

Static computer-aided implant surgery (s-CAIS) analysing patient-reported outcome measures (PROMs), economics and surgical complications: A systematic review

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Abstract

Objective: To systematically evaluate the scientific literature for patient-reported outcome measures (PROMs) in static computer-aided implant surgery (s-CAIS).

Methods: A PICO strategy was executed using an electronic (MEDLINE, EMBASE, CENTRAL), plus manual search up to 15-06-2017 focusing on clinical studies investigating s-CAIS with regard to patients' pain & discomfort, economics and/or intra-operative complications. Search strategy was assembled from multiple conjunctions of MeSH Terms and unspecific free-text words. Assessment of risk of bias in selected studies was made at a "trial level" applying the Cochrane Collaboration Tool and the Newcastle–Ottawa Assessment Scale, respectively.

Results: The systematic search identified 112 titles. Seventy abstracts were screened, and 14 full texts were included for analysis. A total of 484 patients were treated with s-CAIS for placement of 2,510 implants. Due to the heterogeneity of the included studies, meta-analyses could not be performed.

Conclusions: The number of identified studies investigating s-CAIS for PROMs was low. Scientifically proven recommendations for clinical routine cannot be given at this time; however, the number of clinical complications with s-CAIS seems to be negligible and comparable to conventional implant surgery. s-CAIS may offer a beneficial treatment option in edentulous cases if a flapless approach is applicable. Nevertheless, the economic effects in terms of time efficiency and treatment costs are unclear. Clinical investigations with well-designed RCTs investigating PROMs with standardized parameters are compellingly necessary for the field of s-CAIS.

KEYWORDS

static computer-aided implant surgery (s-CAIS), guided surgery, patient-reported outcome measures, systematic review, virtual implant planning

1 | INTRODUCTION

A restorative-oriented treatment concept is key for success in implant therapy with predictable outcomes in an interdisciplinary approach that manages the competences of prosthodontics,

periodontology, oral surgery, radiology, and dental technology. Optimal 3D implant positioning is mandatory to achieve these goals (Chen & Buser, 2014).

Conventional freehand implant placement is challenged by difficult interpretation and secondary transfer of 2D radiographic

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diagnostics into the 3D clinical situation plus a limited visualization of the operative field of interest in general (Kourtis, Kokkinos & Roussou, 2014). However, computer-assisted workflows with 3D imaging and virtual simulations offer powerful instruments for treatment planning, further surgical placement and prosthetic rehabilitation with respect to both anatomic as well as restorative parameters. A thorough pre-operative planning will free the clinician's mind allowing more time to concentrate on the patient and the tissue handling (Marchack & Chew, 2015).

Today, several systems are available for the translation of a virtually planned implant scenario to the clinical situation. For static computer-aided implant surgery (s-CAIS), static surgical implant guides are currently most often applied—in contrast to dynamic systems for navigation (Vercruyssen, Fortin, Widmann, Jacobs & Quirynen, 2014).

s-CAIS involves either a guided pilot drilling approach or a fully guided protocol for the entire drilling sequence regularly including implant placement through the surgical guide. The indications range from single-unit rehabilitation concepts to complete edentulous patients for mono- or bimaxillary treatment. The surgical implant guides can be distinguished according to their functional design, whether tooth-retained, mucosa-, or bone-supported or in any type of combination. In addition, the surgical placement can be performed completely flapless with soft tissue punches, or open flap varying from small crestal incisions up to the preparation of a full-thickness mucoperiosteal flap with complete exposure of the alveolar bone (Laleman et al., 2016).

Computer-aided methods realize the 3D visualization of the implant recipient site including the neighboring anatomical structures. Prior to any invasive treatment, the clinician has the opportunity to gain insights into the patient's individual situation considering prosthetic and surgical requirements. Complex and invasive treatment steps can be anticipated in advance for a predictable and safe outcome (Pozzi, Polizzi & Moy, 2016).

Recent systematic reviews focused mainly on accuracy and precision for static guided implant surgery with a mean overall inaccuracy of the final implant 3D position of 1.1 mm at the entry point, 1.4 mm at the implant apex, and an average angular deviation of 3.9 degrees, respectively (Jung et al., 2009; Schneider, Marquardt, Zwahlen & Jung, 2009; Tahmaseb, Wismeijer, Coucke & Derksen, 2014; Vercruyssen, Hultin et al., 2014). Besides these technical analyses, information on patients' convenience, surgical and/or prosthetic complications, time efficiency, and cost-benefit-analyses, as so-called reported outcome measures (PROMs), are scarce.

Therefore, the aim of this systematic review was to analyse the scientific literature to evaluate PROMs, economics, and intra-operative complications of s-CAIS compared with conventional implant placement.

2 | MATERIAL AND METHODS

This systematic review was conducted in accordance with the guidelines of Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA; Moher, Liberati, Tetzlaff & Altman, 2009).

2.1 | Search strategy

Based on the PICO criteria, a search strategy was developed and executed using an electronic search. The PICO question was formulated as follows: "In patients receiving implants, is static computer-aided implant surgery (s-CAIS) beneficial in terms of patient-reported outcomes, economics and surgical complications?"

Any virtual implant planning system using a 3D software application in combination with implant placement by means of a CAD/CAM-processed surgical guide was defined as s-CAIS. Implant placement either freehand or assisted by a laboratory manually produced template was defined as conventional implant surgery.

A systematic electronic search of PubMed MEDLINE, EMBASE, CENTRAL, including the gray-literature of Google Scholar, up to 2017-06-15 was performed for English-language publications in dental journals. Search syntax was categorized in population, intervention, comparison, and outcome; each category was assembled from a combination of Medical Subject Headings [MeSH Terms] as well as free-text words in simple or multiple conjunctions:

(((((dental implants [MeSH Terms]) OR (endosseous implant*) OR (dental implant*)))) OR (((dental implantation, endosseous [MeSH Terms]) OR (implant placement*) OR (implant insertion*) OR (implant surgery*)))) AND (((computer-aided surgery [MeSH Terms]) OR (computer-assisted surgery [MeSH Terms])) OR ((guided surgery OR guided implant placement OR computer-guided OR ((drill guide OR template) AND computer) OR surgical template OR simplant OR co-DiagnostiX OR SMOP OR nobel guide)))) AND (((dental implantation, endosseous [MeSH Terms]) OR (implant placement*) OR (implant insertion*) OR (implant surgery*)))) AND (((patient outcome assessment [MeSH Terms]) OR (patient-centered outcomes [MeSH Terms]) OR (satisfaction*))) OR (((economics [MeSH Terms]) OR (costs, cost analysis [MeSH Terms]) OR (efficiency [MeSH Terms])))) OR (((complications [MeSH Terms]) OR (adverse event*) OR (safety*)))) [Figure 1].

Additional manual searches of the bibliographies of all full-text articles and related reviews, selected from the electronic search, were also performed. Furthermore, manual searching was conducted in the following journals:

Clinical Implant Dentistry & Related Research, Clinical Oral Implants Research, Dentomaxillofacial Radiology, European Journal of Oral Implantology, Implant Dentistry, International Journal of Oral & Maxillofacial Implants, Journal of Clinical Periodontology, Journal of Computerized Dentistry, Journal of Dental Research, Journal of Oral & Maxillofacial Surgery, Journal of Oral Implantology, Journal of Periodontal & Implant Science, and Journal of Periodontology.

2.2 | Inclusion/exclusion criteria

This review was based on reports from randomized controlled trials, prospective or retrospective cohort studies as well as case-control studies and case series retrieved by the systematic literature search outlined above.

Detailed inclusion criteria for study selection were as follows:

Population	Fully or partially edentulous patients treated with dental implants #1 – ((dental implants [MeSH Terms]) OR (endosseous implant*) OR (dental implant*))
Intervention	Implant planning using computer-aided software applications for surgical placement #2 – ((computer-aided surgery [MeSH Terms]) OR (computer-assisted surgery [MeSH Terms])) #3 – (guided surgery OR guided implant placement OR computer guided OR ((drill guide OR template) AND computer) OR surgical template OR simplant OR codiagnostix OR SMOP OR nobel guide)
Comparison	Conventional (non-computer-aided) treatment protocols #4 – ((dental implantation, endosseous [MeSH Terms]) OR (implant placement*) OR (implant insertion*) OR (implant surgery*))
Outcome	Patient-reported outcomes; economics, as (time-) efficiency & cost analysis; complications #5 – ((patient outcome assessment [MeSH Terms]) OR (patient-centered outcomes) OR (satisfaction*)) #6 – ((economics [MeSH Terms]) OR (costs, cost analysis [MeSH Terms]) OR (efficiency [MeSH Terms])) #7 – ((complications [MeSH Terms]) OR (adverse event*) OR (safety*))
Search combination	(#1 or #4) AND (#2 or #3) AND (#5 or #6 or #7)

FIGURE 1 Search strategy according to the focused PICO question

- Clinical trials only;
- Studies at all levels of evidence, except expert opinions;
- Case report(s) including at least 10 patients;
- Studies reporting on digital implant planning including the used systems (software, applications, techniques etc.) based on (cone beam) CT imaging for static guided implant surgery under consideration of the PROMs:
 - Discomfort and pain; and/or
 - Economics (in terms of time efficiency); and/or
 - Intra-operative complications (surgical and prosthetic).

In addition, explicit exclusion criteria were as follows:

- Animal studies;
- Insufficient information on defined outcome criteria;
- Absence of objective parameters;
- Multiple publications on the same patient population;
- No author response to inquiry email for data clarification;
- Zygoma, pterygoid, and/or orthodontic implant planning.

2.3 | Data extraction

Three reviewers independently screened (T.J., W.D., and S.K.) the retrieved titles and abstracts according to the defined outcomes.

Disagreements were resolved by discussion. Following this, abstracts of all agreed titles were obtained and screened again for meeting the inclusion criteria. The selected articles were then obtained in full texts. If any titles and abstracts did not provide sufficient information regarding the inclusion criteria, the full texts were obtained as well. Again, disagreements were resolved by discussion. Finally, the selection based on in-/exclusion was made for the full-text articles.

Data were extracted independently by the three reviewers using a data extraction form. Disagreement was resolved by discussion. Following information was collected for further analysis:

- Author(s), year of publication, trial design;
- Defined outcome(s);
- Number of included subjects and implants plus calculated ratio of implants per subject;
- Follow-up in months, patient dropout(s), and number of implant failures;
- Implant indication(s) and jaw localization;
- Implant system(s) and virtual implant planning software;
- Timing of implant placement;
- Flap design;
- Design of the implant guide(s) plus fabrication technique(s);
- Timing of prosthetic loading and type of restoration.

Included studies were divided into subgroups according to their defined outcomes:

(i) “pain & discomfort”; (ii) economics, in terms of “time efficiency”; as well as (iii) “intra-operative complications.”

The reported results of the studies were specified according to the defined outcomes on a patient level, and if feasible, a meta-analysis was conducted.

Assessment of risk of bias in individual studies was made at a “trial level” including random sequence generation, allocation concealment, blinding, completeness of outcome data, selective reporting, and other bias using the Cochrane Collaboration Tool (<http://ohg.cochrane.org>) for randomized controlled trials (RCTs). A judgment of risk of bias was assigned if one or more key domains had a high or unclear risk of bias. For non-randomized studies, the Newcastle–Ottawa Assessment Scale (http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp) was applied to evaluate the selection of the study groups, the comparability of the groups, and the ascertainment of either the outcome of interest.

3 | RESULTS

3.1 | Included studies

The systematic search was completed on 2017-06-15, and results are current as of this date (Figure 2). Of the 112 titles retrieved by

the search, 70 abstracts were further screened, and successively, 42 full texts identified. A total of 28 full texts were excluded from the final analysis (Annex I).

The reasons for exclusion were as follows:

- Not matching study outcome ($n = 10$);
- Case report(s) with <10 patients ($n = 6$);
- No clinical trial ($n = 5$);
- No virtual implant planning and/or static guided implant surgery ($n = 5$);
- Multiple publications reporting on duplicated patient data ($n = 2$).

Finally, 14 full texts were included for data extraction (Abad-Gallegos et al. 2011; Arisan et al. 2010; di Torresanto et al. 2014; Fortin et al. 2006; Komiyama et al. 2008; Marra et al. 2013; Meloni et al. 2010; Merli et al. 2008; Nikzad & Azari 2010; Nkenke et al. 2007; Pomares 2010; Pozzi et al. 2014; Sannino & Barlattani 2016; Vercruyssen et al. 2014; Annex II). Included studies were judged to be of sufficient quality considering the specific study design. Figure 3a,b displays assessments of the risk of bias for included studies (Figure 3a,b).

Detailed information of each study is tabularized for general data, implant-specific characteristics, surgical, and prosthetic treatment protocols including virtual planning, and defined outcomes in Tables 1–3. Publication dates ranged from 2006 to 2016. Study types were categorized in RCTs ($n = 4$), retrospective cohort studies ($n = 5$),

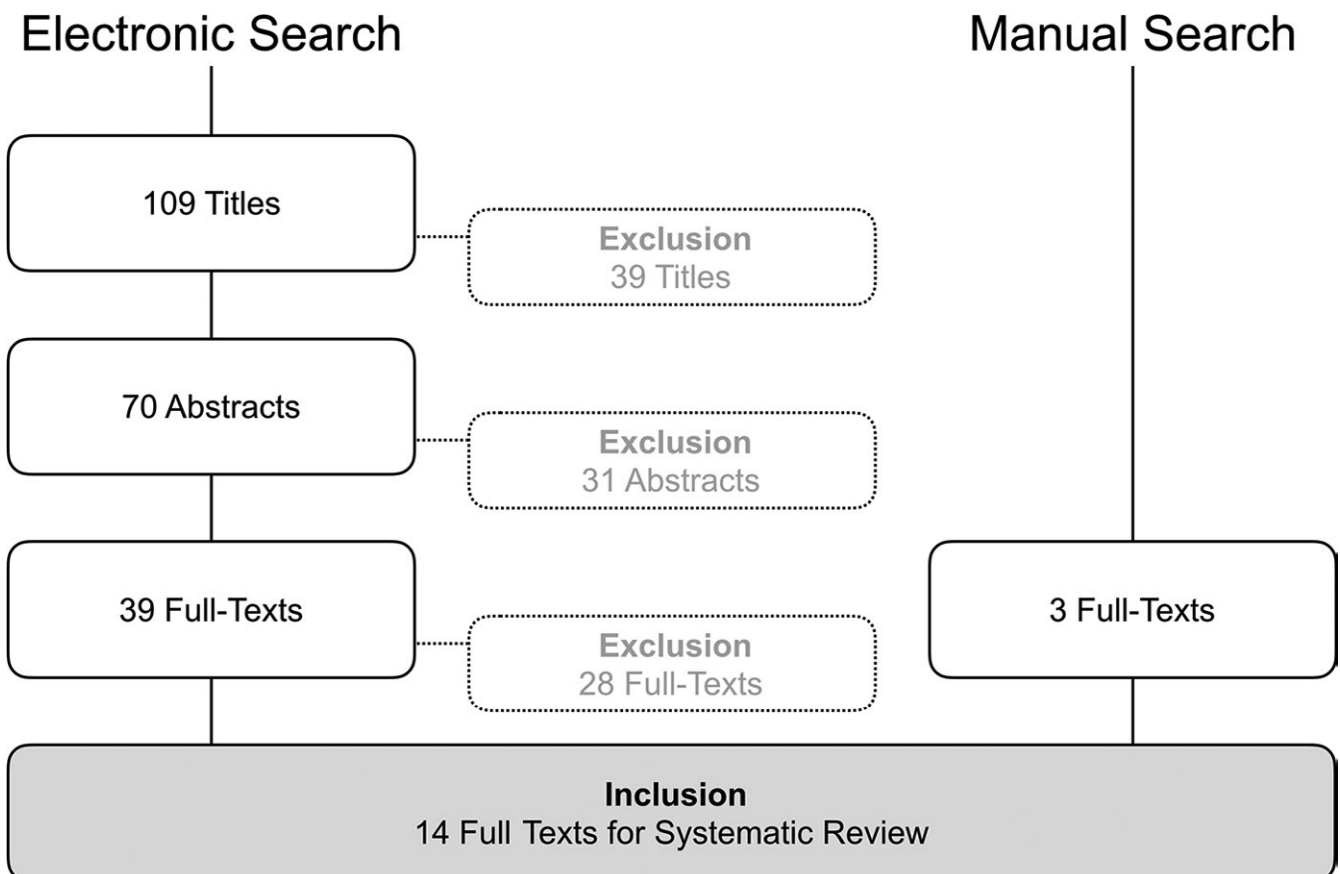
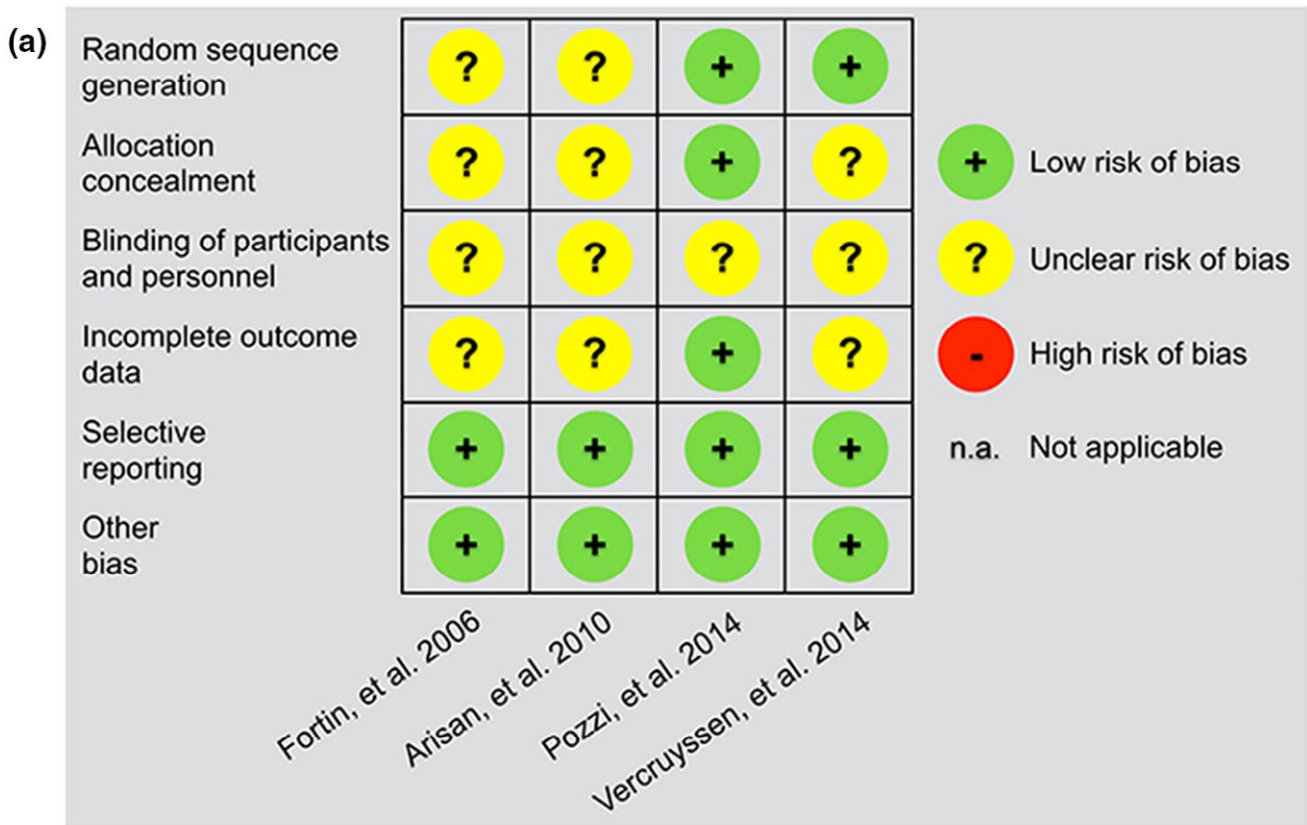


FIGURE 2 Flowchart of the systematic search results



(b)

	Selection [max. 4 stars]	Comparability [max. 2 stars]	Outcome [max. 4 stars]
Nkenke, et al. (2007)	★★★★	★	★★★
Komiyama, et al. (2008)	★★★★	—	★★
Merli, et al. (2008)	★★★★	—	★★
Meloni, et al. (2010)	★★★★	—	★★★
Nikzad & Azari (2010)	★★★★	—	★★
Pomares (2010)	★★★★	—	★★★
Abad-Gallegos, et al. (2011)	★★★★	—	★★
Marra, et al. (2013)	★★★★	—	★★★
di Torresanto, et al. (2014)	★★★★	—	★★
Sannino & Barlattani (2016)	★★★★	—	★★★

FIGURE 3 (a) Presentation of risk of bias evaluation for included RCTs according to the Cochrane Collaboration's tool (<http://ohg.cochrane.org>). (b) Presentation of risk of bias evaluation for included non-RCTs according to the Newcastle-Ottawa assessment scale (http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp)

prospective cohort studies ($n = 4$) and case series ($n = 1$). A total of 484 patients were treated with 2,510 dental implants resulting in a calculated ratio of 5.2 implants per patient. Six patient dropouts were reported, whereas five studies did not reveal any dropout information. Follow-up ranged from 0 days up to 44 months, in which 54 implants were lost (Table 1).

Nobel Clinician was the most often used implant planning software ($n = 5$), followed by Procera ($n = 4$), Simplant ($n = 2$), CADImplant, and Materialise ($n = 1$), respectively. Nine studies applied one single implant system, two studies multiple systems, and

three studies gave no specific information. Nobel Biocare was the most often applied implant system ($n = 7$). The design of the used implant guide varied from mucosa-supported ($n = 8$), combined mucosa- plus bone-supported ($n = 4$), to solely tooth-supported ($n = 1$); one study did not specify the guide design (Table 2).

Ten studies reported on treatment protocols for edentulous patients, three studies for both, edentulous and partially dentate patients, and one study for partially dentate patients. Most often studies reported on implants placed in both jaws ($n = 7$), followed by studies using s-CAIS only in the maxilla

TABLE 1 General data of the 14 included trials: study design, defined outcome(s), number of subjects, and implants as well as ratio of implants per patient, follow-up period, and patient dropouts

No.	Study (year)	Study design	Outcome(s)	No. subjects	No. implants/ controls	No. implants/ patient	Follow-up (months)	Patient dropouts
1.	Fortin et al. (2006)	RCT (2 arms)	Patient satisfaction (Surg)	30 (+30 controls)	80 (+72 controls)	2.7 (AVG) (+2.4 controls)	0.25	Not reported
2.	Nkenke et al. (2007)	Prospective case-control study	Patient satisfaction (Surg)	5 (+5 controls)	30 (+30 controls)	6 (+6 controls)	12	0
3.	Komiyama et al. (2008)	Prospective cohort study	Complications (Surg+Prosth)	29	176	6.1 (AVG)	44	Not reported
4.	Merli et al. (2008)	Case series	Patient satisfaction (Surg); Time efficiency (Surg+Prosth); Complications (Surg)	13	89	6.9 (AVG)	8	1
5.	Arisan et al. (2010)	RCT (3 arms)	Patient satisfaction (Surg); Time efficiency (Surg)	37 (+21 test-1)+16 test-2) (+15 controls)	341	6.6 (AVG) (+4.7 test-1)+6.3 test-2) (+9.4 controls)	0.25	Not reported
6.	Meloni et al. (2010)	Retrospective cohort study	Patient satisfaction (Surg)	15	90	6	18 (6 mo recall)	0
7.	Nikzad & Azari (2010)	Prospective cohort study	Patient satisfaction (Surg)	16	57	3.6 (AVG)	12 (1.3,6,12 mo recall)	Not reported
8.	Pomares (2010)	Retrospective cohort study	Patient satisfaction (Surg); Time efficiency (Surg+Prosth)	30	195	6.5 (AVG)	12 (1.3,6,12 mo recall)	0
9.	Abad-Gallegos et al. (2011)	Retrospective cohort study	Patient satisfaction (Surg); Complications (Surg)	19	122	6.4 (AVG)	Not reported	Not reported
10.	Maira et al. (2013)	Retrospective cohort study	Patient satisfaction (Surg); Time efficiency (Surg+Prosth)	30	312	10.4 (AVG)	36 (12 mo recall)	0
11.	Pozzi et al. (2014)	RCT (2 arms)	Patient satisfaction (Surg); Time efficiency (Surg+Prosth); Complications (Surg)	25 (+26 controls)	103 (+99 controls)	4.1 (AVG) (+3.8 controls)	12	0
12.	di Torresanto et al. (2014)	Prospective cohort study	Patient satisfaction (Surg)	15	60	4	24 (6 mo recall)	5
13.	Vercruyssen et al. (2014)	RCT (3 arms)	Patient satisfaction (Surg); Time efficiency (Surg)	59	314	5.3 (AVG)	0	Not reported
14.	Sannino & Barlattani (2016)	Retrospective cohort study	Time efficiency (Surg+Prosth)	85	340	4	36 (12 mo recall)	0

TABLE 2 Implant-specific data summarizing software implant planning, design, and fabrication of implant guides, used implant systems and implant failures

No.	Study (year)	Software implant planning	Design implant guide	Fabrication implant guide	Implant system	No. implant failures
1.	Fortin et al. (2006)	CADImplant	Not reported	Mixed	Not reported	0
2.	Nkenke et al. (2007)	Procera	Mucosa-support	Stereolithography	Not reported	0
3.	Komiyama et al. (2008)	Procera	Mucosa-pin-support	Stereolithography	Nobel Biocare	19
4.	Merli et al. (2008)	Procera 1.6	Mucosa-pin-support	Not reported	Nobel Biocare	5
5.	Arisan et al. (2010)	3D StendCad/Simplant	Mucosa- & bone-support	Stereolithography	Thommen (n = 180); Xive (n = 161)	0
6.	Meloni et al. (2010)	Nobel Guide	Mucosa-pin-support	Not reported	Nobel Biocare	2
7.	Nikzad & Azari (2010)	Simplant 10.0	Tooth-support	Stereolithography	Straumann (n = 19); Zimmer (n = 13); Easy Implant (n = 13); Astra (n = 12)	2
8.	Pomares (2010)	Procera 1.6/2.0	Mucosa-pin-support	Stereolithography	Nobel Biocare	4
9.	Abad-Gallegos et al. (2011)	Nobel Guide	Tooth- & mucosa-pin-support	Stereolithography	Not reported	10
10.	Marra et al. (2013)	Nobel Guide	Mucosa-pin-support	Stereolithography	Nobel Biocare	6
11.	Pozzi et al. (2014)	Nobel Guide	Tooth- & mucosa-pin-support	Stereolithography	Nobel Biocare	0 (+1 controls)
12.	di Torresanto et al. (2014)	SimPlant 9.0	Mucosa-pin-support	Stereolithography	Camlog	0
13.	Vercruyssen et al. (2014)	Materialise + Facilitate	Mucosa- & bone-support	Stereolithography; conventional	Astra	0
14.	Sannino & Barlattani (2016)	Nobel Guide	Mucosa-pin-support	Stereolithography	Nobel Biocare	5

(n = 3) and mandible (n = 3), and one study did not include information about the implants' location. Seven studies compared a flapless approach vs. conventionally raised flap design, and the remaining other seven studies described only flapless s-CAIS (Table 3).

3.2 | Descriptive analysis

Of the 14 selected studies, the following PROMs could be distinguished as follows:

- 12 studies exploring "pain & discomfort" (A);
- six studies calculating "time efficiency" (B); and
- seven studies investigating "intra-operative complications" (C).

Multiple outcome categories were incorporated in three studies focusing on all criteria described above; three studies on "pain &

discomfort" plus "intra-operative complications," and two on the combination of "pain & discomfort" plus "time efficiency"; further, single outcomes were solely allocated each for "pain & discomfort" (n = 4), "time efficiency" (n = 1) and "intra-operative complications" (n = 1), respectively (Table 4–6).

Different research techniques and methods were used, and the timing of evaluation of defined patient-centered outcomes with or without follow-up period varied largely. Due to the heterogeneity of the included studies, a direct comparison among the identified publications was not deemed possible; and subsequently, a meta-analysis could not be performed. Therefore, the review of the included full texts followed a descriptive analysis. No additional analyses were performed.

3.2.1 | (A) Pain & discomfort

Within the 12 included studies investigating pain & discomfort, different methodological approaches specified (sub-) outcomes and

TABLE 3 Data showing detailed information with regard to implant indication, jaw localization, flap design, timing of implant placement, type of restoration, and timing of prosthetic loading

No.	Study (year)	Implant indication	Jaw localization	Flap design	Timing implant placement	Prosthetic restoration	Timing prosthetic loading
1.	Fortin et al. (2006)	Partial & complete edentulous	Maxilla & mandible	Flap & flapless	Not reported	Not reported	Not reported
2.	Nkenke et al. (2007)	Complete edentulous	Maxilla	Flapless (controls with flap)	Type 4	Not reported	Mixed
3.	Komiyama et al. (2008)	Complete edentulous	Maxilla & mandible	Flapless	Not reported	Fixed	Immediate
4.	Merli et al. (2008)	Complete edentulous	Maxilla	Flap & flapless	Types 3; 4	Fixed screw-retained	Immediate
5.	Arisan et al. (2010)	Complete edentulous	Not reported	Flap & flapless	Type 4	Not reported	Not reported
6.	Meloni et al. (2010)	Complete edentulous	Maxilla	Flapless	Types 3; 4	Fixed screw-retained	Immediate
7.	Nikzad & Azari (2010)	Partial edentulous	Mandible	Flapless	Type 4	Fixed	Conventional
8.	Pomares (2010)	Complete edentulous	Maxilla & mandible	Flap & flapless	Types 2; 3; 4	Fixed	Immediate
9.	Abad-Gallegos et al. (2011)	Partial & complete edentulous	Maxilla & mandible	Flapless	Not reported	Fixed	Mixed
10.	Marra et al. (2013)	Complete edentulous	Maxilla & mandible	Flapless	Not reported	Fixed screw-retained	Immediate
11.	Pozzi et al. (2014)	Partial & complete edentulous	Maxilla & mandible	Flap & flapless	Types 1; 3; 4	Fixed screw-retained	Immediate
12.	di Torresanto et al. (2014)	Complete edentulous	Mandible	Flapless	Type 4	Removable	Conventional
13.	Vercruyssen et al. (2014)	Complete edentulous	Maxilla & mandible	Flap & flapless	Not reported	Mixed	Not reported
14.	Sannino & Barlattani (2016)	Complete edentulous	Mandible	Flapless	Types 1; 4	Fixed screw-retained	Immediate

subjective evaluation analyses during various follow-up protocols were described (Abad-Gallegos et al. 2011; Arisan et al. 2010; di Torresanto et al. 2014; Fortin et al. 2006; Marra et al. 2013; Meloni et al. 2010; Merli et al. 2008; Nikzad & Azari 2010; Nkenke et al. 2007; Pomares 2010; Pozzi et al. 2014; Vercruyssen et al. 2014; Table 4).

Post-surgery pain occurrence was the most often defined outcome for convenience assessment of s-CAIS. The consumption of painkillers was the method of choice to evaluate the quantity and quality of pain in a total of six studies (Arisan et al. 2010; Fortin et al. 2006; Merli et al. 2008; Nkenke et al. 2007; Pozzi et al. 2014; Vercruyssen et al. 2014). Merli et al. (2008) noticed a median consumption rate of two painkillers per patient for the treatment with s-CAIS in the complete edentulous maxilla; with a range of 0–7 painkillers. Fortin et al. (2006) stated that painkiller

consumption was significantly lower for s-CAIS with flapless surgery compared with conventional implant placement with an open-flap procedure ($p = .03$). Arisan et al. (2010) reported on the influence of the guide design and the consumption of painkillers. Patients who were treated with mucosa-supported guides in a flapless approach demonstrated a significantly reduced intake of painkillers ($n = 4$) compared with those treated with bone-supported guides and conventionally raised full-thickness flap ($n = 11$; Figure 4).

Other studies quantified pain using visual analogue scales (VAS; Arisan et al. 2010; di Torresanto et al. 2014; Nikzad & Azari 2010; Nkenke et al. 2007). Again, heterogeneity was present among these studies as different scales and questionnaires for pain assessment were applied. Nikzad & Azari (2010) reported on the postoperative development of the patients' pain intensity after 2 and 7 days,

TABLE 4 Results of $n = 12$ included trials reporting on “pain & discomfort”

No.	Study (year)	Outcome
1.	Fortin et al. (2006)	Post-surgery pain occurrence: test < controls ($p < .01^*$) Post-surgery pain decrease: test < controls ($p = .05^*$) Consumption of painkillers: test < controls ($p = .03^*$) Number of patients feeling pain at all: test 57% vs. controls 80%
2.	Nkenke et al. (2007)	Post-surgery “discomfort & pain”: (6 h, 1 day, 7 days) consumption of painkillers VAS (1 day): repetition of the procedure; bleeding; duration of surgery; recommendation of procedure Face scanning for analysis of soft tissue swelling (upper lip & cheeks)
4.	Merli et al. (2008)	Post-surgery: (3 days) five patients no pain/eight mild pain; six patients no swelling/seven mild swelling Average consumption of painkillers: 2 (range: 0 – 7)
5.	Arisan et al. (2010)	Average consumption of painkillers: mucosa-supported guide $n = 4$ vs. bone-supported guide $n = 11$ vs. controls $n = 10$ Overall VAS pain score: mucosa-supported guide < bone-supported guide ($p < .01^*$) < controls ($p < .001^*$)
6.	Meloni et al. (2010)	Post-surgery “discomfort & pain”: (3 days) 10 patients no pain/five mild pain; seven patients no swelling/eight mild swelling
7.	Nikzad & Azari (2010)	Mean pain score: (2 days) VAS 35 points; (7 days) VAS 10 points Post-surgery pain occurrence: (2 days / 7 days) no pain 6.2%/81.2%; moderate pain 81.2%/6.2%; high pain 6.2%/6.2%; unbearable pain 6.2%/6.2%
8.	Pomares (2010)	No postoperative complications (pain, inflammation, or hematoma) No postoperative problems (phonetic, aesthetic, or chewing ability)
9.	Abad-Gallegos et al. (2011)	Post-surgery comfort: poor 5.3%; good 42.1%; very good 31.6%; excellent 21.1%
10.	Marra et al. (2013)	Post-surgery discomfort, such as swelling and pain, was negligible
11.	Pozzi et al. (2014)	Post-surgery pain occurrence: test 0.32 (SD 0.56) vs. controls 0.92 (SD 0.74) ($p = .002^*$) Post-surgery swelling occurrence: test 0.48 (SD 0.65) vs. controls 1.00 (SD 0.85) ($p = .024^*$) Painkiller consumption: test 2.08 (SD 1.35) vs. controls 3.00 (SD 1.90) (NS $p = .082$)
12.	di Torresanto et al. (2014)	VAS: pain during surgery 2.4 (SD 0.84); pain after Surgery 1.3 (SD 0.64); swelling/bleeding 0.6 (SD 0.70)
13.	Vercruyssen et al. (2014)	Painkiller consumption Swelling Surgical time [Little difference could be found between postoperative discomfort of flapless vs. non-flapless-guided surgery, and in comparison with conventional implant placement; tendency of more pain in conventional and flapped protocols; duration of surgery is shortened with flapless-guided implant placement]

TABLE 5 Results of $n = 6$ included trials reporting on “time efficiency”

No.	Study (year)	Outcome
4.	Merli et al. (2008)	Average time planning: 145 min (70–370 min) Average surgical time: 53 min (35–72 min) Average prosthetic time: 85 min (20–210 min)
5.	Arisan et al. (2010)	Average surgical time: mucosa-supported guide 23.53 min (SD 5.48) vs. bone-supported guide 60.94 min (SD 13.07) vs. controls 68.71 min (SD 11.40)
8.	Pomares (2010)	Average surgical time: 15–45 min Average prosthetic time: 60–150 min
10.	Marra et al. (2013)	Average surgical + prosthetic time: 90–150 min
11.	Pozzi et al. (2014)	Average surgical time: test 42.68 min (SD 21.44) vs. controls 42.31 min (SD 23.33) (NS $p = .953$) Average prosthetic time: test 51.40 min (SD 3.34) vs. controls 50.40 min (SD 15.34) (NS $p = .859$)
14.	Sannino & Barlattani (2016)	Average surgical time “all-on-4” edentulous mandibles flapless-guided implant surgery: 15–25 min Average prosthetic time immediate loading provisional screw-retained cross-arch prosthesis: 30–50 min

respectively. Mean VAS pain scores were 35 points after 2 days and 10 points after 7 days (with a scale definition of: “no pain” = 0 points up to “maximum pain” = 100 points). Secondary, pain categories were divided into “no pain,” “moderate pain,” and “high pain.” Mean results were 6.2% vs. 81.2% for “no pain” after 2 days and 7 days, 81.2% vs. 6.2% “moderate pain,” and 6.2% vs. 6.2% for “high pain,” respectively.

The degree of post-surgical swelling was an alternative parameter for the estimation of patients’ discomfort for the treatment with s-CAIS. Meloni et al. (2010) stated after 3 days of s-CAIS with a flapless procedure that 47% of the patients had no swelling, while 53% suffered from mild swelling.

Pomares (2010) observed no postoperative complications, such as pain, inflammation, or hematoma, and also no phonetic, aesthetic, or

TABLE 6 Results of $n = 7$ included trials reporting on “intra-operative complications”

No.	Study (year)	Outcome
3.	Komiyama et al. (2008)	Prosthetic fitting: five of 29 cases could not be immediately treated with fixed cross-arch screw-retained reconstructions; and three of 29 cases needed extensive occlusal adjustments of the implant reconstruction Surgical guide fracture ($n = 3$)
4.	Merli et al. (2008)	Prosthetic fitting: four of 13 cases could not be immediately treated with fixed cross-arch screw-retained reconstructions Surgical guide fracture ($n = 1$)
6.	Meloni et al. (2010)	Prosthetic fitting: two of 15 cases could not be immediately treated with fixed cross-arch screw-retained reconstructions
8.	Pomares (2010)	Surgical guide fracture ($n = 3$)
9.	Abad-Gallegos et al. (2011)	Lack of primary implant stability 26.3% Lack of primary stability precluded the placement of an immediate provisional prosthesis in four cases All implant failures occurred in complete edentulous cases and after immediate loading
11.	Pozzi et al. (2014)	Explicit statement that no intra-surgical complications occurred
12.	di Torresanto et al. (2014)	Prosthetic fitting: five of 15 cases could not be treated according to the study protocol with mandibular locator-retained over dentures Lack of keratinized peri-implant mucosa in eight of 40 implants

chewing ability problems. Marra et al. (2013) summarized that patients' postoperative discomfort such as swelling and/or pain was negligible.

3.2.2 | (B) Time efficiency

Six studies defined time efficiency of s-CAIS as outcome (Arisan et al. 2010; Marra et al. 2013; Merli et al. 2008; Pomares 2010; Pozzi et al. 2014; Sannino & Barlattani 2016; Table 5).

Only one study calculated the time used for the implant planning software. Merli et al. (2008) described an average time of 145 min per case for virtual planning for the treatment with fixed screw-retained prostheses in the edentulous maxilla.

The reported average duration of the implant surgery using a s-CAIS approach varied from 15 min up to 72 min (Merli et al. 2008; Arisan et al. 2010; Pomares 2010; Pozzi et al. 2014; Sannino & Barlattani 2016). Here, a RCT showed that s-CAIS using mucosa-supported guides in a flapless approach in complete edentulous maxillary cases was significantly faster (23.53 min; SD 5.48) compared with bone-supported guides using a conventionally raised full-thickness flap (60.94 min; SD 13.07) and controls with a conventional approach (68.71 min; SD 11.40), respectively (Arisan et al. 2010). In contrast, another RCT could not observe any significant differences between s-CAIS (42.68 min; SD 21.44) vs. conventional surgery (42.31 min; SD 23.33) for the rehabilitation of partially and fully edentulous patients (Pozzi et al. 2014).

Within the included studies, the average prosthetic time immediately after surgery varied widely from 20 to 210 min (Merli et al. 2008; Pomares 2010; Pozzi et al. 2014; Sannino & Barlattani 2016). However, even within single studies, the duration for the prosthetic protocol was heterogeneous: Merli et al. (2008) reported 20 to 210 min and Pomares (2010) 60 to 150 min.

For the “all-on-4” concept in edentulous mandibles, Sannino & Barlattani (2016) reported an average surgical time with flapless-guided implant placement of 15 to 25 min, and an average prosthetic time for the treatment of immediate loaded provisional screw-retained cross-arch prostheses of 30 to 50 min (Figure 5).

3.2.3 | (C) Intra-operative complications

Seven studies reported on complications, either for the surgical protocol or the immediate implant-prosthetic reconstruction (Abad-Gallegos et al. 2011; di Torresanto et al. 2014; Komiyama et al. 2008; Meloni et al. 2010; Merli et al. 2008; Pomares 2010; Pozzi et al. 2014; Table 6).

The total number of surgical complications at implant placement was 12 out of 408 interventions using s-CAIS (2.9%). In detail, the reported complications were the lack of primary implant stability ($n = 5$; Abad-Gallegos et al. 2011), and fractures of the implant guide ($n = 7$; Komiyama et al. 2008; Merli et al. 2008; Pomares 2010).

With regard to the immediate insertion of the (provisional) implant-prosthetic reconstruction, three studies reported on problems placing full-arch prostheses in a correct position in five of 29 cases (Komiyama et al. 2008), four of 13 cases (Merli et al. 2008), and two of 15 cases (Meloni et al. 2010), respectively. Di Torresanto et al. (2014) observed a lack of keratinized peri-implant mucosa in 20% of the implants placed in edentulous mandibles with a flapless approach using s-CAIS.

4 | DISCUSSION

The trend of digitization is a ubiquitous sensation today; both, in social media and in dentistry (Schoenbaum, 2012; Weston, 2016). In general, the digital dental impact can be categorized into (i) clinical performance using different tools and applications investigating feasibility; (ii) technical accuracy and precision of virtual simulations and the translation into reality; (iii) PROMs for analysis of safety- and convenience-related treatment protocols; and (iv) changing learning methods in the field of higher university dental education (Joda, Ferrari, Gallucci, Wittneben & Bragger, 2017).

Digital protocols are increasingly influencing implant treatment concepts (Patel, 2010; van Noort, 2012). Since the introduction of s-CAIS, technical accuracy, and its clinical applicability have been

Ø PAIN KILLER CONSUMPTION

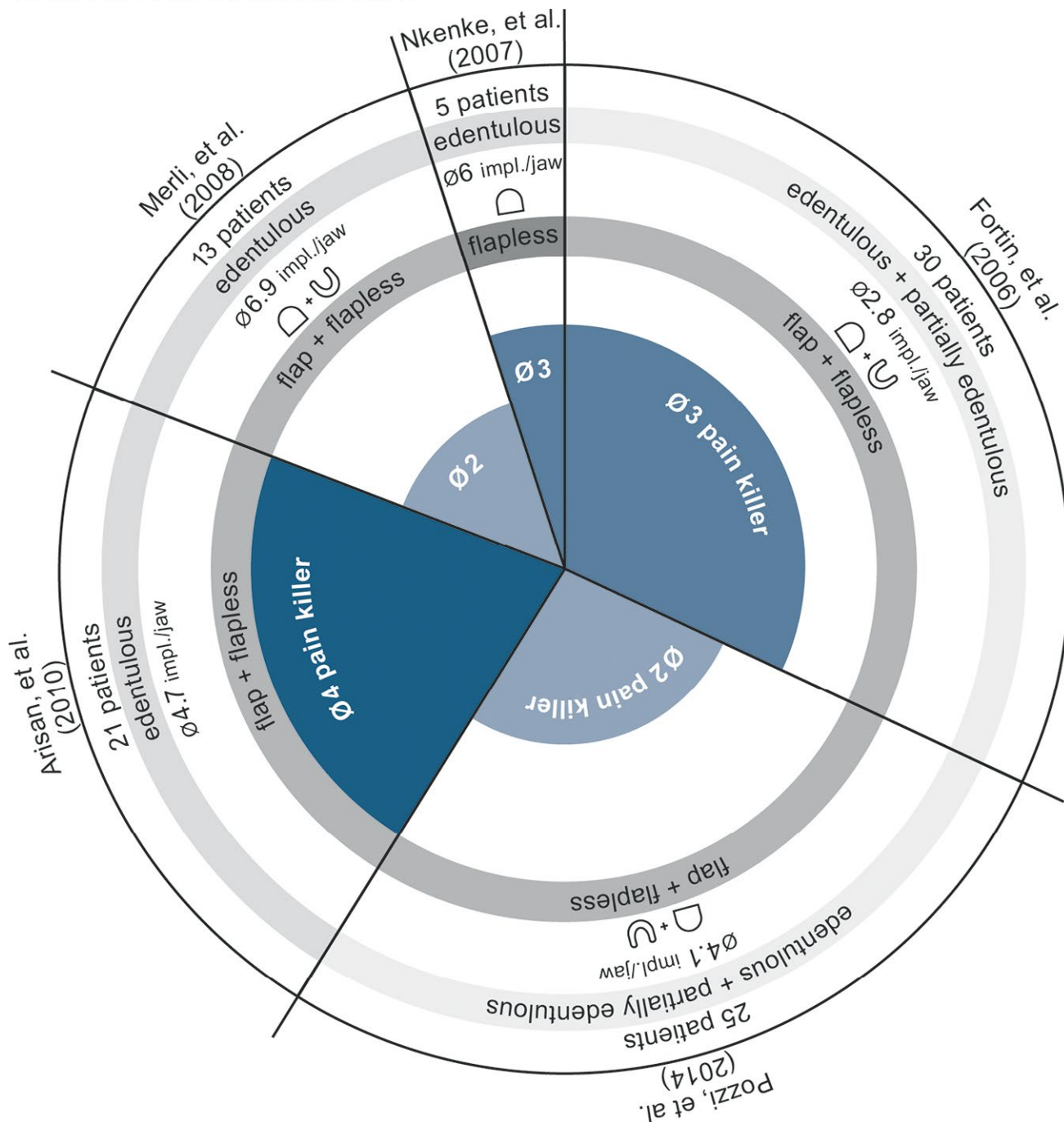


FIGURE 4 Pie chart depicting included studies with major trial characteristics analysing “pain & discomfort” with regard to patients’ painkiller consumption for the treatment with CAIS

investigated in several reports and trials, and these results were summarized in no fewer (systematic) reviews so far (Jung et al., 2009; Schneider et al., 2009; Tahmaseb et al., 2014; Vercruyssen, Hultin et al., 2014). However, the scientific output of clinical studies analysing s-CAIS with regard to PROMs is low.

The systematic search of this review revealed a total of 14 studies, which met the defined inclusion criteria. Only four RCTs could be identified, whereas most trials were classified as cohort studies

with a lower level of evidence. Due to the heterogeneity of included trials with various study designs, implant indications, applied virtual implant planning software, fabrication systems, and treatment protocols, no meta-analyses could be performed.

Pain is a qualitative human impression, extremely patient-dependent, and therefore, a very subjective criterion for the evaluation of medical/dental treatments in general. Most studies selected the number of painkillers taken as surrogate parameter for

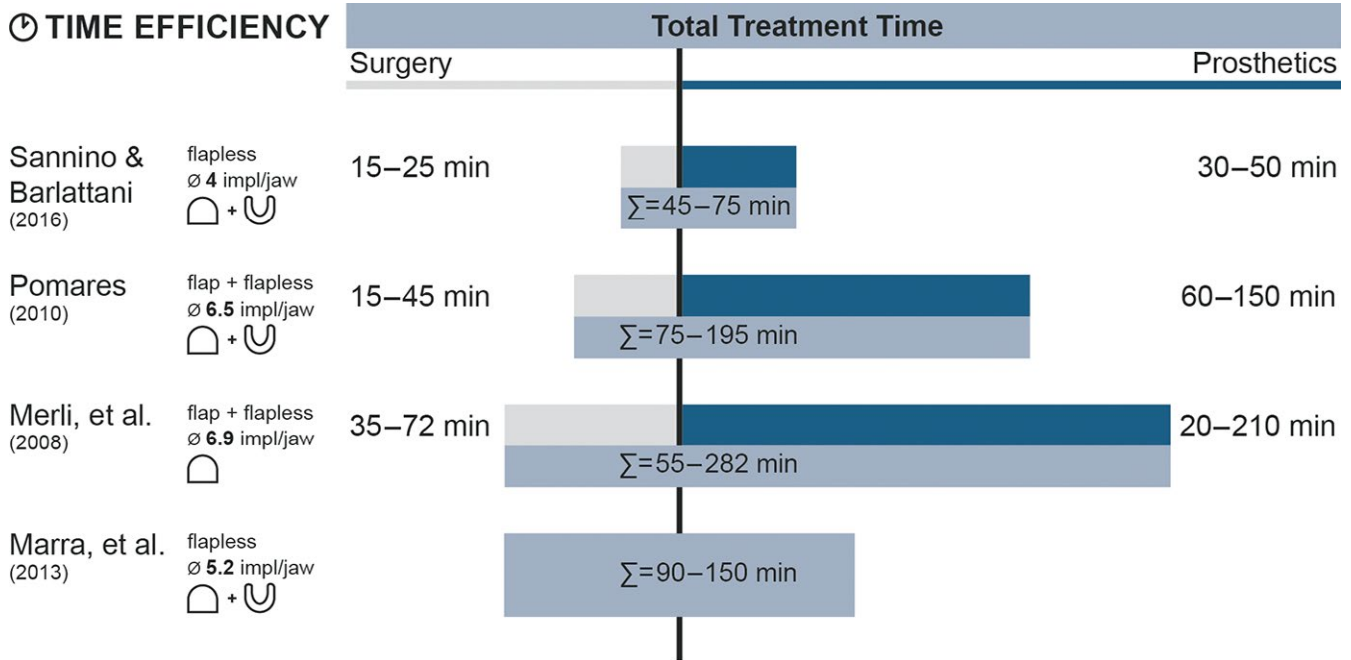


FIGURE 5 Bar graph showing included studies with major trial characteristics analysing “time efficiency” split in surgical + prosthetic treatment for the treatment with CAIS

quantification of comfort on a patient-based level for the treatment with s-CAIS. Unfortunately, no standardized protocols were used for the assessment of painkiller consumption with varying time points and no exact specifications of type of medication. Some studies reported on occurrence of pain operating a dichotomic index “yes/no” or with graduated categories, such as severe, mild, or no pain. Others used trial-specific visual analog scales (VAS) for registering patients’ level of pain & discomfort. One study tried to visualize time-related swelling after s-CAIS using facial scanning and a superimposition technique.

With regard to the heterogeneous evaluation methods of patients’ pain & discomfort, it can be concluded that the number of clinical complications was negligible and equivalent to conventional implant surgery. Especially, the use of s-CAIS combined with mucosa-supported guides for flapless implant placement may be beneficial in edentulous cases by means of postoperative pain intensity and related analgesic drug intake. Although the data cannot support this clearly, the improved comfort seems to be more associated with the flapless procedure than with the application of s-CAIS per se (Arisan et al. 2010).

Clinical chair time needed for s-CAIS varied largely between the included studies from 15 min up to 72 min. Due to the diverse implant indications of partially dentate vs. complete edentulous patients in combination with different flap designs, and consecutively, mucosa- and bone-supported guides in the maxilla or mandible, no comparisons between the studies could be made. Nevertheless, a positive correlation may occur between lower scores of patients’ pain & discomfort and reduced duration of surgery.

The time needed for the prosthetic rehabilitation with immediate (provisional) reconstructions showed a widespread range of 20 to 210 min, indicating a sort of study protocol-based inaccuracy for the transfer of

the virtual planning to the final 3D positioning of the implant(s). Maybe as a consequence, three cohort studies described problems placing full-arch prostheses in 11 of 57 cases, resulting in a success rate of 81% for immediate implant-prosthetic rehabilitation of edentulous patients.

Fracture of the surgical guide was only a rare problem, but this issue has to be considered as a major complication with a high risk for the overall success of the treatment. In such a scenario, the clinical team must be able to switch to conventional implant protocols, or the surgery has to be canceled and repeated at an additional appointment.

Yet it is important to consider the time spent by the dental team before the surgical procedure itself, especially the virtual planning process and necessary technical production of the guide. As a secondary economic factor, no trial could be identified estimating the direct costs, a cost-benefit-ratio, or a cost-time-analysis for the patient and/or the dentist.

Overall, the economic effects in terms of time efficiency and treatment costs seem to be unclear at this time; either based on the heterogeneity of the included studies which made a direct comparison impossible or simply on lacking evidence. Also, the additional exposure to radiation can be an important factor in the decision for a s-CAIS procedure.

The advancement of computer technology allows new treatment options. At present, s-CAIS protocols are feasible using complete digital workflows with superimposition technique of a virtual prosthetic setup (STL) with 3D rendering of the cone-beam computed tomography (DICOM) without prior radiographic templates (Flügge et al. 2017). This development approximates the interfaces of surgical and prosthetic treatment steps, from the virtual planning, plotted implant guides, to the CAD/CAM-based design, including production of the final prosthetic reconstruction (Joda &

Buser, 2013). As a result, economic factors, such as treatment and interdisciplinary planning time, but also the entire treatment itself could be shortened realizing a simplified treatment concept with predictable treatment outcomes under consideration of the individual patients' situation (Laleman et al., 2016). Major advantages might arise to reduce production costs, improve time efficiency, and to satisfy patients' perceptions and expectations in a modernized treatment concept. Therefore, s-CAIS might have the potential to become a game changer in implant therapy (Pozzi et al., 2016).

Selecting appropriate indications is a prerequisite, and the correct application of s-CAIS is absolutely crucial for the success of the overall therapy, and finally, for a satisfied patient reaching a predictable implant treatment outcome (Joda & Bragger, 2016). For virtual implant planning and consecutively implant placement using static s-CAIS, a teamwork approach is even more important and equally affects the prosthodontist, the oral surgeon, and the dental technician (Di Giacomo, Cury, de Araujo, Sendyk & Sendyk, 2005; Fortin, Isidori & Bouchet, 2009). Here, an increasing learning curve of the entire team has to be considered, and the level of treatment quality might be dependent on the operators' experience combined with the used implant system, the software application, and processing technology for s-CAIS guide production (Rungcharassaeng, Caruso, Kan, Schutyser & Boumans, 2015; Sarment, Al-Shammari & Kazor, 2003).

5 | CONCLUSIONS

Overall, the number of identified studies investigating s-CAIS for PROMs was low. The included studies presented heterogeneous trial designs, various therapy indications and applied techniques, which focused on different PROMs. Therefore, scientifically proven recommendations for PROMs cannot be given using s-CAIS at this time.

However, the number intra-operative complications with s-CAIS seems to be negligible and comparable to conventional implant surgery. s-CAIS may offer a beneficial treatment option in edentulous cases if a flapless approach is applicable. Nevertheless, the economic effects in terms of time efficiency and treatment costs are unclear. Clinical investigations with well-designed RCTs investigating PROMs with standardized parameters for the assessment of pain & discomfort, time efficiency & costs, as well as complications, are compellingly necessary in the field of s-CAIS.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the supporting information tab for this article.

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ANNEX I

Excluded full texts [n = 28]

Not matching study outcome (n = 10)

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No virtual implant planning and/or static-guided implant surgery (n = 5)

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Multiple publications reporting on duplicated patient data (n = 2)

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ANNEX II

Included full texts (n = 14)

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