes to predict success	52.9%
	8	Post-operative care education	82.4%
	9	Oral hygiene education	76.5%
	10	Anxiety	41.2%
	11	Pain	64.7%
	12	Patient-reported outcomes of temporary phase	52.9%
	13	Professional experience	100%
Living with dental implants	1	Treatment cost	70.6%
	2	Professional training methods for maintenance	88.2%
	3	Professional training methods for complications	88.2%
	4	Motivation for oral care	88.2%
	5	Oral hygiene effectiveness	88.2%
	6	Maintenance frequency	70.6%
	7	Extracted tooth status	56.3%
	8	Success of implant failure re-treatment	93.8%
Having dental implants, your most important outcome	1	Technical complications	87.5%
	2	Affordability	70.6%
Other outcomes	1	Overall function	94.10%
	2	Overall appearance	82.4%
	3	Setting	58.8%

receive a score of 7–9 by at least 70% of respondents, or that received a score of 1–3 from 15% of respondents in the second Delphi questionnaire. 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. The participants in this third round were then 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, which resulted in 13 essential outcomes organized into nine categories (function, surgical complications, loss of tissue health, adverse device events, implant/restoration survival/success, implant loss/failure/fracture, quality of life, overall satisfaction and effort for maintenance) (Figure 5). These essential outcomes represented the final core set list from the Delphi project, which will be further used for the ID-COSM initiative's next phase, aligned with the theoretical framework developed by the OMERACT project.

4 | DISCUSSION

The ID-COSM initiative was developed with the aim of achieving agreement on a core set of essential outcomes for implementation in future clinical trials in implant dentistry. The Delphi process agreed upon 13 outcome areas that were considered essential to capture implant dentistry's benefits and harms. The list comprises the expected functional benefits of implant dentistry, the associated morbidity and adverse device events, the impact on quality of life and patient satisfaction, as well as long-term performance and loss of peri-implant tissue health. This list includes areas that both professional and patient-reported outcomes can capture. Its complexity and broad scope reflect the difficulty of capturing the benefits and harms of implant dentistry with fewer parameters. Nevertheless, this list can be used for the final process of the ID-COSM initiative according to the OMERACT methodology and can be the basis for the final consensus development phase of the ID-COSM project (Tonetti et al. 2023).

The development and application of core outcome sets (COS) are expanding across all areas of health research (Kirkham et al., 2016), and the interest in reporting and adopting a more structured and standardized approach towards COS is increasing, emphasizing the need for adequately reporting the methods to achieve the COS, and for a greater public engagement (Gorst et al., 2016). Among the tested methods to achieve agreement on selecting a potential

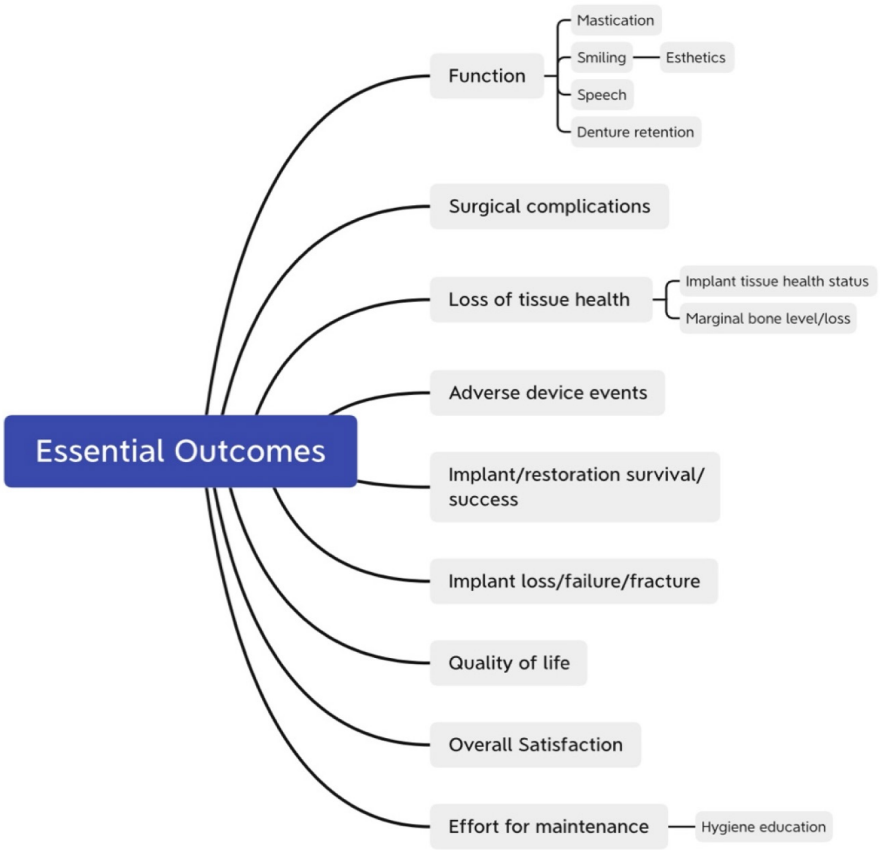

FIGURE 5 Mind map of the essential outcome areas identified by the Delphi process.

core set of outcomes, the Delphi methodology has become popular, even though Delphi-based studies must be of sufficient quality to be considered valid (Sinha et al., 2011). In fact, Delphi methodology is progressively spreading in scientific publications in the different medical specialities (Carter et al., 2021; Millward et al., 2022; Mitchell et al., 2022; Munblit et al., 2022; Prorok et al., 2022; Rosala-Hallas et al., 2022) and also in dentistry (Alarcón, Sanz-Sánchez, López-Pacheco, et al., 2021; Alarcón, Sanz-Sánchez, Shibli, et al., 2021; Sanz et al., 2019). This is partially due to the ability of the Delphi method to distil relevant problems where knowledge is unclear, and by applying a structured process of gathering information from experts and other stakeholders through subjective-intuitive foresight thinking, a final agreement is reached.

In the present study, we have applied the Core Outcome Set-STAndards (COS-STAD) guideline to drive consensus by first undertaking a Delphi-based project to agree on a set of outcome areas that could be further discussed for the final COS development. As suggested by the COMET initiative, this process has been based on three key processes (scope, stakeholders and consensus gathering) (Kirkham et al., 2017).

The quality of Delphi studies depends to a large extent on the composition of the panel, underlining the importance of including a sample of experts representing diverse disciplines and reflecting the target population (Prinsen et al., 2016). In the present study, we have included as stakeholders not only professional experts (dental and industry) but also patients with experience in implant therapy (PWLE) who were able to freely express their views without dominant opinions (Williamson et al., 2012). The final sample who completed round 2 of the Delphi questionnaire represented stakeholders, including 100 dental experts from broad international settings across different disciplines, seven industry-related experts and 17 PWLE, with a retention rate of 100% (Tugwell et al., 2007). All participants signed a consent form and a declaration of potential conflict of interest, which ensured the necessary transparency for a quality Delphi study (Williamson et al., 2012). The inclusion of industry-related experts as stakeholders in this project aimed to include their different perspectives, bring additional insight into regulatory requirements and best industry practices and raise their specific perspective because dental implant companies are essential in research and development in implant dentistry. Even though this stakeholder group filled and scored the same questions as dental professionals, the separate data analysis allowed for identifying these potentially different perspectives and the likely different weighting when selecting the COS outcomes for future studies in implant dentistry. On the other hand, the PWLE group revealed their own perspective and opinion, thus providing a more global perspective to the COS development (Sawinski et al., 2022).

The strengths of the present study include the rigorous and inclusive selection process of candidate outcomes, the broad multi-stakeholder constituency of the participants and the rigorous methodology adopted in the design, execution and analysis of the Delphi process.

Although the outcomes that surpassed the pre-determined level of agreement by dental professionals highly correlated with those derived from the systematic reviews (Table 1), when compared with the other stakeholders, industry-related experts gave

a significantly higher weight for the following outcomes: implant fracture, framework fracture, post-surgical complications and adverse device events, which clearly reflects their interest in the product, rather than on its performance. This result is in line with other publications highlighting the interest from the industry in developing good-quality products for a highly productive environment (Cook et al., 2014; Shimura et al., 2014a, 2014b). Similarly, we included PWLE as one of the key stakeholders in this study to provide insight into outcomes not previously identified by professional experts or, in some cases, were in conflict with professional views and recommendations (Bruera et al., 2021). As an example, the patients´ attitudes and experiences changed the recommendation on disease-modifying anti-rheumatic drugs (DMARDS) in the treatment of rheumatoid arthritis (RA) and spondylarthritis (SpA) because the impact in their quality of life outweighed their well-proven biological activity (Kelly et al., 2018).

In this study, the PWLE group scored the maximum consensus (100%) for chewing power, comfort, absence of complications and professional experience, which were eventually included as essential outcome areas.

5 | CONCLUSION

This study described the Delphi process of the ID-COSM initiative project aimed to identify essential outcomes for future research on implant dentistry. The use of Delphi methodology through a three-round multi-stakeholder process achieved high levels of agreement and selected 13 essential outcome areas for consideration in the final ID-COSM consensus process.

AUTHOR CONTRIBUTIONS

Maurizio S. Tonetti and Mariano Sanz co-chaired the process and conceived the Delphi project. Ana Carrillo de Albornoz and Mariano Sanz designed the questionnaires and coordinated the Delphi project and drafting of the manuscript. Conchita Martín carried out the data analysis and participated in the drafting of the manuscript. Ian Needleman coordinated the PWLE focus groups and participated in the selection of outcomes from this stakeholder group. All co-authors participated in all stages of the Delphi project and critically reviewed the manuscript.

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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, which are 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, which are unrelated to the present work. Ian Needleman is an Editor with Cochrane Oral Health. Ana Carrillo de Albornoz and Conchita Martin declare no conflict of interest related to this study.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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