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CONSENSUS REPORT

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Fabrication, workflow and delivery of reconstruction: Summary and consensus statements of group 4. The 6th EAO Consensus Conference 2021

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Abstract

Objectives: To report assessments of four systematic reviews (SRs) on (i) clinical outcomes of all-ceramic implant-supported crowns (iSCs), (ii) production time, effectiveness, and costs of computer-assisted manufacturing (CAM), (iii) computer-assisted implant planning and surgery (CAIPS) time and costs, and (iv) patient-reported outcome measures (PROMS).

Material and Methods: An author group consisting of experienced clinicians and content experts discussed and evaluated the SRs and formulated consensus on the main findings, statements, clinical recommendations, and need for future research.

Results: All four SRs were conducted and reported according to PRISMA and detailed comprehensive search strategies in at least three bibliometric databases and hand searching. The search strategies were deemed reproducible. Variation was noted regarding language restrictions and inclusion of grey literature, but the search comprehensiveness appeared persuasive. The SRs included bias risk assessments of the primary studies, and their study methodology impacted the interpretations of the extracted data.

Conclusions: (i) There is limited evidence (49 NRCT) showing that veneered and monolithic all-ceramic iSCs have excellent outcomes observed up to 3 years. (ii) There is no evidence evaluating production time and effectiveness comparing subtractive and additive CAM of implant models, abutments and crowns. (iii) There is limited evidence (4 RCT) that CAIPS involves more time and costs when considering the entire workflow and for diagnostics, manufacturing, and insertion of the restoration. Time seems to be the decisive factor for higher costs. (iv) Patients' comfort increases when optical compared to conventional impressions are used for fabricating iSCs and short-span FPDs (2 RCT, 5 NRCT).

KEYWORDS
clinical research, clinical trials, prosthodontics

1 | A SYSTEMATIC REVIEW AND META-ANALYSIS EVALUATING THE SURVIVAL, THE FAILURE AND THE COMPLICATION RATES OF VENEERED AND MONOLITHIC ALL-CERAMIC IMPLANT SUPPORTED SINGLE CROWNS

1.1 | Major findings from the review (**Pjetursson et al., 2021**)

- The review identified 49 prospective clinical studies of moderate-to-high methodological quality reporting on 57 patient cohorts totalling 2,160 all-ceramic implant-supported single crowns (iSCs). The included studies were conducted in an institutional environment and private practice settings. Most of the studies were published recently, with 2018 (or 2019) as a median publication year.
- Meta-analyses estimated a 3-year survival rate of veneered reinforced glass-ceramic iSCs of 97.6% (95% CI: 87.0%–99.6%). Estimated 3-year survival rates for other materials and designs were: 97.0% (95%CI: 94.0%–98.5%) for monolithic reinforced glass-ceramic iSCs, 96.9% (95%CI: 93.4%–98.6%) for veneered densely sintered alumina iSCs, 96.3% (95%CI: 93.9%–97.7%) for veneered zirconia iSCs, 96.1% (95%CI: 93.4%–97.8%) for monolithic zirconia iSCs and 36.3% (95%CI: 0.04%–87.7%) for resin nano-ceramic iSCs. Apart fromiSCs made from resin nano-ceramic ($p < .0001$), the differences in estimated survival rates between the materials did not reach statistical significance.
- The annual complication rate of 3.9% for the veneered all-ceramic iSCs tended to be higher than the annual complication rate of 1.8% for monolithic all-ceramic iSCs ($p = .06$).
- The annual surface chipping rate for veneered all-ceramic iSCs (1.65%) was higher than that for monolithic all-ceramic iSCs (0.39%). Meta-analysis based on multivariable Poisson regression indicated that the difference was statistically significant ($p = .01$). The location of the all-ceramic iSC in the dental arch, anterior versus. posterior, did not significantly influence the survival rate and the annual chipping rate.
- The handling of veneered and monolithic all-ceramic restorations is technique sensitive, and the steps of the manufacturing procedure must be followed meticulously. Moreover, the cementation protocol significantly influences the clinical outcomes.

1.2 | Consensus statements

- Monolithic and veneered all-ceramic implant-supported crowns (iSCs) show comparable short-term (3 years) survival rates (96.1%–97.6%)
- Monolithic iSCs show lower overall complication rates compared to veneered all-ceramic iSCs.
- Monolithic iSCs show a significantly lower rate of surface ceramic chipping compared to veneered all-ceramic iSCs.
- Monolithic reinforced glass-ceramics iSCs and monolithic zirconia iSCs perform equally well concerning survival and complication rates.

- Resin nano-ceramic iSCs show low survival rates, mainly due to fractures and retention problems.
- The knowledge and precise application of appropriate adhesive cementation protocols following manufacturer recommendations are crucial for the successful outcome of veneered and monolithic iSCs.

1.3 | Clinical recommendations

- Both monolithic and veneered all-ceramic (reinforced glass-ceramics and zirconia) implant-supported single crowns (iSCs) can be recommended.
- Monolithic iSCs or iSCs with minimal application of aesthetic veneering ceramic in non-functional areas shall be preferred to veneered iSCs, to reduce the risk of superficial ceramic chipping.
- Resin nano-ceramic cannot be recommended for iSCs.
- Thorough knowledge and the precise application of recommended adhesive cementation protocols, both extraoral and intraoral cementation, are crucial for the outcome of all-ceramic iSCs.

1.4 | Recommendations for future research

- Long-term cohort studies on restoration materials should be prospective and have complete follow-up information preferentially with a similar length of follow-up for all study participants. Data should be reported on well-defined periods for the entire cohort, especially for the different years after the restoration.
- Randomized comparative studies of different types of veneered and monolithic ceramics (lithium disilicate, zirconia, and resin-nano-ceramic) need to be performed to obtain outcomes after medium- to long-term follow-up.
- Reports on clinical performance must provide detailed information on a set of core variables and outcomes:
  - The restorative materials used, for example, types and generation of zirconia.
  - The presence or absence of technical complications should be reported in detail, preferably in a standardized way, using established clinical indices and ratings.
  - The design of the implant abutments and crown/abutment screw channels.
  - The composition and materials of the restoration (veneered, micro-veneered or monolithic) should be reported in detail.
  - Fractures of ceramic materials should be detailed and explicitly stated if the fracture is catastrophic, leading to the loss of the crown.
  - Chipping of the ceramic material should clearly be described as either: (a) minor chipping—polishable; (b) medium chipping—repairable; (c) major chipping—non-repairable or non-acceptable by the patient
  - The position of the ceramic fracture/chippings should be reported with characteristics of the occlusion and function.

2 | PRODUCTION TIME, EFFECTIVENESS AND COSTS OF ADDITIVE AND SUBTRACTIVE COMPUTER-ASSISTED MANUFACTURING (CAM) OF IMPLANT PROSTHESES - A SYSTEMATIC REVIEW

2.1 | Major findings from the review (**Mühlemann et al., 2021**)

- No clinical trials of adequate scientific quality were identified evaluating efficiency, effectiveness, and costs of digital workflows comparing subtractive-CAM and additive-CAM. Nine clinical studies were included reporting on subtractive CAM (s-CAM; 8 studies) and one study on additive CAM (a-CAM; 1 study) applied for the manufacturing of implant-supported reconstructions.
- When single implant crowns were manufactured, production time, effectiveness, and costs are thoroughly documented for digital workflows involving subtractive-CAM.
- Production time and effectiveness substantially depended on the type of restoration and the CAD–CAM systems involved (chairside, laboratory, or outsourced).
- Production time in a digital workflow applying subtractive-CAM depended on various reports and not yet investigated factors such as operator's knowledge and experience.
- When looking at laboratory workflows, monolithic CAD–CAM implant crowns required less chairside (51%) and laboratory adjustments (11%) compared to veneered CAD–CAM crowns (chairside 93%, laboratory 19%).
- No clinical trials of adequate scientific quality exist investigating production time in a digital workflow applying additive-CAM to manufacture fixed and removable implant-supported reconstructions.
- One clinical trial reported an implant bar's effectiveness in retaining a maxillary overdenture manufactured in an additive-CAM workflow.

2.2 | Consensus statements

- For both additive-CAM and subtractive-CAM, production time is affected by (i) the location of CAD and CAM (chairside, laboratory, and outsourced), (ii) the applied software/hardware systems, and (iii) the need for customization (abutment, veneering, and staining) and post-processing.
- Post-processing CAM products is a time-consuming process and depends on the CAM technology applied and the restoration materials processed.
- The development of materials to be processed through additive-CAM and successfully applied in implant prosthetics is still in its early phase.

2.3 | Clinical recommendations

- To reduce the need for chairside adjustments of monolithic crowns produced in a digital workflow, outsourcing to subtractive-CAM is advised.
- For the use of additive-CAM, no clinical recommendations can be provided, as no scientific evidence exists on production, effectiveness, and costs.
- The less manual post-manufacturing is expected, the better CAM procedures are suitable for the manufacturing of reconstructions.

2.4 | Recommendations for future research

- Clinical studies investigating efficiency and effectiveness should compare the use of additive versus subtractive manufacturing of fixed and removable implant-supported reconstructions and specify details on the prosthetic and auxiliary components as well as the materials processed.
- When the time efficiency and effectiveness of CAM technologies are investigated, methods of calibration should be reported.
- Time efficiency studies should report on manufacturing and delivery time.
- At delivery, effectiveness should be reported by (a) the number of adjustments the restoration needed, (b) the type of adjustments, and (c) the time required for each of these.
- Additive manufacturing workflows should specify the applied additive technology, the individual settings (e.g., layer thickness and printing direction) and the processed materials.
- For additive CAM-technologies, the operation time for preparation (e.g., the addition of support structures and operating nesting software) and post-processing (e.g., debedding, sintering/crystallization, cleaning, curing, and surface treatments) should be documented.

3 | TIME AND COSTS RELATED TO COMPUTER-ASSISTED VERSUS NON-COMPUTER-ASSISTED IMPLANT PLANNING AND SURGERY - A SYSTEMATIC REVIEW

3.1 | Major findings from the review (**Keul et al., 2021**)

- Scientific evidence of the time and cost involved with computer-assisted implant planning and surgery (CAIPS) protocols versus non-computer-assisted implant surgery protocols is rare, and data are reported heterogenetic. Only two RCTs report on duration and costs as the primary outcome, two as secondary outcomes.
- The comparison of time and costs within studies shows that CAIPS diagnostic and planning procedures take more time (3%-45%) and involve higher costs (58%–73%). Contradictory findings are reported on the time and costs involved with the implant surgery procedure itself.
- When evaluating the entire workflow (diagnostics, implant surgery, the manufacturing of the prosthetic parts and insertion of the final implant restoration), the costs involved are higher (8%–11%) for computer-assisted implant surgery protocols.
- When evaluating the entire workflow (diagnostics, implant surgery, the manufacturing of the prosthetic parts and insertion of the final implant restoration), the time involved is reported to be either longer (9%) or shorter (39%) when computer-assisted implant surgery protocols are applied.
- This review focused only on costs and time involved with the procedures, while clinical outcomes and other factors that we perceive as important in everyday practice were not in focus here. It should be recognized that the evidence basis is weak for formulating consensus statements and clinical recommendations regarding economic aspects.

3.2 | Consensus statements

From the everyday clinical perspective, the time and cost parameters are often decisive for implementing new technologies in the clinical routine. When evaluating the economic aspects like time and costs involved with computer-assisted implant planning and surgery (CAIPS) versus non-computer-assisted implant planning and surgery (non-CAIPS), the entire procedure workflow (diagnostics, planning, surgery and prosthetic restoration) needs to be considered.

Because operating costs are the driving economic factors in the implant dentistry practice, the time involved with the procedures seems to be the decisive factor for economic considerations.

3.3 | Clinical recommendations

3.3.1 | What is the efficiency regarding diagnostics, planning and surgical time when following a computer-assisted implant planning and surgery protocol?

The diagnostics and planning when following computer-assisted implant planning and surgery are higher than in non-computer-assisted procedures concerning costs and time. Based on the analysed data, no conclusions can be drawn regarding the time and costs involved with the surgical procedure itself.

3.3.2 | How do economic factors compare when following a computer-assisted implant planning and surgery protocol instead of a non-computer-assisted protocol

Because operating costs are the driving economic factor in the implant dentistry practice, material costs (including hardware and

software) and the time involved with different procedure steps need to be taken into account. When balancing economic factors against implant placement accuracy reported in other systematic reviews done by the EAO on the subject, computer-assisted implant procedures are esteemed to lead to more precise implant positioning.

3.3.3 | When considering the total workflow (implant planning, surgery and prosthetic rehabilitation) and the time and costs involved in the treatment, is the computer-assisted implant planning and surgery approach preferable?

Clinicians should consider weighing the additional time and costs against the expected improvement in the precision of position when placing multiple implants. The costs involved with computer-assisted implant surgery become less per implant the more implants are simultaneously placed, and the costs and time involved with the workflow become less per occlusal unit.

3.3.4 | How can clinicians keep the overview over different digital concepts and workflows in implant dentistry?

- Terminology regarding digital workflows in implant dentistry is confusing. We suggest the following terminology:
- Concerning computer-assisted implant planning and surgery, the following steps are included: (1) implant planning software is applied, (2) implant positioning is determined by prosthetic and 3D radiological information, and (3) the planned osteotomy position is transferred to a dynamic or static implant surgery system. In a static implant surgery system, a surgical stent guides the implant drill into the predetermined position (pilot-guided and fully-guided); in some clinical workflows, the implant can also be placed through the surgical stent.

3.4 | Recommendations for future research

- The definition of computer-assisted implant planning and surgery (CAIPS) is not always apparent in the literature. Future reporting on those procedures should precisely describe the full CAIPS protocol, including the diagnostics, planning, surgery, and prosthetic restoration phases.
- Time recording should be reported in minutes recorded (by a third party) for every step in the treatment protocol. The start and endpoint should be clearly defined.
- All costs should be calculated in absolute numbers and recorded for every step in the treatment protocol.
- General costs, for example, stated as costs calculated by the dental laboratory should be specified in time and currency.
- Randomized trials analysing the time and costs of computer-assisted implant planning and surgery should also include patient-reported outcomes and clinician-related outcomes.

4 | PATIENT-REPORTED OUTCOME MEASURES (PROMS) OF IMPLANT-SUPPORTED RECONSTRUCTIONS USING DIGITAL WORKFLOWS. A SYSTEMATIC REVIEW AND META-ANALYSIS

4.1 | Major findings from the review (**Bishti et al., 2021**)

- Among 1,062 titles identified, 14 studies were included in the systematic review. Seven studies were only analysed qualitatively due to heterogeneity, while the remaining seven studies were eligible for meta-analysis.
- The majority of clinical studies reporting on PROMs have been published during the last ten years and are limited to implant-supported single crowns and short-span fixed prostheses in the posterior region of the jaws. The following PROMs could be distinguished: pain during implant surgery, the number of analgesics consumed post-operatively, post-operative morbidity including swelling and trismus, satisfaction with the implant surgical procedure, impression time, impression taste, pain/discomfort and anxiety during impression taking, nausea or gag reflex during the impression, convenience, function, aesthetics, and general satisfaction with the final restoration.
- Flapless surgery following computer-assisted surgery workflows was associated with less pain than different implant surgical procedures (conventional and computer-assisted) when raising a flap.
- For impressions procedures, statistically significant differences in taste, anxiety, nausea, pain, shortness of breath, and discomfort favoured optical impressions ($p \leq .003$, random-effects model). However, no significant difference in the subjective perception of the duration of an optical or conventional impression could be reported ($p = .05$, random-effects model).
- Patients with implant-supported single crowns in the posterior area reported no difference between veneered and monolithic posterior restorations ($p \geq .05$, random-effects model) for aesthetics, oral functions and general satisfaction.

4.2 | Consensus statements

- Papers reporting PROMs on implant-supported fixed restorations have applied various and frequently non-validated evaluation tools, which impedes direct comparison of study outcomes.
- Optical impression procedures are rated more favourably than conventional impressions (less anxiety, nausea, pain, discomfort and a better taste) (meta-analysis including 2 RCTs, four prospective and one retrospective studies).

- Studies reporting aesthetics, oral function and general satisfaction showed no influence by conventional or different digital manufacturing workflows for the fabrication of posterior implant-supported single crowns (meta-analysis including 2 RCTs, one prospective study)
- Less invasive implant surgical procedures that do not include the elevation of a flap are associated with favourable PROMs (lower pain during surgery, post-operative use of pain killers, and swelling and satisfaction with the surgical procedure) compared to raising a flap (no meta-analysis; the statement is based on 2 RCTs, three prospective and one retrospective studies).

4.3 | Clinical recommendations

- Optical impressions are recommended for implant-supported single crowns and short-span FPDs to increase the patient's comfort.
- Irrespective of the type of impression, clinicians need to ensure that the associated laboratory manufacturing workflow leads to clinically acceptable accuracy, function, aesthetics and long-term stability of the implant-supported restoration.
- Based on PROMs, no recommendations can be formulated concerning the final implant-supported restoration resulting from conventional or different digital workflows.

4.4 | Recommendations for future research

- Standard questionnaires for PROMs, similar to the Oral Health Impact Profile (OHIP) used in the field of removable restorations, should be developed and validated in implant dentistry.
- RCTs using standardized and validated PROM evaluation tools are needed for comparing conventional and different digital workflows in various clinical situations.
- Assessment of patient expectations before treatment versus evaluation of PROMs post-treatment should be encouraged.
- Clinician-reported outcome measurements ("CROMs") standard questionnaires should be developed and validated for use in the field of implant dentistry.

CONFLICT OF INTEREST

None of the authors has any conflict of interest or material interests in products, equipment, publications, or services from any mentioned commercial producers.

AUTHOR CONTRIBUTION

Asbjørn Jokstad: Writing-original draft (lead); Writing-review & editing (lead). **Bjarni Elvar E. Pjetursson:** Writing-review & editing (supporting). **Sven Mühlemann:** Writing-review & editing (supporting). **Daniel Wismeijer:** Writing-review & editing (supporting). **Stefan Wolfart:** Writing-review & editing (supporting).

ETHICS APPROVAL

Ethics approval was not required for this consensus paper.

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