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Evaluation of a Navigation System for ENT with Surgical Efficiency Criteria

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The aim of this study is the evaluation of a navigation system (NaviBase) for ENT surgery. For this purpose, a new methodology for the evaluation of surgical and ergonomic system properties has been developed. The practicability of the evaluation instruments will be examined using the example of the overall assessment of the system in comparison with the current surgical standard and with other systems using clinical efficiency criteria. The evaluation is based on 102 ENT surgical applications; of these, 89 were functional endoscopic sinus surgeries (FESS). The evaluation of surgical and ergonomic performance factors was performed by seven ENT surgeons. To evaluate surgical system properties, the Level of Quality (LOQ) in 89 cases of the FESS was determined. It compares the existing information of the surgeon with that of the navigation system on a scale of 0 to 100 and with a mean value of 50 and places it in a relationship to the clinical impact. The intraoperative change of the planned surgical strategy (Change of Surgical Strategy) was documented. The ergonomic factors of the system with the categories of Overall Confidence (Trust), awareness of the situation (Situation Awareness), influence on the operating team, requirements for specific skills (Skill Set Requirement), and cognitive load (Workload Shift) were recorded for all surgical procedures as Level of Reliance (LOR). In the evaluation of the surgical system properties, an average evaluation of the quality of the information, as an LOQ of 63.59, resulted. Every second application of the navigation system (47.9%), on average, led to a change in the surgical strategy. An extension/enhancement of the indication of the endonasal approach through the use of the navigation system was shown in 7 of 102 (6.8%) cases. The completion of the resection in the FESS was rated by 74% of group I and 11% of group II as better in comparison with the standard approach. Total confidence shows a positive evaluation of 3.35 in the LOR. To supplement the evaluation of the navigation system, the technical parameters were included. The maximum deviation, A_{max}, of the displayed position of the reference value amounted to 1.93 mm. The average deviation was at 1.29 mm with an SD above all values, s_d, of 0.29. The subsequent economic evaluation resulted in an effective average extra expenditure of time of 1.35 minutes per case. The overall evaluation of the system imparts application-relevant information beyond the technical details and permits comparability between different assistance systems. ***Key Words:*** **Ergonomics, evaluation, FESS, Navibase, navigation, trust.**

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INTRODUCTION

After introduction of navigation to ENT surgery 15 years ago, the systems are now widespread.[1] However, the application of navigation is controversial. This relates above all to the conception of the instruments. Usually, it is a matter of modified systems of the first generation. A systematic development in accordance with classical system engineering (subdivided into concepts, specification, rough design, fine specification, detailed design, imple-

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[1]Treated at the Department for ENT/Plastic Surgery of the University of Leipzig. [2]Postoperative computed tomographic (CT) data in this study are indicated due to postoperative recurrent complaints. [3]Multiple use of the system in a region of interest was summarized. On average there were per case 1.9 navigated regions of interest of which 0.91 applications resulted in a change of the surgical strategy. [4]The total number of 13 does not permit a detailed representation. [5]The evaluations of the ergonomic system properties are based on a scale between 1.0 and 4.0. Values above 2.5 signify a predominance of the positive evaluation.

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TABLE I.
Efficiency Categories of a Medical Engineering System, Exemplary Explanation of Computer Assisted Surgery (CAS) Navigation System for Functional Endoscopic Sinus Surgery (FESS).

Category	Details	Exemplary Explanation of CAS Navigation System for FESS
Technical system properties	Accuracy	Surgical accuracy of the system in the region of interest (ethmoid, sphenoid sinus)
	Precision	Repeating accuracy of the system
Surgical system properties	Quality of the information (Level of Quality, LOQ)	Information content of the offered information (14)
	Change of the surgical strategy (Change of Strategy, COS)	Conversion of the original plan to an alternative strategy with lower risk or shorter operation time
	Indications	Extension of the indications of the surgical approach (e.g., resection of malignant tumors by way of an endonasal approach)
	Postoperative Outcome	1. Early outcome: Radicality of polypectomy, configuration of resulting compartment, functional deficits 2. Late outcome (24 months postoperative): recurrent polyposis, nasal mucosa function, olfactory function
Ergonomic system properties	Confidence in overall system (Trust)	Mixed evaluation of the system: comprehensibility of the function, handling of the pointer, stringency of the operability, behavior in exceptional situations, readability of the monitor, comprehensibility of the icons
	Situation awareness (Situation Awareness)	Distraction through additional optical or acoustic signals
	Distribution of tasks and performance of the operating team	Nursing personnel imports record, aligns navigation camera; surgeon registers patient; continuous observation of the bulb dropped.
	Skill requirements (Skill set requirements)	Nursing personnel: preparation of a new instrument filter for navigation, see aboveSurgeon: knowledge about functionality and system error potential of the navigation system, possible loss of surgical detailed knowledge
	Reaction to system failure (Recovery from systems failure)	Typically, a continuation of the operation is possible without problems; in the case of a biopsy in petroclival angle or eye socket the further, procedure is to be evaluated more critically
	Workload (Workload-Shift)	Increasing cognitive burden of the surgeon due to a multitude of pictorial information
	Acceptance of technology	Obvious (but not proven) correlation
Economic system properties	Time requirement	Requirement for data input, structure, registration, application of the systemSaving through changed surgical strategy
	Investments	
	Consumables	Fiducials, masking material
	Period of rest	Correlates with the early outcome of the patient
	Fee	DRG fee, if necessary additional fees
	Complication costs	Correlates with the outcome of the patient
	Personnel costs	Correlates with additional personnel requirements (Assistant for operation) and time

DRG = diagnosis related groups.

mentation/prototyping, testing phase, application, and maintenance) took place only in the rarest of cases with inclusion of the user.[2] Furthermore, not much data are available on the efficiency of the application of the navigation systems. A medical engineering development such as a navigation system has an effect on the patient, the surgeon/personnel, and the cost bearer. Ideally, all three groups will benefit from an efficient new development. In this connection, distinguishing between effectiveness ("Doing the right things") and efficiency ("Doing things right") is of importance.

Completion of an evaluation of a navigation system comprises the following criteria:

1. Technical System Properties;
2. Surgical System Properties;
3. Ergonomic System Properties;
4. Economic System Properties;

Table I explains these criteria for a computer assisted surgery (CAS) navigation system in paranasal sinus surgery. It is of particular importance that all the results of this evaluation be compared with the generally recognized standard (so-called gold standard) of the relevant surgical intervention. Previous studies have been predominantly concerned with technical system properties. Surgical and economic system properties are only occasionally discussed. Only recently have influences on the surgical operating sequence been examined.[3]

Automation

Automation defines a system that fulfills a function completely or partially that was previously performed entirely or partially by the user.[4] In the case of a navigation system for paranasal sinus surgery, this function is the intraoperative landmark detection and orientation. It is well known that ergonomic properties are gaining in importance,[5] with an increasing degree of interaction between humans and machine (automation). The ergonomics of medical engineering systems has only been partially investigated up to now. This also applies to navigation systems, although a navigation system for paranasal sinus surgery can be classified as automation degree 3 (Table II).[6]

Ergonomics (Human Factors)

In accordance with ISO 6385, ergonomics deals with the clarification of the interaction between human and other elements of a system. Ergonomic principles are applied to the system layout, with the object of optimizing the performance of the overall system. Ergonomic investigations are widespread in other fields and sometimes are the prerequisite for approval of a system. The following factors can be derived from this, which are of importance for a harmonization of an automatic assistance system and the operator in surgery (Table I).[5]

Confidence (Trust)

The use of an assistance system depends on the confidence of the user.[7] Confidence is the result of different factors such as reliability, comprehensibility, manageability, and user friendliness. However, it is also dependent on the self-confidence of the user.[5] The target criterion of an efficient assistance system is a well-founded confidence.

Situation Awareness

Surgical assistance systems distract the user to a certain degree. The target criterion of an efficient surgical assistance system is an unchanged or higher degree of situation awareness.

Distribution of Tasks and Performance of the Operating Team (OP Team)

Assistance systems change the distribution of tasks within the OP team.[8] The target criterion of an efficient surgical assistance system is an unchanged or lower degree of overall performance of the OP team in proportion to the other efficiency criteria.

Requirements for Skills (Skill Set Requirements)

Assistance systems change the requirements for the user. Some skills become less important, and new requirements are added. The target criterion of an efficient surgical assistance system is the preservation or improvement of the surgically relevant knowledge.

Reaction to System Failure (Recovery from Systems Failure)

A system failure requires an adequate strategy on the part of the user to recover from it. The target criterion of an efficient surgical assistance system is preservation of the ability of the surgeon to convert the technology without loss of quality in the conventional procedure.

TABLE II.
Degree of Automation (Human Being-Machine Interaction) of Medical Engineering Systems.

	System		Human Being		Example
Degree	Planning	Surgical Treatment	Planning	Surgical Treatment	
10 (high)	System plans autonomously and executes surgical treatment without assistance of the surgeon		No influence of the surgeon		
9	Autonomous	Autonomous	Is informed about strategy	None	
8	Autonomous	Autonomous	Information can be queried by surgeon	None	
7	Automatic	Autonomous	Passive with control function	Passive with control function	
6	Assistance function	Automatic treatment	Assisted by system	Passive with control function	Robotic cutter
5	Assistance function	Automatic assistance	Assisted by system	Active with assistance	Navigated control
4	Assistance function	Active assistance	Assisted by system	Active with assistance	Tracked instruments with warning function, telemanipulator
3	Assistance function	Passive assistance	Assisted by system	Active with assistance	Navigation system
2	Assistance function	No assistance	Assisted by system	Active without assistance	3-D planning system
1 (low)	No influence of the medical engineering system		Surgeon plans autonomously and executes surgical treatment without assistance of the system		

Modified by Parasuraman et al.[6]

Workload (Workload Shift)

The workload shifts as a result of the use of an assistance system from the physical to a more cognitive-perceptive quality. The target criterion of an efficient surgical assistance system is the relative reduction of the cumulative workload in consideration of the cognitive limits of an average user.[9]

Technology Acceptance

The attitude toward surgical assistance systems correlates to the successful implementation in the surgical work flow. The target criterion of an efficient surgical assistance system is the best possible independence from this factor.

MATERIALS AND METHODS

The objective of the present study is the systematic evaluation of a navigation system for ENT surgery. The results should allow a comparability of the overall performance of the system in comparison with the previous standards from efficiency criteria of surgical applications. The following tasks were the focus of the study: 1. Development of a methodology for the evaluation of surgical system properties; 2. Development of a methodology for the evaluation of ergonomic system properties; 3. Overall evaluation of a navigation system in clinical application on the basis of technical, surgical, ergonomic, and economic performance data.

Design of Study and Methods of Investigation

Navigation system and patients. The evaluation of a navigation system was performed using the example of the NaviBase (Group of Prof. Tim Lueth, Munich) system. The clinical application took place in the time period of September 1, 2004 to May 31, 2005 on a total of 102 patients.[1] Nearly all of these patients underwent functional endoscopic paranasal sinus (FESS) operations (Table III). The indication for navigation with the FESS took place in accordance with clinical criteria (Table IV). In all cases, a CT record was used according to a routine protocol for navigation (Collimation 0.5, reconstructed film thickness 0.75, 120 kV, 100 mAs). Two different software versions were used (Table III). In the resulting groups, there is an approximately uniform distribution of the indications and degrees of difficulty of the operations.

Users. The evaluation of the surgical and ergonomic performance factors was performed by seven ENT surgeons. The users were divided into two groups according to their experience with the operation: group I, Learning (<50 surgeries), with four surgeons and group II, Experienced (>50 surgeries), with three surgeons. All evaluations are based on comparison with the previous standard procedure with the respective surgery without navigation assistance.

TABLE IV.
Indications for Application of Navigation System in Functional Endoscopic Sinus Surgery according to Guidelines of Clinic for ENT, University Clinic Leipzig.

Inclusion of the posterior ethmoid (both primary as well as revision operation)
Necessity of sphenoidotomy
Frontal sinus drainage according to Draf II or III
Low frontal base or other anatomical anomalies (Haller's cells, Onodi cells, thinned out orbital lamina)
Children (unusual anatomy)

Technical system properties. The results of the specification of the technical system properties Accuracy and Precision were included in the overall evaluation.[10] However, they are not the subject of the present study.

Surgical system properties. All the results of the surgical system properties are to be judged in comparison with the standard procedure. To guarantee comparability, only the results of the FESS surgeries (89 patients) were included in the evaluation for the determination of the Level of Quality (LOQ) and Change of Strategy (COS). To assess the quality of the information of the navigation system, the quality of the navigation information LOQ and the impact on the surgical strategy COS were determined. Both items of information have proven themselves in other studies.[11] They were collected by means of a questionnaire. The LOQ compares the existing information of the surgeon with that of the navigation system on a scale of 0 to 100 and a mean value of 50 and places it in a relationship to the clinical impact (Table V). The values are without units. An LOQ above 50 indicates helpful additional information about the system, whereas values below 50 permit the inference of a detrimental influence of the system on the operation. The intraoperative change of the planned surgical strategy (COS) was also documented. In the process, the surgeon should also evaluate the influence of the information gained through the navigation system on the next OP steps and their change in relation to the planned strategy.[11] The evaluation of the COS is indicated with "Yes" or "No." The extent of the resection, protection from risk structures, and invasiveness of the surgery were recorded by the surgeon. In addition, in 9 of 89 patients, a postoperative CT evaluation of paranasal sinuses was performed in response to recurrent complaints. Twenty-one post-

TABLE III.
Classification of Patients by Indication of Surgery and Version of Navibase Navigation System Used.

	Group I (Software 1.0)	Group II (Software 2.0)	
Functional endoscopic sinus operation (FESS)	44	45	
Number of first surgeries	31	26	
Number of revisions	13	19	
Esthesioneuroblastoma	1	0	
Squamous cell carcinoma ethmoid	0	2	
Lymphoma ethmoid	1	2	
Sampling transsphenoidal parasellar	1	3	
Sampling intraorbital	1	2	
Total	**48**	**54**	**102**

TABLE V.
Level of Quality (Information of Navigation System in Comparison with Existing Information of Surgeon and Resulting Outcome).

	Quality of Information of Navigation System	Quality of Information of Surgeon	Clinical Impact of Resulting Treatment in Comparison with Originally Planned Treatment
0	False	Correct	Fatal
30	False	Correct	Slight
50	Correct	Correct	None
70	Correct	False	Slight
100	Correct	False	Prevention of a fatal outcome

operative CT of 66 patients who had undergone FESS without intraoperative CAS support in same period were available (Table VI).[2] The present study does not include any documentation of surgical long-term results.

Ergonomic system properties. The quality of the interaction between surgeon and assistance system was recorded for all 102 patients using a questionnaire. The individual evaluation took place with the help of five preformulated possible answers. Ten questions (items) examine the preoperative ergonomics, 24 items examine the intraoperative ergonomics, and 6 items characterize the surgical procedure itself. A total of 4,021 items were included in the evaluation of the categories of the ergonomic system properties listed in Table I. The evaluation of the results is based on a scale between 1.0 and 4.0, whereby values above 2.5 signify a predominance of positive evaluations. The values for the ergonomic system properties are without units.

Economic system properties. The determination of the economic system properties is not the subject of this study. However, the economic consideration of a medical engineering investment also always includes a comprehensive evaluation of the specifics already described. To provide a guide for a cost/benefit analysis and a justifiable investment from the user's point of view, the possible effects on patients and complications were added as "soft factors" to the objective available data, such as duration of operation, consumables, diagnosis related groups (DRG), and methodically conditioned diagnostic expenditure in the overall evaluation.

RESULTS

Surgical System Properties

The surgical system properties LOQ and COS were evaluated exclusively for FESS patients (89 of 102 cases, 87.3%) for the purpose of better comparability. Thirty-two (35.9%) of these cases dealt with a revision operation (Table III). For a total of 792 evaluations of the application of the navigation pointer, an average LOQ of 63.59 resulted. There were significant differences between group I (learning surgeons, n = 4) and group II (experienced surgeons, n = 3), whereby group I used the navigation system more frequently in all cases and assessed the value of the resulting information as higher in comparison with group II (Fig. 1). The following were the regions with the greatest gain of information: sphenoid sinus, orbital lamina, frontal base, frontal recess (in order of the average LOQ).

On average, 47.9% of the applications of the navigation system during FESS resulted in a change of the surgical strategy (COS).[3] There are significant differences between group I and group II (Fig. 2). The learning surgeons corrected their strategy far more frequently using the navigation system than did the experienced group. Indicated particularly frequently was the conversion of an originally planned transethmoidal approach to a transnasal approach in the sphenoid sinus. In the remaining operations (biopsies, tumor operations), there were higher conversion rates after application of the navigation than was the case with FESS.[4]

An expansion of the indication of the endonasal approach through the use of the navigation system was indicated in 7 of 102 (6.8%) cases. There were four transsphenoidal and three intraorbital biopsies that were evaluated as not performable through this approach without navigation.

The completeness of the resection in the FESS was rated as better by 74% of group I and 11% of group II in comparison with the standard procedure by the surgeons. Twenty-one of 66 patients (group A) and 9 of 89 patients (group B) complained of headaches and postnasal drip after surgery. Fourteen (66%) of the re-examined patients in group A showed a nonsufficient drainage of sphenoid sinus. No one patient of the re-examined patients treated by Navigation FESS showed comparable radiologic findings. Anterior and posterior ethmoid sinuses as well as the sphenoid sinus were drained sufficiently (Table VI). The survey time requirement for the surgical system proper-

TABLE VI.
Comparison of Postoperative Computed Tomography (CT) after Functional Endoscopic Sinus Surgury (Anterior and Posterior Ethmoidectomy and Sphenoidotomy).

	Group A: with Navigation (%)	Group B: without Navigation (%)
Patients with postoperative headaches/postnasal drip (n)	9/89 (10.1)	21/66 (31.8)
Insufficient drainage of sphenoidal sinus in postoperative CT (n)	0 (0)	14 (66)

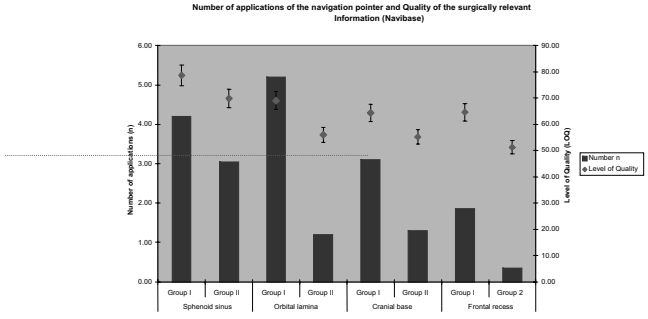

Fig. 1. Average frequency of application of navigation pointer and quality of supplied information (Level of Quality) in dependency of region of interest (System Navibase, n = 89 functional endoscopic sinus surgeries, 178 pages, 792-time use of the pointer). Group I = learning surgeons with less than 50 surgeries; group II = experienced surgeons with more than 50 surgeries.

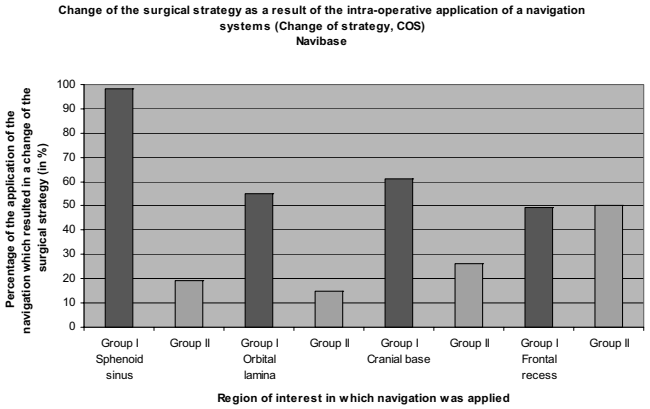

Fig. 2. Change of surgical strategy (COS) by means of information from navigation system (89 FESS; 7 surgeons; group I = learning surgeons with < 50 surgeries, group II = experienced surgeons with > 50 surgeries).

ties proved to be practicable, with an average time of less than 2 minutes for filling out the questionnaire.

Ergonomic System Properties

The ergonomic system properties could be evaluated for all 102 documented surgeries. The results[5] of the overall confidence in the navigation system including selected subcategories are listed in Figure 3. The confidence of the user was rated in the testing phase of the first version of the system (48 surgeries) on average with 2.0 points. After that, the detail design was adapted according to the defaults/standards of the users and with the help of the available results. Version 2.0 was used on 54 patients and evaluated again after implementation. There was an average evaluation of 3.35. The individual results and the modifications of the second version of the system are given in Figure 3.

The results of further ergonomic parameters show a predominance of negative evaluations in comparison with the standard procedure (<2.5) for the following criteria: system-specific professional demands on the surgical personnel and the nursing staff and new distribution of tasks for the nursing team. There was a predominance of positive evaluations in comparison with the standard procedure for the parameters of situation awareness of the surgeon (distraction from the actual operation process), new distribution of tasks for the surgeons, and total of the workload for the surgeons (Fig. 4). The survey time required for the ergonomic system properties proved to be practicable, with an average time of less than 3 minutes for filling out the questionnaire.

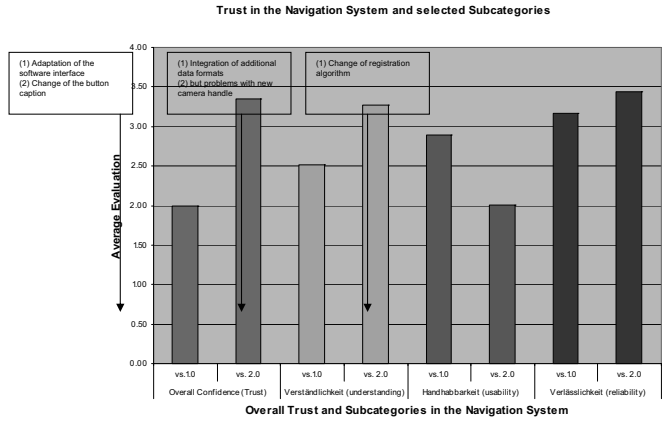

Fig. 3. Overall confidence in navigation system with selected subcategories (n = 48 surgeries with version 1.0; 54 surgeries with version 2.0). Explanations of essential differences between both versions. 2.5 represents boundary between overwhelmingly positive (>2.5) and overwhelmingly negative evaluations.

Technical System Properties

The maximum deviation, A_{max}, (difference of the displayed position from the reference value) was specified for the NaviBase navigation system at 1.93 mm. The average deviation amounts to 1.29 mm, with a SD above all values, s_d, of 0.29.

Economic System Properties

The average additional time requirement for the delivery, the intraoperative application, and the postoperative removal of the navigation system for the surgeon according to the available data in the examined 102 operations amounts on average to +10.29 minutes (SD 2.23). The preoperative preparation of the system proved to be especially time consuming (provide and check record, prepare for registration) at 7.30 minutes on the average. In contrast, there is a documented presumed time savings resulting from the change in the surgical strategy of -8.94 minutes on average (SD 3.77). This results in an average effective additional time expenditure for all 102 operations of 1.35 minutes per case (Fig. 5). If one considers the chronological effect only for the duration of the anesthesia, a time savings of −6.47 minutes on average for all 102 operations can be shown.

No costs for consumables accrue in the case of the examined navigation system because the marker balls made of glass can be autoclaved. It was possible to use the diagnostic CT as a navigation record in 46.6% of the FESS patients. In all other cases, a current CT was necessary.

In 31.8% (28 of 88 patients) of the FESS patients, the desire for the application of the navigation was expressed preoperatively by the referring physician or the patient. The average postoperative period of rest for the 88 FESS

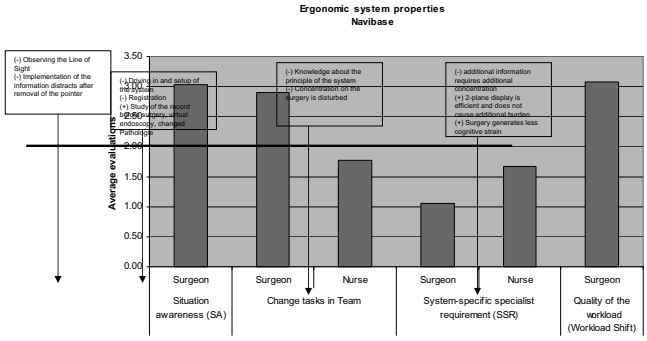

Fig. 4. Average evaluation of ergonomic system properties with selected comments of users (n = 102 surgeries, 7 surgeons) (see also Table I). 2.5 represents boundary between predominantly positive (>2.5) and predominantly negative evaluations.

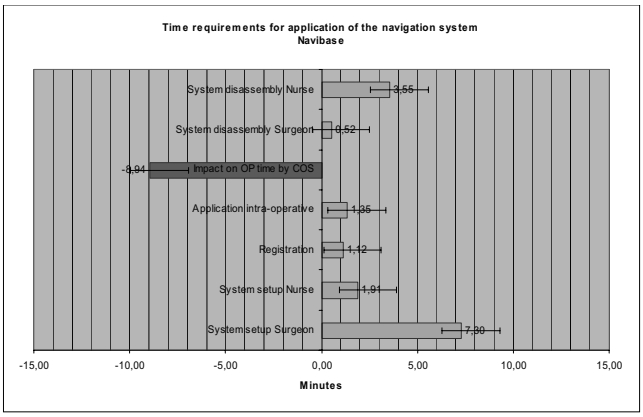

Fig. 5. Time requirement for application of navigation system Navibase (n = 102 surgeries). Impact of the COS on OP time based on estimated data of the surgeons.

patients was 3.21 days, whereas it was 5.98 days for the other 14 patients. There were no extensions of the period of rest caused by complications. No additional operation personnel were required (Table VII).

DISCUSSION

The present surgical system properties data convincingly show a clinical benefit of the information made available by the navigation system. The average evaluation of the quality of the provided information (LOQ) at 63.59 points can be interpreted as additional relevant information that was not available to the surgeon solely by virtue of his existing knowledge. The opening of an additional posterior ethmoid sinus after use of the pointer would be one example, which otherwise would not have been resected out of respect for the eye socket. Only in a total of 3 of 792 applications was the information of the navigation system below 50 and thus evaluated as detrimental to the course of the operation. In two of these cases, it was a matter of navigation in the region of the frontal recess and in one case, in the region of the orbital lamina. There were no consequences for the ultimate result of the operation. The information gained through navigation in biopsies in the eye socket was even more clearly recognized. Without the application of a system, the surgeries documented here would not have been feasible by way of the selected minimally invasive approach. The consequence of the change of the surgical strategy (COS), which in the present examination followed every second application of the navigation, correlates with this result. The data on the quality of the information in comparison to one's own knowledge and to the conversion rate of an originally planned procedure are subject to a high subjective influence (self-confidence, self-criticism), which cannot be measured with the present methods. At this point, the surgeons themselves become a partial target of the study. The evaluations were, for this reason, anonymized outside the clinic to rule out the danger of an internal "ranking" of the operating surgeons. Higher values were shown for the information quality of the navigation system and conversion rate as well as a better interpretational capacity of the comments in the questionnaires after the first 25 operations. This circumstance/fact is to be interpreted through the established/steadfast confidence of the participating surgeons in the survey methodology. The correlation of the COS with the experience of the operating surgeons additionally indicates a suitability of the selected survey methods. Nevertheless, it is a matter of "soft" factors whose results are only interpreted here as a trend.

Expansion of the indication of the endonasal approach is being frequently discussed. Navigation surely plays an important role in the process. However, this supposition can only be confirmed as a trend given the low case numbers of these operations.

Because methodology available up to now, it has not been possible to record the surgical long-term results. Nonetheless, this criterion represents a significant aspect of the evaluation of the surgical system properties and must be included in subsequent studies. Only for the short-term results can a trend be shown here: for the examined patients, clearly improved results can be ascertained for the drainage of the sphenoid sinus through use of the navigation system.

The ergonomic overall evaluation of the examined system proves to be irregular. The overall confidence of

TABLE VII.
Exemplary Calculation of Application of Navigation System on Basis of 89 Functional Endoscopic Sinus Surguries and Economic Outline Conditions at the University Clinic Leipzig.

		Basis of Calculation	(-) EUR	(+) EUR
Expenditure of time	+1.35 min	10 EUR/min operating room costs	13.50	
Consumables	-		0.00	0.00
Additional CT	50% of the cases	300 EUR costs for CT-Paranasal sinuses	150.00	
DRG surcharge		58 EUR		58.00
Assumed effect on assignments	10% of the cases	Missed turnover: cases		188.76
Assumed effect on complication costs	-0.01 day	500 EUR daily rate equals EUR 5.00		5.00
Total			163.50	251.76
				+ 88.26

CT = computed tomography; DRG = diagnosis related groups.

3.35 shows a positive result in comparison with the standard operation (FESS). The reliability of the registration and the comprehensibility of the examined system, Navibase, are the essential causes for the favorable evaluation. In qualification of these points, a learning and habituation effect is to be presumed, which is not recorded by the present data. Modifications to hardware or software are clearly shown in the results regarding the confidence in the system. At the same time, there was also a negative development to be observed from Version 1.0 to 2.0 through the installation of an unsuitable locking mechanism for the camera or changing of the patient registration. Particularly in the case of software modifications, the necessity for changes at soft– or hardware can be described more easily. For better clarity, the results of further ergonomic categories of both versions of the system were combined. The criteria of Change in the Quality, Workload, and the Situation Awareness of the surgeon appear to be of prominent importance. The results are to be judged in relation to relief of the surgeon during the operation, particularly in stress phases (e.g., the locating of the sphenoid sinus or the cranial base). The surgeon benefits accordingly more from the intraoperative possibility of an additional orientation and resulting cognitive relief at that moment when he or she is distracted and stressed by the additional information given by the system. An objective measurement of the stress parameters could reinforce this evidence.[12] The prejudice that the additional technical presence would distract the surgeon from the actual events can be refuted. The necessity of special system knowledge for nursing personnel and surgeons is assessed as a disadvantage compared with the standard procedure. The necessity of special knowledge for a new device is indisputable. In this respect, the mentioned evidence is worthy of discussion, particularly because the relationship between cost and benefit is described overall as favorable. It may be assumed that this evaluation shows a dependence on familiarity with the system.

The results on the ergonomics of medical engineering systems will only gain in significance with the increasing standardization of the test methods and the comparisons of different systems and versions. The technical system properties of the NaviBase could be taken from the present examinations and will only be discussed here from the aspect of the overall evaluation of the system. They show a sufficient surgical accuracy and a high precision of the Navibase navigation system: the determination of the position in situ is sufficiently accurate and the measurements lie precisely together on repetition (they vary only a little). In comparison with other studies, the tolerances lie in the favorable lower third of the deviations. According to the data gleaned from this study's bibliography, we can assume that an accuracy of the navigation of up to 10 mm deviation still permits use in terms of a cartography (degree of automation of 3, Table II) and can consequently offer certain benefits for the progress of the operation. For assistance systems with automation levels greater than 3, other conditions apply. The surgeon can no longer be taken for granted as a corrective factor, although he can fulfill this function in isolated cases. The examined system allows an inclusion of further medical engineering components such as, for example, a navigated-controlled shaver system[13] (degree of automation 5) and also fulfills the technical system requirements in this regard. The generally expected miniaturization and optimization of individual components allows for the expectation of an additional productivity on the part of surgical navigation systems.

The economic system properties are subject to constant changes in the general conditions. In this respect, a concluding evaluation is only useful in individual cases. However, the surveyed data show that even without inclusion of the ergonomic factors, economic use of the navigation system is possible (Table VII). Through the evaluation of surgical long-term results, a further improvement in the cost/benefit ratio is conceivable.

CONCLUSION

The present study evaluates a navigation system for the most frequent application in ENT surgery according to technical, surgical, ergonomic, and economic criteria. An evaluation of the quality of information according to the LOQ and the COS subcategory has proven to be practicable. The ergonomic characteristics could be collected with the Level of Reliance. The overall evaluation of the system conveys application-relevant information above and beyond the technical details and possibly allows comparability between different assistance systems.

References to Existing Patents

The methods for determination of the system ergonomics (Level of Reliance, Level of Quality, Change of Strategy) were published for the first time by Strauss G, Röttger S et al. in the year 2005.

NaviBase was developed by the Group of Prof. Tim Lueth.

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BIBLIOGRAPHY

1. Schlondorff G, Mosges R, Meyer-Ebrecht D, Krybus W, Adams L. CAS (computer assisted surgery). A new procedure in head and neck surgery] *HNO* 1989;37:187–190.
2. Robertson DC. *CAD system use and engineering performance in mechanical design* Boston: Massachusetts Institute of Technology (MIT) Sloan School of Management 2003.
3. Lemke HU, Trantakis C, Koechy K, et al. *Workflow analysis for mechatronic and imaging assistance in head surgery* In: Lemke H, Vannier M, Inamura Keds. Amsterdam: Elsevier B.V., 2004:830–835.
4. Dzindolet MT, Peterson SA, Pomranky RA, et al. The role of trust in automation reliance *Int J Hum Comput Stud* 2003; 58:697–718.
5. Kelly C, Boardman M, Goillau P, Jeannot E. *Guidelines for trust in future ATM systems.* Brussels: 2003:1–59.
6. Parasuraman R, Sheridan TB, Wickens CD. A model for types and levels of human interaction with automation *IEEE Trans Syst Man Cybern A Syst Hum* 2000;30:286–297.
7. Lee JD, See KA. Trust in automation: designing for appropriate reliance *Hum Factors* 2004;46:50–80.

8. Wright MC, Kaber DB. Effects of automation of information-processing functions on teamwork *Hum Factors* 2005;47: 50–66.
9. Gonzalez C. Task workload and cognitive abilities in dynamic decision making *Hum Factors* 2005;47:92–101.
10. Hofer M, Strauβ G, Koulechov K, Dietz A. (2005) *Definition of accuracy and precision: evaluating CAS systems* Amsterdam: Elsevier B.V., 2005:548–552.
11. Strauss G, Trantakis C, Winkler D, et al. Die Wertigkeit der CT-basierten Navigation für den transsphenoidalen Zugang zur Hypophyse. In: Boeker D, ed. Wien: Springer-Verlag 2004:7–15.
12. Vereczkei, A, Feussner H, Negele T, et al. Ergonomic assessment of the static stress confronted by surgeons during laparoscopic cholecystectomy *Surg Endosc* 2004;18: 1118–1122.
13. Strauβ G, Koulechov K, Richter R, et al. Navigated control: a new concept for computer-assisted ENT-surgery. *Laryngo-rhinootologie* 2005;84:567–576.
14. Metzger U, Parasuraman R. Automation in future air traffic management: effects of decision aid reliability on controller performance and mental workload *Hum Factors* 2005;47: 35–49.
15. *European market for image guided surgery systems in 2003.* Toronto, Canada: Millenium Research Group Inc., 2003: 1–29.