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Visual Navigation System used to Coagulate Bleeding in a Semibiological Model

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Abstract

Objective: Endoscopical procedures in the ventricles for the treatment of hydrocephalus or removal of solid tumors are commonly used in neurosurgery. Even a minimal blood amount leads to a complete loss of visibility ("red out") endangering the patient. To enable coagulation of a bleeding vessel in "red-out" we developed and tested the VN-Software-System.

Methods: An optical-positioning-system (OPS) receives signals from 3 infrared Light-Emitting-Diodes (LED) on the endoscope and digitalized endoscopic images are created reproducing the real position of the endoscope. An imaging software correlates the transmitted images (max 8/sec) with the positional data. The virtual images of the VN-Software are available next to the real image of the endoscope-camera. In cases of bleeding a "red-out-sensor" activates the "virtual mode" and the surgeon can navigate the endoscope based on the positional coordinates and the saved images of the software program. The bleeding vessel can be localized and coagulated.

Results: When the target region included a radius of 2 mm around the epicenter the success rate was 96.9%. Only in 3.1% of the experiments the target was missed of more than 2 mm. The mean precision in all experiments was 0.81 mm around the epicenter. The mean time of target finding and coagulation was 48.23 sec.

Conclusion: Localizing a bleeding vessel in a "red-out" condition with the VN-Software is reliable and will improve endoscopical safety in removal of highly vascularised tissue. The VN-software showed a high precision-rate in finding a given target in "red-out" conditions.

Keywords: Neuroendoscopy; Neuronavigation; Ventricle

Introduction

In neurosurgical approaches there is always a high risk of injuring healthy brain tissue approaching a lesion and therefore minimal invasive techniques have been developed. Even when minimal invasiveness is feasible the effectiveness of a procedure can suffer when the preoperative planning is not adequate [1]. Neuroendoscopy is a method, which offers minimal invasiveness but because of limitations, such as decreased visibility and limited movement freedom with the endoscope to name a few has a limited number of indications.

Since 1985 neuroendoscopy became increasingly popular and the reason of such popularity is technical achievements which allowed neuroendoscopy to perform huge leaps. Nowadays intraventricular tumors, hydrocephalus occlusus, intracranial cysts belong to the standard indications of neuroendoscopy [2-4].

Apart of the standard indications other pathologies which can be accompanied by high risk of bleeding such as cavernomas, are removed endoscopically [5-9]. Especially neuroendoscopical tumor surgery is very challenging, because of a high bleeding risk [10,11].

One of the obstacles in neuroendoscopy is the limited potential of coagulation when bleeding occurs. In cases of an acute intraventricular bleeding in which the visibility is completely lost, a so called "red-out", coagulation of the bleeding vessel becomes impossible and such a bleeding can be in some cases fatal [12,13]. Studies showed that even a dilution of blood in Ringer´s solutions of 1:101 could lead to a significant decrease of visibility for endoscopic procedures [14]. Since the endoscopic approach is through a small trephination the alternatives to manage a bleeding are essentially bipolar coagulation, compression with a fogarty-catheter and rinsing.

Bipolar coagulation can only be used in cases the visibility is not completely lost since blinded coagulation into the ventricle can have deleterious effects. Some authors recommend prophylactic bipolar coagulation of vessel around cysts or on the floor of the 3rd ventricle to avoid a red-out [15].

A fogarty-catheter can only be used when compression of the vessel between the catheter and an anatomical structure is given.

The only possibility to stop bleeding in cases of red-out until now is extensive rinsing to dilute the amount of blood in the ventricle and to await the physiological hemostasis. A real bleeding intervention is not given by rinsing.

Navigational systems become more and more popular in neuroendoscopy today. The VN-System has been developed to increase the options and to improve endoscopical procedures [16]. Especially in cases of red-out, the VN-System replaces the real image with a virtual endoscopic image which was created by the transmission of endoscopic images during the procedure.

The aim of the present study was to develop a semibiological model for the application of the VN-System concerning the effectivity of red-out-mode. Following factors will be studied: reproducibility of

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the experiments, applicability on animal models or even substitution of animal models. Different Software modes and techniques as well as different experimental conditions will be used and statistical evaluation to compare the different parameters will be done. The main aim is localisation of a bleeding source and coagulation. The factors, which we are going to analyse in the results, are: precision, time until bleeding source is found and stopped, relation of time until bleeding source is found and precision.

Material and Methods

VN-system

The VN-system is assemblied by a PC with a Windows NT workstation and the VN-Software (Version 2.0) as described previously by Scholz et al. [16], a position detecting system (OPMS, Philips, Eindhoven, Netherlands) a camera stand and a stare lens endoscope (5.9 mm, Type Camaert; Wolf, Knittlingen, Germany) which bears 3 LEDs on it. The endoscope was previously calibrated in order to connect every image point exactly to a 3D point in space. The VN computer stores the 3D coordinates of the endoscope together with the image at the distinc position. The endoscope is connected to a cold light source. For bipolar coagulation an electrocoagulation fiber (2.0 mm, Wolf, Knittlingen, Germany) with a milimeter labelling on its shaft was used. The position of the coagulation fiber can be registered by the surgeon by the help of a graphic overlay in the previously stored virtual image. The current power used was 15mA and the coagulation time was standardized on 1 sec. Currently the VN-System is relatively cheap because only a normal computer or laptop is needed equipped with the mentioned software. LEDs and a position measurement system are used which can be taken or bought second hand also from older navigation systems. These position measurements are included in our days in many computer games.

Simulation model

For the present study a semibiologic model has been developed. In this model a slice of ham was sewn on a mesh, which was placed in a two sides accessible tube (Ostendorf, Vechta, Germany). The meshes with the ham build the semibiologic membrane. The down side of the mesh was isolated by a plastic layer and the upper compartment of the tube was filled with 200 ml of fluid to imitate a fluid filled intracranial space. Different angulations of the tube allowed the angulation of the semibiologic membrane of 0°, 15° and 30°. The tube system was fixed on a table and was vibration free. The down side of the mesh was accessible and could be punctured and penetrated. The endoscope stand as also fixed on the table. Supplementary Figure 1A and 1B illustrates the semibiologic membrane model.

To measure the distance intracavitary a millimeter scale (0.5 mm scaling, 1 cm^2, transparent) is used allowing a precision of 0.25 mm.

Experimental design

The procedure for every experimental cycle was standardized. First a landmark in the operation field has been identified. The endpoints of a sutured cross on the membrane were used as such landmarks (suture with Dagrifil®; Aesculap, Tuttlingen, Germany). Supplementary Figure 2 shows the real endoscopic image of such a landmark (on the VN-system screen). The landmark had to be easily identified on the homogenous membrane to allow imitation of an anatomical landmark. The marked point on the membrane was chosen by clicking on the point (on the screen). Automatic tracking identified and saved the point as landmark.

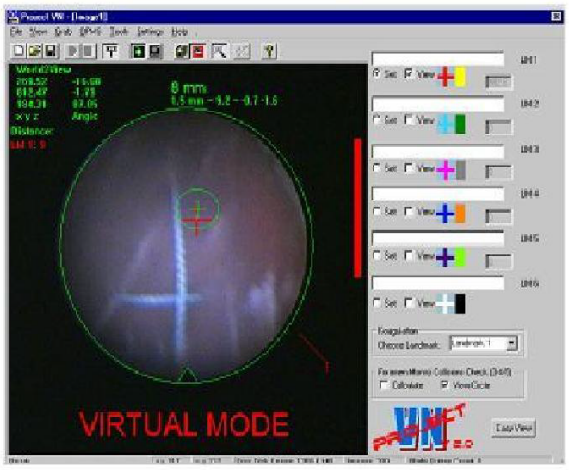

Figure 1: Virtual mode of endoscopic image
Landmark is identified by the red cross, the coagulation fibre position with the green cross. The distance to the surface if given over the endoscopic image with 8 mm.

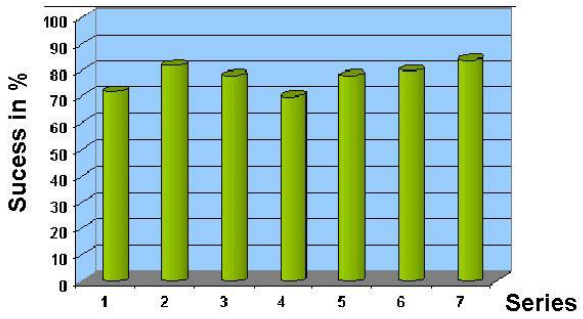

Figure 2: Success rates of all experimental series.
There were no statistical significant differences between the success rates of coagulation in the different series.

After choosing a landmark the endoscopic images are saved for at least 1 min in the VN-software. The VN-software records images at a frequence of maximum 8 images/sec (in our experiments 4 images/sec for 60 sec). The number of saved images over 1 min were adequate enough to allow working on the virtual mode of the VN system.

The saved images were used by switch to the virtual mode of the program. Since the positional data of the endoscope were given by the LEDs the virtual mode of the VN system showed the image, which was the latest saved one to the actual endoscope position. In the virtual mode the position of the coagulation fibre was brought over the position of the chosen landmark (Figure 1). The distance of the coagulation fibre to the surface was given by the software in mm and the fibre could be moved into the depth with the help of the mm scale on the coagulation fibre. After coagulation we measured the distance of the epicenter of the coagulated area to the chosen landmark.

Experimental series

The landmark can be chosen automatically after injecting red ink into the tube system. The blur of vision leads to a change of the VN-system mode from real to virtual. In the manual mode the mode of the VN system from real images to the virtual images, which are saved

is switched without adding red ink to the tube but only by manually switching the mode on the VN-software. The experiments were all done by a single person (first author), which was a student of the last author and was trained by him extensively prior to the experiments.

We decided to do 7 different experimental series. Every cycle was repeated 50 times.

The series were:

1. Direct choice of a landmark. In the VN-software a landmark on the membrane has been chosen. This is the landmark, which has to be found and coagulated after switch in the virtual mode. The landmark was chosen automatically be one click on the screen from only one endoscopic position.

2. Similar to series 1 with exception of the landmark identification technique. The landmark was identified by pointing to it 3 times from 3 different endoscopic positions.

3. In contrast to series 1 and 2 the chosen landmark in series 3 is not the point of the virtual bleeding. Here we have chosen a "safety" landmark in the area around a possible bleeding spot. Therefore the coagulation fibre after switch to the virtual mode is not aiming the chosen landmark but has a new target which is the virtual bleeding spot. Standardized we used as a virtual bleeding spot the first end of the sutured cross in a clockwise direction. One click identification of the landmark.

4. Similar to 3 but again identification of a landmark from 3 different endoscopic positions.

5 and 6. Similar to series 2 the experiments in series 3 and 4 were repeated in a membrane angulation of 15° and 30° to the horizontal plane.

7. The last experimental cycle simulates a real bleeding situation. Red ink is injected to the tube after chosing a landmark, followed by an automatic switch to the virtual mode.

The difficulty of this series is that the bleeding time point has to be recorded in order to identify the bleeding spot. In cases the bleeding spot is not identified (i.e. when the bleeding occurred outside of the endoscopic field), coagulation is impossible.

Evaluation

Data Analysis

In all experiments we evaluated the following data:

t(s): time from switch to the virtual mode until coagulation

d(mm): distance from the bleeding spot to the coagulation epicentre

ed(mm): estimated distance of the coagulation fibre to the membrane surface.

The coagulation fibre has a diameter of 2 mm. With the used current of 15 mA the diameter of the coagulated area is 2 mm. Therefore a d <1 mm indicates a successful coagulation whereas a d ≥ 1 mm indicates a failed coagulation.

The values of t and d are measured by the user whereas the ed value is measured by the VN-Software and is given on top of the virtual mode image.

For the purpose of failure analysis problems which occurred during the experimental cycles were documented.

For every experimental coagulation 4 images on the software screen had been saved (Supplementary Figure 3):

1. identification of the landmark (l m)

2. correlation of the coagulation fiber with the target (vm)

3. coagulated area in the real image mode (ko)

4. measuring the distance d with millimeter scale (messen)

Statistics

The following parameters were included in the statistical analysis

- analysis of success- and precision rate

- analysis of the needed time (t) for coagulation. Creation of learning curves

- analysis of the distance (d) in a box-and-whiskers plot

- correlation of d and t

The statistical analysis had been performed with the program SPSS® (Version 11.5.1).

Results

Analysis of Success-and precision rates

For every experimental series the precision rate was evaluated (Figure 2). The success rates of the coagulation were between 70-84% with a mean of 77% for all the experiments. The most successful series was series Nr. 5 with a real bleeding simulation (84%).

The statistical analysis of the success rate of the series compared to each other has been done by a chi-square analysis.

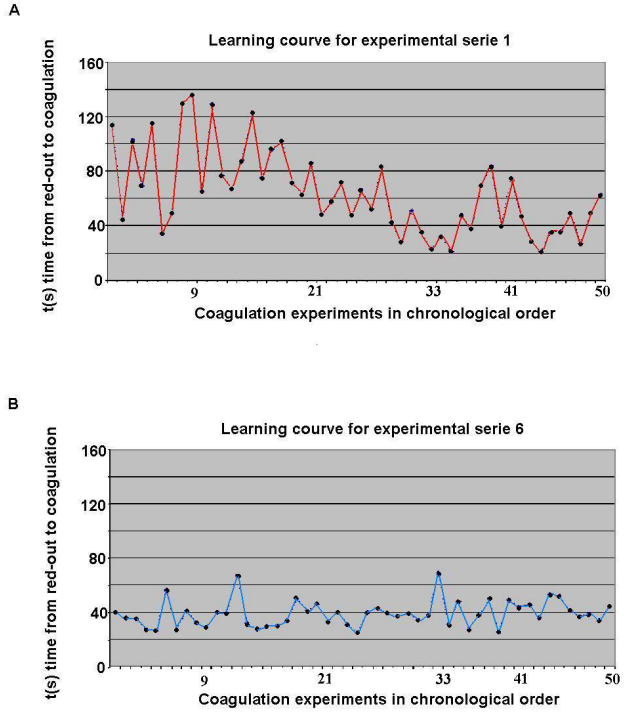

Figure 3: A. Learning curve for experimental group 1
B. Learning curve for experimental group 6.

The comparison of the automatic ("one click") identification of a landmark to the manual ("3 clicks") identification was used to compare the new version of the VN-System (Version 2.0) to the old version which used the "3-clicks" marking, by specifying the landmark form 3 different endoscope positions. Aim of this comparison is to evaluate if the landmark identification method plays a crucial role in the success of coagulation. The differences between the success rates between the groups 1 and 2 as well as 3 and 4 were not statistically significant.

The direct identification of a landmark as bleeding spot and the coagulation of a virtual bleeding spot after specification of a "safety" landmark were compared in matters of coagulation success (Series 1 and 2 compared to 3 and 4). There was no statistical significant difference between these groups indicating that the choice of a safety landmark does not influence the success rate of the coagulation.

The membrane angle is changed to 15° or 30° to the horizontal (series 5 and 6) was compared to the series 1-4. No statistical difference could be seen indicating that the different angle of the membrane does not influence the success rate of the coagulation.

Series 7 is simulating a real bleeding situation. A "safety" landmark is specified and the bleeding spot is randomised in some area of the endoscopic visual field. The distance of the bleeding spot to the "safety" landmark is also random. Because of the given situation we though that the success rate would be lower in this experimental series but to our surprise this group showed the highest success rate with 84% (no significant difference).

Coagulation experiments in living animals showed that even when the distance of the coagulation epicentre is 1.5-2 mm from the bleeding spot coagulation of the bleeding source was still possible [17,18]. This observation lead to an expansion of our success definition to a $d \leq 2$ mm. Expansion of success definition to a $d \leq 1.5$ mm resulted in 84.6% success rate and if d was ≤ 2 mm only 11 of 350 experimental procedures failed the target of > 2 mm. If the new defined success includes a $d \leq 2$ mm the success rate increases to 96.9% (339 of 350).

Analysis of time needed to identify and coagulate the bleeding spot

The learning curve correlated to the time needed from bleeding start (i.e. switching to virtual mode) until finding and coagulating the bleeding spot. The development of the learning curve and the operational experience is illustrated in the figures showing a time reduction between the first experiments of a series and the last ones. Figure 3A shows the learning curve for group 1. The first 15 coagulations in this group were longer than the rest. The mean time needed to coagulate the bleeding spot was X(t1-15)=89.53 sec. For the rest of the coagulations in group 1 the mean time was x (t16-50)=53.17 sec. After 15 coagulations the mean time needed to coagulate a bleeding spot was reduced for 36.36 sec. For comparison the learning curve of group 6 is illustrated in Figure 3B. It is clearly shown that after 6 experimental cycles the huge variations in the group were reduced and that the time for coagulation was even shorter. The mean value for group 6 was x (t1-50)=38.92 sec. The needed time could be reduced for additional 14.25 sec compared to the time of coagulation of 16-50 in group 1. In summary, the mean time used to find and coagulate a bleeding spot was 48.23 sec. In the series 4-6 without a real bleeding simulation the mean time was about 39 sec.

In the 7th group the time to coagulation increased again to X (t1-50)=62.76 sec. Although the time was increased in the first 11 experimental coagulation (x (t1-11)=87.45 sec) it could be reduced effectively in the rest of the experiments (x (t12-50)=55.79 sec.

After observation of the time reduction in the learning curves we wanted to investigate if the time reduction is statistically significant. Univariate analysis with F-test had been performed. We choosed the Bonferroni-Holm post-Hoc-test and the calculation had been performed with SPSS®.

The statistically analysis showed that there were significant differences in the time from red-out to coagulation between groups 1 and 7 and not between groups 2-6. The groups 2-6 represent a plateau phase in the learning curve.

Analysis of the distance d(mm)

The analysis of the precision measured by the distance of the coagulation epicentre to the bleeding spot (d(mm)) is also important. In summary the mean d value for all experiments was 0.81 mm (in the successful experiments d mean value=0.57 mm, in the failed ones d=1.65 mm). Even when the mean values do not show extreme differences between the experimental groups there were some values which deviated extremely from the mean. Therefore a box-plot-diagram had been created too which is shown in Figure 4. In the box-plot-diagram there was still the impression that there were no differences between the d in the experimental groups.

In the statistical analysis with F-test (post-Hoc and Bonferroni-Holm for multivariate analysis) no significant differences between the experimental groups could be seen.

Analysis of correlation between time t(s) and distance d (mm)

Aim of this analysis was to evaluate if a shorter time was correlated with a greater d implicating that a failure could correlate with a hasty procedure. On the other side a longer t could correlate with procedural difficulties which could also correlate with a greater d. The analysis of the correlation between d and t aims in objectifying the experimental results. The linear correlation of both parameters (positive or negative) is of interest. Supplementary Figure 4 shows the scatter plot, which had been calculated for t and d. There is no linear correlation between the 2 values. The values are grouped in a cloud and a line cannot be drawn. A further statistical analysis (Pearson-Correlation coefficient) was not necessary since the scatter plot failed to demonstrate a correlation.

Discussion

Since the indications of neuroendoscopical procedures are broadened in the last decade the endoscope is improved technically. Complementary navigational systems have been developed to deal with complications like intraventricular bleeding etc. [19,20]. In the present work we tested the VN-system in matters of the red-out mode. To test the VN-system a model was developed to imitate a bleeding situation and to avoid animal studies.

Most neuronavigational systems use preoperative CT or MRI data (Vector Vision®, BrainLab). The precision of the systems is <3 mm and therefore very good [21]. In a cadaveric study navigational endoscopy to the prepontine cistern showed a deviation of 5.24 mm and in another study for clipping of distal arteria cerebri anterior aneurysm the deviation was 0.5-1.5 mm (mean 0.88 mm) [22,23]. In summary the neuronavigational systems allow a satisfying precision and orientation even in the absence of anatomical landmarks which allowed endoscopic surgeries in cysts [24,25].

In cases of a bleeding during an endoscopical procedure rinsing was the less risky intervention. Never the less it could be shown that toxic effect like fever, cephalgias caused by meningeal irritation occurred. Additionally extensive rinsing changed the CSF values of

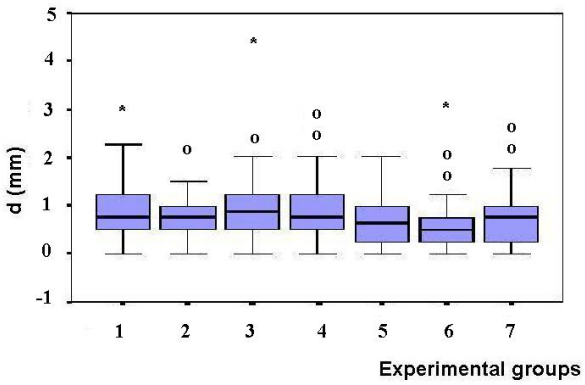

Figure 4: Box-plot diagram of the d values in mm
The median is given as a horizontal black line. The box gives the values between the 25th and the 75th percentile. The biggest and lowest are given as whiskers and the extreme values which are 3 times greater than the boxes are simbolized by * and values which are 1.5 times greater than the boxes are simbolized by O.
The values were calculated with SPSS®.

pH, Oxygen and other parameters [26]. Increased intracranial pressure with a complicating postoperative course as well as hyperthermia (in children) could occur too [27-29]. Especially in cases where extensive rinsing is performed brain herniation can lead to a patient's death if a second endoscopic channel is occluded. Fabregas et al. suggest the application of an intraventricular pressure monitor during such procedures [28,29].

Irrespective of new procedures and developments in neuroendoscopy a perfect visibility is essential in neuroendoscopy. The development of new techniques which could use a precise coagulation in cases of red-out is important for the further introduction of endoscopy to other fields especially tumor surgery or identification of anatomical details and cranial nerves [5,19,30].

The developed semibiological system proved itself as a good training model with a steep learning courve. The precision rate of the VN-system used in the present work is comparable to that of the established ones (d = 0.81 mm (0.44-1.88 mm) vs. 2.1 mm (0.4-3.1 mm) [31].

There is different CT- and LED- based neuronavigational systems in application, especially in nasal sinus surgeries. The application of LED-based neuronavigation has a number of advantages like the waiving of pre-operative MRI-data for neuronavigation to name one [32].

The precision and therefore "success" definition for a $d \leq 0.5$ mm was very stringent chosen. In animal experiments it could be shown that coagulation in a distance of 1.5-2 mm from the bleeding spot coagulation was successful in 8 out of 9 animals [17,18]. The main question for the future will be if neurosurgeons are able to interact in a described man-machine interaction using software for difficult tasks. Operation will become a multitasking action; therefore robotic steering of the coagulation fibre or e.g. aiming to the landmark by robotic assistance could probably improve the system and enable shorter coagulation times [22,33,34].

Conclusion

In summary we can conclude that the VN-software is a valuable tool in real-image-navigation and could be used in addition to the already established CT- and MRI-based neuronavigational devices. Especially in a red-out situation the visual-mode of the program can be used without influencing the procedural freedom of the surgeon but robotic assistance would be the next project undertaken by our group. The future will show how valuable the software will become in real surgery.

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