




ORIGINAL RESEARCH

Augmented reality-enhanced navigation in endoscopic sinus surgery: A prospective, randomized, controlled clinical trial

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Abstract

Objective: Endoscopic sinus surgery represents the gold standard for surgical treatment of chronic sinus diseases. Thereby, navigation systems can be of distinct use. In our study, we tested the recently developed KARL STORZ NAV1 SinusTracker navigation software that incorporates elements of augmented reality (AR) to provide a better preoperative planning and guidance during the surgical procedure.

Methods: One hundred patients with chronic sinus disease were operated on using either a conventional navigation software (n = 52, non-AR, control group) or a navigation software incorporating AR elements (n = 48, AR, intervention group). Incidence of postoperative complications, duration of surgery, surgeon-reported benefit from the navigation system and patient-reported postoperative rehabilitation were assessed.

Results: The surgeons reported a higher benefit during surgery, used the navigation system for more surgical steps and spent longer time with preoperative image analysis when using the AR system as compared with the non-AR system. No significant differences were seen in terms of postoperative complications, target registration error, operation time and postoperative rehabilitation.

Conclusion: The AR enhanced navigation software shows a high acceptance by sinus surgeons in different stages of surgical training and offers potential benefits during surgery without affecting the duration of the operation or the incidence of postoperative complications.

Level of evidence: 1b.

KEYWORDS

augmented reality, endoscopic sinus surgery, navigation systems, randomized controlled clinical trial

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1 | INTRODUCTION

Since more than 20 years functional endoscopic sinus surgery (FESS) represents the gold standard in surgical treatment of paranasal sinuses diseases.^{1,2} Thereby, rigid 0° to 90° angled endoscopes with an approximately 25x magnification are used with their optical and technical properties being continuously improved.² Since the late 1980s, navigation systems are used for image guided sinus surgery.³ These systems are based on preoperative CT or MRI scans and facilitate an intraoperative guidance using specific instruments, which are preoperatively adjusted to the imaging data. Image guidance facilitates anatomical orientation, which can be particularly helpful in cases of anatomical variants, revision surgery, skull base surgery and tumor diseases.⁴⁻⁹ Mental workload of the surgeons can be reduced¹⁰ and intraoperative complications can be avoided.¹⁰⁻¹² In addition, navigation systems can be a useful tool for young sinus surgeons at the beginning of their surgical training.^{2,9,13} However, there are studies reporting no reduction of complications and a prolongation of operation time when using a navigation system.¹⁴⁻¹⁹ Hence, the clinical benefit of navigation systems in FESS though being widely used in clinical practice still has to be substantiated.

Navigation systems show a continuous improvement in quality and accuracy as well as software properties.²⁰ While the illustration of an instrument's localization matched with the CT scan data represents the basic function of any navigation system in FESS, new systems enable additional functions, for example, integrated elements of augmented reality (AR), image fusions, acoustic warning signals and the usage of

intraoperative CT.²¹⁻²⁵ The basic principle of all AR-based navigation systems is an overlay of preoperative imaging on the conventional endoscopic view.^{1,26-28} The development of new AR-applications, a continuous improvement of the underlying software and a successful transfer of AR-based navigation systems into clinic have the potential to become an important milestone in the modern treatment of sinus diseases.

Against this background, KARL STORZ SE & Co. KG developed the NAV1 SinusTracker navigation software integrating new AR elements that enable the surgeon to draw so called "surgical pathways" in the CT scan series. Intraoperatively, these pathways can be fused with the endoscopic image indicating the surgeon where to continue with preparation (Figure 1).

In our study, we investigated the potential benefit of these new tools incorporated in this AR navigation system (intervention group), which was applied during FESS procedures of 48 patients and compared with another 52 procedures using a non-AR navigation system as a control (control group). The study was designed as a prospective, randomized, controlled monocentric clinical trial.

2 | MATERIALS AND METHODS

2.1 | Study concept

The aim of our study was to evaluate the potential benefit of the KARL STORZ NAV1 Sinus Tracker software (AR, intervention group)

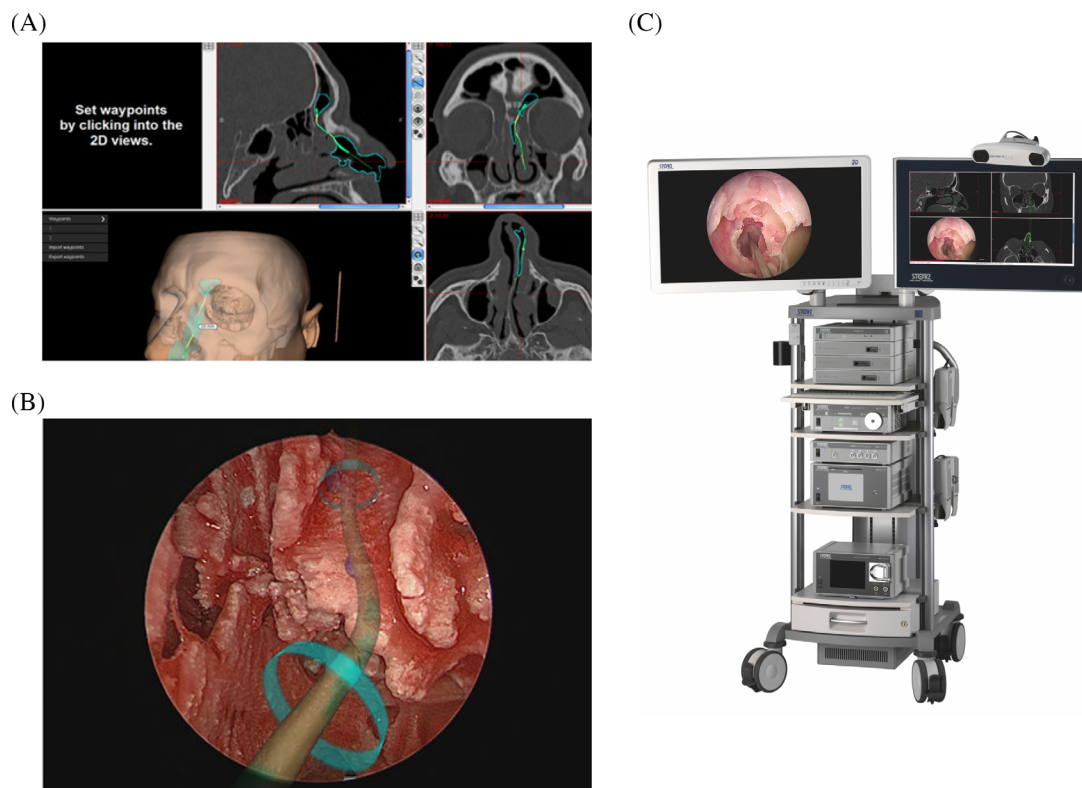


FIGURE 1 Surgical pathways as an element of augmented reality in the NAV1 SinusTracker software. A, Preoperative setting of the surgical pathway to the left frontal sinus. B, Intraoperative overlaying of the surgical pathway on the endoscopic image. C, Combined navigation cart with an optical and an electromagnetic navigation system

for the surgeon as well as for the patients when comparing it to the KARL STORZ NAV1 optical system as control (non-AR, control group). Furthermore, we wanted to see if a different benefit could be seen for a surgeon at an early stage of surgical training compared with a more experienced surgeon. In total, 100 patients (≥ 18 years of age) were included in our study and distributed to four treatment arms (Figure 2A): one half of the patients was operated on using a conventional optical navigation system (non-AR), and the other half was operated on using an electromagnetic navigation system with the AR system. In both groups, patients were again distributed to two subgroups, and either one senior physician or one resident as the surgeon performed their operations. The same surgeons ($n = 2$) operated with both navigation types. Both surgeons had no prior experience using the AR features apart from theoretical training by the company's representative. The surgical experience of the senior physician and the resident in paranasal sinus surgery comprised >3000 procedures for the senior physician and approximately 150 procedures for the resident, respectively. The distribution of the patients to the four treatment groups was performed using the stratified randomization technique considering

age, sex and the extension of surgical intervention as covariates. The study was designed as single-blinded study.

2.2 | Patient characteristics

Patients were recruited from September 2017 to December 2018 and treated at the Department of Otorhinolaryngology, Head and Neck Surgery (Saarland University Medical Centre, Homburg, Germany). Sample size calculation was based on a power analysis (Power $(1 - \beta) = 0.8$; $\alpha = 0.05$; Group A mean (μ_A) = 6; Group B mean (μ_B) = 8; SD (σ) = 3; sampling ratio ($\kappa = n_A/n_B$) = 1).

Inclusion criteria comprised an age ≥ 18 years, a medical indication for endoscopic sinus surgery due to chronic sinus disease excluding benign or malignant tumors as well as written informed consent. Exclusion criteria comprised an age < 18 years, a lacking medical indication for endoscopic sinus surgery, ongoing treatment with anticoagulants or thrombocyte aggregation inhibitors, inherited coagulation disorders as well as a permanent treatment with analgesic medication. The Saarland Medical Association ethics review committee approved

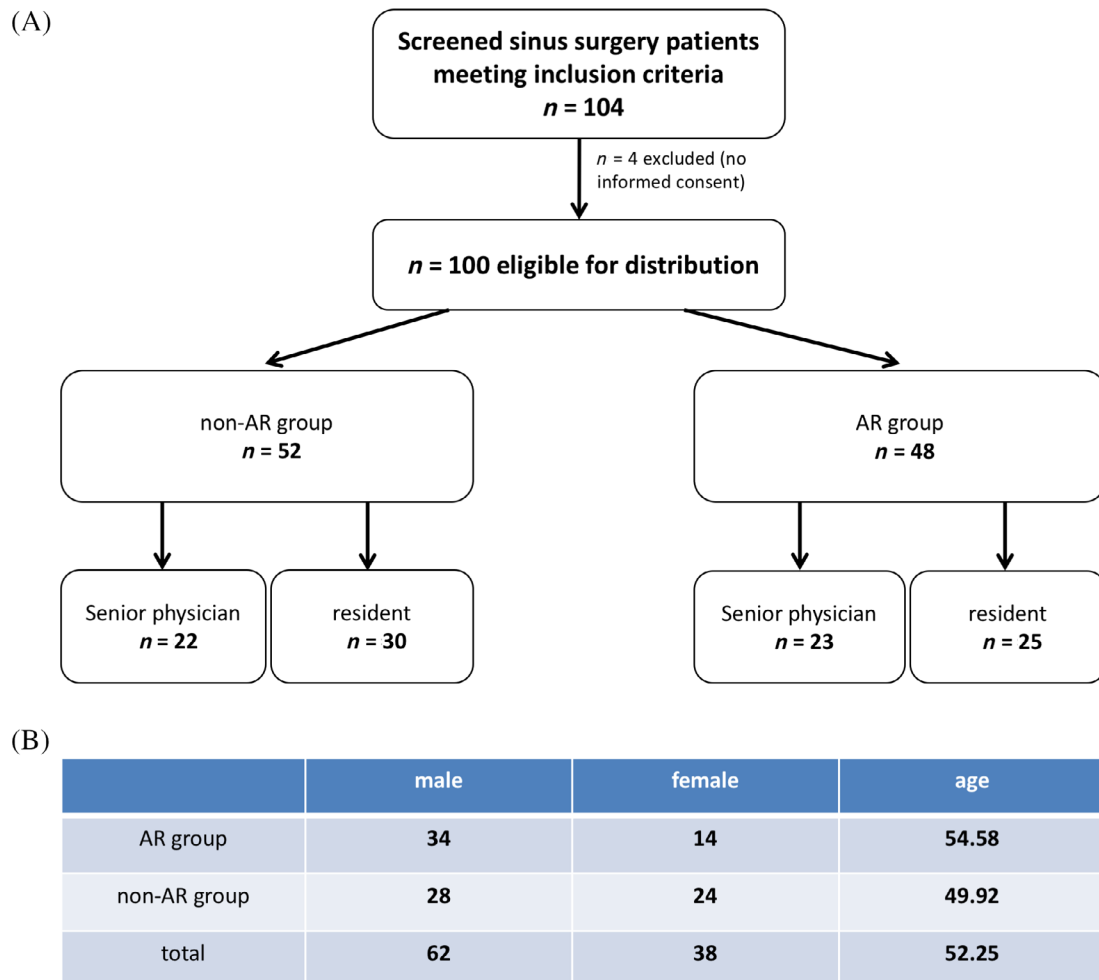


FIGURE 2 Study flowchart and distribution of age and sex in the different treatment groups. A, Study flow chart, the number of patients per study arm is indicated in the boxes. B, Distribution of age and sex in both study arms; for age, the mean value is indicated

this study (index-number 168/17). Written informed consent was obtained from all patients. The study was prospectively registered at the German Clinical Trials Register (DRKS-Nr. 00013508). Details of the distribution of age and sex among the four treatment groups are shown in Figure 2B. The extent of surgical intervention was balanced between the AR and non-AR group is listed in Table 1.

2.3 | Navigation systems

In our study, two different navigation systems were compared and used in combination with a 2D endoscope, respectively: the NAV1 SinusTracker software with an electromagnetic navigation unit (AR, intervention group) and the NAV1 optical system with standard navigation software (non-AR, control group). For both systems preoperative CT-scans of the patients were used for registration. For all cases, a registration by setting four registration markers on the reconstructed patient surface was performed. Although both systems can illustrate the localization of special surgical devices placed in the intraoperative situs on a screen with the patient's CT images, the AR system has an additional key feature: the illustration of preoperatively defined "surgical pathways," for example, to the frontal sinus, overlaying the endoscopic image and suggesting to the surgeon where to continue with the next surgical steps (AR element).

2.4 | Postoperative treatment

All patients stayed in hospital for 5 days after surgery and were supplied with analgesic medication as requested. From the first postoperative day, patients were instructed how to syringe their nose with 0.9% sodium chloride solution and received a cleaning of their nasal cavity by a careful suctioning and removal of crusts. Depending on the surgeon's decision, patients received a nasal packing with either large tamponades (8 cm, removed on day 1) that were placed in the

nasal cavity and/or small tamponades (3 cm, removed on day 4) that were placed in the middle nasal meatus or no nasal packing at all.

2.5 | Questionnaires

The patients were asked to complete a questionnaire every day for the first five postoperative days starting at the first day after surgery. Herein, the patients had to answer two questions (Figure S1). First, pain level had to be valued on a numerical analogue scale (NAS) ranging from 1 (no pain) to 10 (strongest imaginable pain). Second, the impairment of general condition had to be assessed on a NAS ranging from 1 (no impairment) to 10 (strongest imaginable impairment of general condition). In the case of incomplete or lacking questionnaires, the respective patient was excluded from the study.

Additionally, the surgeons were asked to complete one questionnaire for each patient (Figure S2). First, they had to value the benefit during surgery supported by the navigation system ranging from 1 (no benefit) to 10 (highest imaginable benefit). Second, they were asked during how many surgical steps the navigation system was used (not at all [1 on NAS], 1-2 steps [2 on NAS], 3-5 steps [3 on NAS], more than 5 steps [4 on NAS]). Third, the surgeons had to state how much time they spent preoperatively with the analysis of the patient's CT images and the planning of the surgical procedure (not at all [1 on NAS], 1-5 minutes [2 on NAS], 5-15 minutes [3 on NAS], more than 15 minutes [4 on NAS]). Fourth, the surgeons were asked to state the accuracy of the navigation system (no TRE [1 on NAS], less than 1 mm [2 on NAS], 1-3 mm [3 on NAS], more than 3 mm [4 on NAS]).

Furthermore, the treating physicians had to document the incidence of postoperative complications, for example, bleedings and postoperative infections, as well as the time of surgery for each patient. To register also late-onset bleedings, all patients were called by phone 20 days after surgery and were asked for bleeding episodes.

The indicated benefit for the surgeons by using the navigation system was defined as primary outcome. Secondary outcomes comprised the number of surgical steps for which the navigation system was used, the time of preoperative planning of the surgical procedure using the CT imaging data, the accuracy of the navigation system (TRE), the pain level as well as the impairment of general condition indicated by the patients, the duration of the surgical procedure as well as the incidence of postoperative complications.

It has to be stated that neither the questionnaire for the surgeon nor the questionnaire for the patients were internally or externally validated before starting the study.

2.6 | Statistical analysis

For statistical analysis, a Mann-Whitney *U*-test was used applying the commercially available software GraphPad Prism 7.0d (GraphPad Software, La Jolla, CA). *P* values <.05 were considered statistically significant.

TABLE 1 FESS procedures in the intervention and control group

	Intervention group (AR)	Control group (non-AR)
Pansinus operation	25 (52%)	23 (44%)
Maxillary sinus + ethmoidectomy only	9 (19%)	12 (23%)
Maxillary sinus only	3 (6%)	4 (8%)
Frontal sinus only	3 (6%)	5 (10%)
Frontal sinus + ethmoidectomy only	8 (17%)	8 (15%)
Total	48	52
One side	7 (15%)	9 (17%)
Both sides	41 (85%)	43 (83%)
Revision cases	15 (31%)	11 (21%)

Abbreviation: FESS, functional endoscopic sinus surgery.

3 | RESULTS

3.1 | Correlation of surgical experience and the used navigation system with operation time

When comparing the operation time between operations performed with the non-AR system and the AR system, no significant difference was seen neither for the resident nor for the senior physician (Figure 3A). Independent of the navigation system that was used, operations performed by the resident lasted significantly longer than operations performed by the senior physician (resident: mean 108.9 minutes, 95% CI 97.68-120.2 minutes; senior physician: mean 70.62 minutes, 95% CI 55.68-85.57 minutes; $P < .0001$; Figure 3B). Importantly, all four groups were matched for extension of surgical intervention as shown in Table 1 thereby trying to minimize a potential bias by differences in surgical procedures regarding the primary and secondary endpoints of the study.

3.2 | Evaluation of the navigation systems by the surgeons

To evaluate the benefit provided by both navigation systems, the surgeons had to complete one questionnaire after finishing the operation as described in materials and methods. As shown in Figure 4, when using the AR system, both the resident as well as the senior physician stated a significantly higher benefit during surgery (Figure 4A), used the new system during the operation with a higher frequency (Figure 4B) and spent a significantly longer time period with preoperative image analysis and image-based planning of the surgical procedure (Figure 4C) as compared with the non-AR system. No significant difference between both navigation systems was seen in terms of the indicated target registration error (Figure 4D). When comparing all operations performed by the resident with all operations performed by the senior physician independent of the navigation system that was used, we found that the resident valued the benefit of using a navigation system in general as significantly lower ($P = .0001$) and indicated a significantly higher TRE ($P = .0013$). No significant difference between the resident and the senior physician was seen in terms of the frequency of using the navigation system during an operation and the time of preoperative image analysis and image-based operation planning (data not shown). Both surgeons reported a high accuracy level of the AR images and AR based target pathways with no relevant changes in accuracy during operation.

3.3 | Incidence of postoperative complications

In total, only minor postoperative trouble was observed among all participants including slight bleedings not requiring surgical revision (5 patients in the intervention group, 4 patients in the control group) and oral antibiotic treatment due to supposed local wound infection (2 patients in the treatment and 3 patients in the control group).

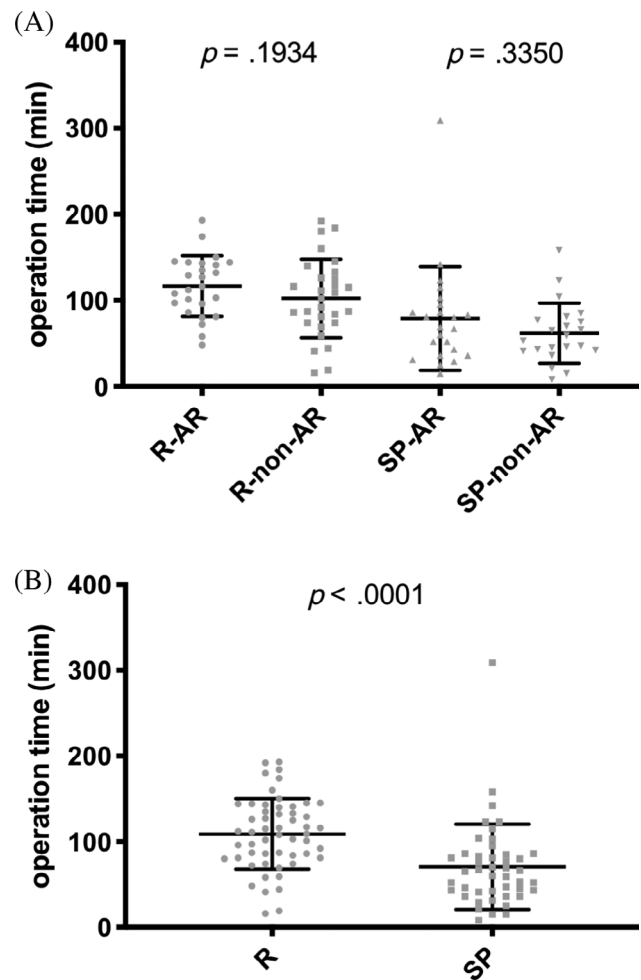


FIGURE 3 Comparison of operation time between the intervention and control group. A, Operation time (min) for all four groups of the study. B, Comparison between operations performed by the resident and the senior physician independent of the navigation system that was used. R-AR: operation performed by the resident with navigation system including augmented reality elements (intervention group); R-non-AR: operation performed by the resident with navigation system not including augmented reality elements (control group); SP-AR: operation performed by the senior physician with navigation system including augmented reality elements (intervention group); SP-non-AR: operation performed by the senior physician with navigation system not including augmented reality elements (control group)

3.4 | Effect of the applied navigation system on postoperative rehabilitation

For all patients, we found a stepwise decrease of pain intensity (Figure 5A) as well as a stepwise improvement of their general condition after the operation with no significant difference between the AR and the non-AR group (Figure 5B). There were also no significant differences in terms of the median pain levels as well as the median impairment of general condition on days 1 to 5 after surgery when comparing the patients operated by the resident with the patients operated by the senior physician (data not shown).

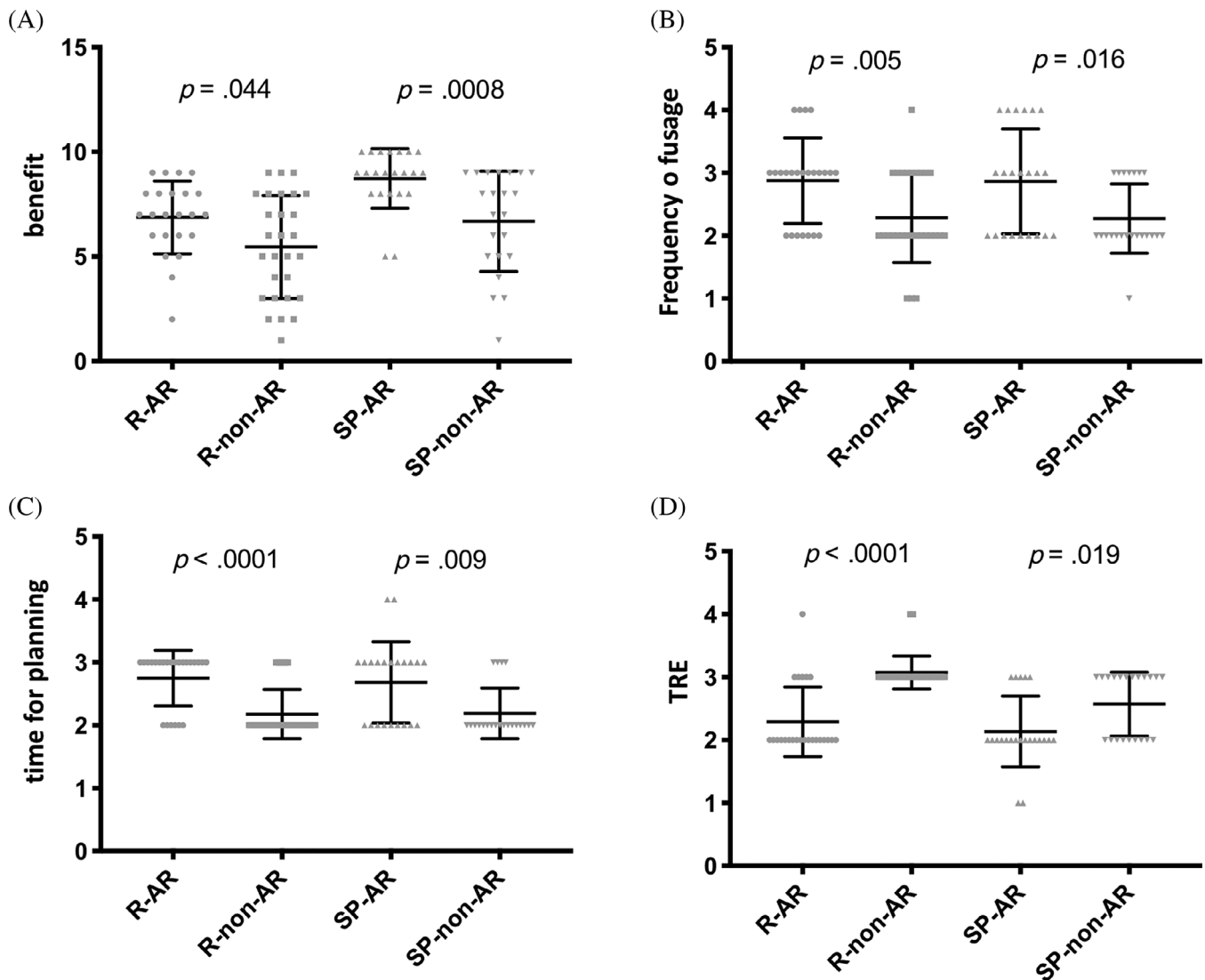


FIGURE 4 Evaluation of the two tested navigation systems by the surgeons. A, Benefit during surgery supported by the navigation system ranging from 1 (no benefit) to 10 (best imaginable benefit). B, Number of surgical steps during which the navigation system was used ranging from 1 (not at all) to 4 (more than 5 steps). C, Amount of time the surgeon spent preoperatively with the analysis of the patient's CT imaging and the planning of the surgical procedure based on these images ranging from 1 (not at all) to 4 (more than 15 minutes). D, Accuracy of the navigation system by assessing the target registration error (TRE) ranging from 1 (no TRE) to 4 (TRE > 3 mm). In panels A to D, medians and inter-quartile ranges are indicated. R-AR: operation performed by the resident with navigation system including augmented reality elements (intervention group); R-non-AR: operation performed by the resident with navigation system not including augmented reality elements (control group); SP-AR: operation performed by the senior physician with navigation system including augmented reality elements (intervention group); SP-non-AR: operation performed by the senior physician with navigation system not including augmented reality elements (control group)

4 | DISCUSSION

In our study, we demonstrated that the AR navigation system shows a high acceptance by sinus surgeons in different stages of surgical training and can offer benefits during surgery when compared with the non-AR system without affecting the duration of the operation or the incidence of postoperative complications. Both surgeons indicated a significantly higher benefit during surgery, used the navigation system during significantly more surgical steps and spent significantly longer time with preoperative image analysis and image-based planning of the surgical procedure when using the AR system as compared with

the non-AR system. No differences were seen between both groups in terms of postoperative complications, target registration error, operation time and postoperative pain as well as the patients' general condition.

Beyond our study, only a few studies investigated the benefit of AR elements in navigation based endoscopic sinus surgery so far. Li et al. developed a system capable of fusing endoscopic images to three-dimensional virtual images and compared this display mode with conventional navigation systems.²⁵ The use of this new navigation mode shortened the duration of surgery and reduced the mental workload of the surgeons. Citardi et al tested a newly developed

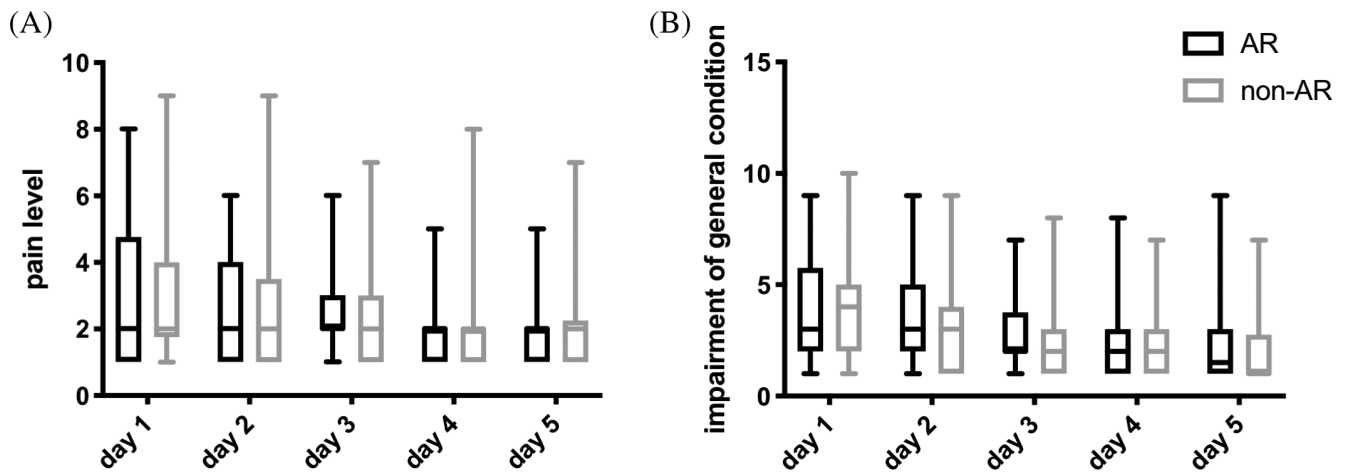


FIGURE 5 Postoperative rehabilitation of the patients. A, Pain level indicated by the patients on a numerical analogue scale ranging from 1 (no pain) to 10 (strongest imaginable pain) for the first 5 days after surgery. B, Impairment of general condition indicated by the patients on a numerical analogue scale ranging from 1 (no impairment) to 10 (strongest imaginable impairment). Values for patients of the treatment group (NAV1 SinusTracker software) are shown in black and values for patients of the control group (NAV1 optical system) are shown in grey using box and whisker blots. Each box represents the range from the first quartile to the third quartile. The median is indicated by a line. The whiskers outside the boxes represent the ranges from the minimum to the maximum value of each group. AR: navigation system with augmented reality elements (intervention group); non-AR: navigation system without augmented reality elements (control group)

“hybrid navigation system” (Scopis Hybrid Navigation) in a cadaver study.²⁹ Thereby, a pre-dissection planning was performed including a modeling of the frontal sinus outflow pathway on CT images. The optic nerve and the internal carotid artery were labeled as anti-targets. Intraoperatively, both the pathway to the frontal sinus as well as the anti-targets were superimposed onto the endoscopic image. The authors concluded that this AR system has the potential to reduce surgical complications and morbidity. Leonard et al. developed a video-based navigation system enabling a surgeon to asynchronously register a sequence of endoscopic images to a CT scan.³⁰ Intraoperatively, this system then allows an overlay of anatomical structures, visible, or occluded, on top of video images. While the authors focused on the stability of this system reporting a position error of 1.09 mm or less, no data are available on the potential clinical use. These data are consistent with our study where both, the resident as well as the senior physician, reported a significantly higher benefit provided by the AR navigation system, which strengthens the previously published data on cadaver dissections indicating a usefulness of AR in endoscopic sinus surgery. In contrast, Yeh and Wickens could show that AR can aid in target detection for expected targets, that is, targets that were preoperatively marked as critical structures, but draw attention away from the presence of unexpected targets implicating a potentially higher risk of intraoperative complications.³¹ However, we saw no higher rate of intra- and postoperative complications in our study when using the AR system.

In terms of postoperative rehabilitation, Riley et al. reported a maximum of patient-reported pain on the third day after endoscopic sinus surgery with a rapid decreasing afterwards,³² which is comparable with our results and goes along with our clinical experience in general.

Considering the accuracy of the navigation systems, the surgeon-reported TRE did not significantly differ between the intervention and the control group. For the majority of cases, both surgeons indicated a TRE of more than 1 mm, which is consistent with previous studies using comparable navigation software.^{1,33-37}

From a critical point of view, it must be stated that despite a careful planning and randomization process the primary endpoint of our study is still based on subjective evaluation of the navigation system and an RCT is anyhow unable to remove this bias. However, no other study design would be able to address this bias either, as blinding of the surgeon is not possible. Furthermore, several factors may have a relevant influence on postoperative pain and general condition and could not be considered in our study. Though a careful matching of all four study groups for the extension of surgical intervention (see Table 1) differences in surgical procedures between the groups were only minimized but not fully eliminated. Furthermore, the fact that an electromagnetic system was used in the intervention group and an optical system in the control group cannot be excluded as a potential bias regarding the subjective benefit stated by the surgeons and the number of surgical steps during which the navigation system was used. Though significant differences were seen between the AR and non-AR group in terms of preoperative time spent with the navigation system and the number of surgical steps when navigation was used, there are numerous potential factors that influence these secondary endpoints so that differences that were seen between the groups cannot exclusively be related to the additional AR technology.

It is hard to speculate on why the resident valued the benefit of intraoperative navigation in general lower than the senior physician. One possible explanation is that due to the limited experience in

working with navigation systems, the TRE was in fact higher when registration was performed by the resident as compared with the senior physician as it is also indicated by the results of the surgeons' questionnaires and therefore, the navigation system showed a lower accuracy when used by the resident.

5 | CONCLUSION

Taken together, the results of our study demonstrated that the incorporation of AR elements in navigation software provides potential benefits during endoscopic sinus surgery as compared to non-AR navigation systems without affecting operation time and complication rates. Both, the experienced surgeon as well as the surgeon in training highly appreciated AR enhanced navigation and recommend an application of this technology especially for revision cases and challenging anatomy. Future studies will have to show if this benefit for the surgeons can also result in significantly better surgical outcome, which due to the limited number of patients and the short follow-up period was not properly addressed in our study.

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CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

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SUPPORTING INFORMATION

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

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