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A single-port operator-controlled flexible endoscope system for endoscopic skull base surgery

Endoscopic surgery has become a standard tool in head and neck surgery for the treatment of various anterior skull base lesions, such as benign and malignant tumors, as well as traumatic, spontaneous, and iatrogenic fluid leaks [11, 18]. The development of sophisticated surgical techniques together with local or free tissue transfer ensures the efficient closure of even large skull base defects [2, 7]. At the same time, transoral robot-assisted surgery (TORS) has gained significant importance in head and neck surgery, with oropharyngeal tumors being the main indication [1]. Since TORS has been approved by the FDA in 2009, multiple other indications in the head and neck region have been identified, including partial laryngectomy [5], tumors of the parapharyngeal space [12], glottic surgery [13], transaxillary thyroidectomy [19], retro-auricular neck dissection [9], and submandibulectomy [3]. However, for skull base surgery, preliminary results with the clinically available robot systems are not satisfying, as summarized by Trevillot et al. [22]. Therefore, new developmental input is strongly needed, and alternative robot systems potentially available for skull base surgery are still being evaluated in preclinical stages: (a) Schneider et al. [16] presented a concentric tube continuum robot taking advantage of an ultra-small diameter for an endonasal approach of one single instrument. (b) Wurm et al. [23] developed a prototype of a fully automated robot, which was used for sphenoidectomy only. (c) Xia et al. [24] provided a surgical robot for skull base surgery, which worked independently in predefined safe areas of the skull base. However, to date

none of the systems has been available for clinical use because requirements for safety, precision, and user friendliness are very demanding [22].

The Medrobotics Flex[®] System is currently being developed for physician-assisted surgical approaches in the head and neck region, and detailed descriptions of the system have been previously published [4, 14]. Of note, the presented tool is not a robotic system, as it does not perform any automated procedures. It is rather an operator-guided computer-assisted endoscope, for which the surgeon always stays in control during the whole procedure. Recently, the system was successfully tested for the transoral approach to the pharynx in a clinical setting treating a patient with oropharyngeal cancer [17]. The Flex[®] system received the CE mark in May 2014 and is available for the treatment of patients even outside of clinical studies. The set-up of the system in the operating room and the handling of the flexible instruments are shown in **Fig. 5**. In the present study, the advantages and limitations of skull base surgery using the Flex[®] System are investigated in a preclinical cadaver study.

Materials and methods

Description of the Flex[®] System

The Flex[®] System contains a console with touchscreen display, a blue base translating electronic signals into mechanical movements, and a flexible endoscope (**Fig. 1a**). The endoscope covers a three-dimensional working space and has a flexibility of 180°. The tip of the flex-

ible endoscope consists of a high-definition (HD) digital camera and six light-emitting diode (LED) sources. One working channel in the inner lumen is used for the lens washer system. The diameter of the tip is 15×17 mm. Two working channels attached to both sides of the flexible endoscope enable delivery of two independent flexible tools directly to the working area. Once introduced into the working channels, instruments show good triangulation in the virtual operation field. Changing of instruments required a maximum of 1 min. Instruments that are currently available for the Flex[®] System include a fenestrated grasper, Maryland dissector, needle holder, laser guide, monopolar spatula, and monopolar needle knife. Instruments can extend 2 cm beyond the camera in the flexible endoscope (**Fig. 1b**). Intraoperative pictures are delivered by the HD digital camera in the endoscope tip directly to a touchscreen, which is operated by the surgeon at the patient's head. Compared to previous studies, the Flex[®] System camera was exchanged for a camera with HD visualization. A representative screenshot of the intraoperative imaging is shown in **Fig. 1c**. The touchscreen allows for selection of the moving modality of the endoscope including quick forward, fine mode, retraction, and automatic retraction in the bottom center section of the screen. The distance travelled by the flexible endoscope is displayed by a green bar on the right side of the screen with the maximum length being 17 cm. The flexible endoscope's shaft itself is moved by the surgeon using a 3D joystick as previously described (**Fig. 1d**).

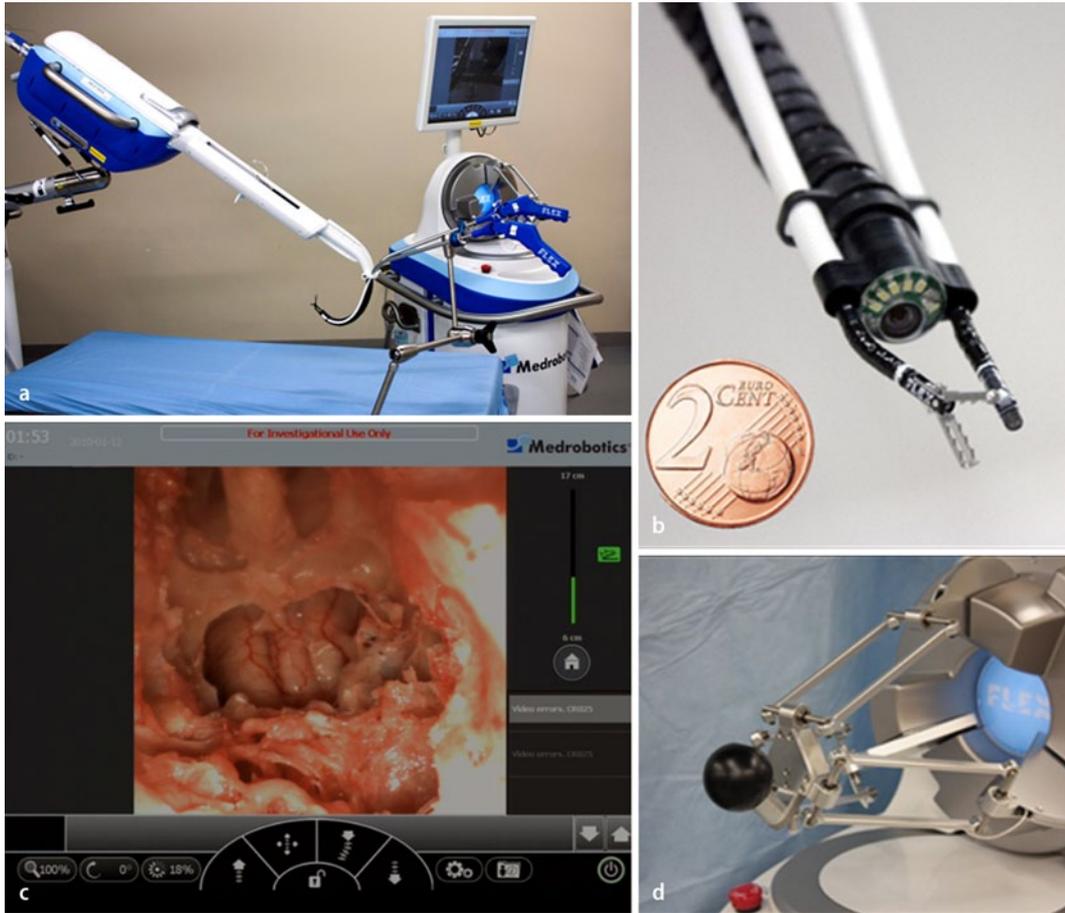


Fig. 1 ◀ **a** The Flex® System contains a console with touchscreen display, a blue base translating electronic signals into mechanical movements, and a flexible endoscope. **b** The tip of the flexible endoscope enables visualization of the surgical field as well as delivery of two compatible surgical instruments for surgical manipulation through two separate working channels. **c** Intraoperative pictures are delivered by the HD camera in the endoscope tip directly to a touchscreen. The center bottom of the screen features various buttons to select the moving modality of the Flex® System. The distance travelled by the endoscope is displayed on the right side of the screen. **d** The flexible endoscope's shaft itself is moved by the surgeon using a 3D joystick



Fig. 2 ◀ **a** The most suitable approach for the Flex® System is the modified midfacial degloving. **b** Parts of the nasal septum and the maxillary frontal recess are resected. Medial turbinectomy is performed bilaterally in order to improve access to the skull base. **c** The tip of the endoscope is introduced into the nasal cavity for visualization of the skull base. **d** Compatible flexible instruments are guided to the skull base by working channels attached to both sides of the Flex® System

Cadaver studies

Four fresh frozen human cadavers were available for preclinical evaluation of the Flex® System. Each specimen used for surgical procedures consisted of a head and neck attached to the upper torso. All relevant anatomy was found to be intact without obvious malignancies upon inspection. Adult human specimens were placed in the supine position on the operating table without the use of headpins. The flexible endoscope was mounted to the surgical table rails and arranged to approach the oral cavity from the caudal direction as previously described [15]. Midfacial degloving was then performed including a bilateral vestibular incision with subperiosteal dissection. The circular intercartilaginous incision of the nostrils was followed by complete degloving of the maxilla and the nose until the nasal cavity was adequately exposed. The L-shaped anterior–dorsal frame of the nasal septum was preserved to allow for stability within the later septal reconstruction, while the rest of the septum was removed in order to create the space necessary for introduction of the Flex® System's endoscope. In cases where septal mucoperichondrial flaps are needed for skull base reconstruction, flaps could be harvested before midfacial degloving. The Flex® System was then introduced in the nasal cavity for further preparation. Complete control of the flexible endoscope was obtained by the surgeon, maneuvering it into the most favorable position with a joystick. Once the flexible endoscope had been docked in the desired position, the surgeon inserted compatible flexible endoscopic instruments into the external accessory channels to perform the procedure of interest. Surgical procedures of the bony sinus system and the skull base were currently performed with nonrobotic standard rigid instruments being assisted by the Flex® System's visualization system. Anatomical landmarks were then reached using compatible flexible instruments, e.g., 3.5-mm grasper forceps and Maryland dissector.

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A single-port operator-controlled flexible endoscope system for endoscopic skull base surgery

Abstract

Objective. In a human cadaver study, a single-port operator-controlled flexible endoscope (Flex® System), facilitated with a high-definition camera and two accessory channels was tested for skull base surgery.

Design. Skull base surgery was performed on human cadavers ($n=4$) using the Flex® System. A modified surgical midfacial approach, performed by rigid standard tools, was used for access to the sinus system, the skull base, and the middle cranial fossa.

Results. Endoscopic skull base visualization with the Flex® System is feasible. Surgical procedures performed included extended sinus surgery, anterior skull base approach, and vi-

sualization of the brain stem in the posterior cranial fossa. Important landmarks of the anterior skull base were visualized and manipulated by flexible compatible tools.

Conclusion. The Flex® System allows for manipulation of the anterior skull base and visualization of the posterior cranial fossa in a preclinical setting. Further studies as well as development of supplemental tools are in progress.

Keywords

Skull base · Flexible endoscope · Camera · Brain stem · Transoral robot-assisted surgery

Flexibles bedienergesteuertes Single-Port-Endoskopsystem für die endoskopische Schädelbasischirurgie

Zusammenfassung

Ziel. Im Rahmen einer menschlichen Kadaverstudie wurde ein flexibles bedienergesteuertes Single-Port-Endoskopsystem für die endoskopische Schädelbasischirurgie (Flex®-System), das mit einer hochauflösenden Kamera und 2 Zusatzkanälen ausgestattet war, für die Schädelbasischirurgie getestet.

Studiendesign. Schädelbasisoperationen wurden an menschlichen Leichen ($n=4$) mit dem Flex®-System durchgeführt. Ein modifizierter chirurgischer Zugang zum Mittelgesicht mit starren Standardinstrumenten diente dazu, die Sinus, die Schädelbasis und die mittlere Schädelgrube zu erreichen.

Ergebnisse. Die endoskopische Darstellung der Schädelbasis ist mit dem Flex®-System machbar. Zu den durchgeführten operativen Maßnahmen gehörten eine ausgedehnte Si-

nusoperation, der Zugang zur vorderen Schädelbasis und die Darstellung des Hirnstamms in der hinteren Schädelgrube. Wichtige Landmarken der vorderen Schädelbasis wurden dargestellt und hierzu geeignete flexible Instrumente eingesetzt.

Schlussfolgerung. Das Flex®-System ermöglicht in einem präklinischen Rahmen das Operieren an der vorderen Schädelbasis und die Darstellung der hinteren Schädelgrube. Derzeit wird an weiteren Studien sowie an der Entwicklung ergänzender Instrumente gearbeitet.

Schlüsselwörter

Schädelbasis · Flexibles Endoskop · Kamera · Hirnstamm · Transorale roboterassistierte Chirurgie

Results

Cadaver studies

The midfacial degloving approach allowed for adequate visualization of the sinus system and the skull base (■ Fig. 2a). The anterior segments of the Flex® System were introduced into the nasal cavity after partial removal of the nasal septum and bilateral maxillary frontal process (■ Fig. 2b). The HD camera system was then used for visualization of subsequent procedures taking advantage of the

flexible endoscopic shaft. The focus of the camera lens was set to 27–35 mm, which is acceptable for the procedures performed. The maxillary sinus was accessed by flexible instruments after medialization of the medial turbinates and removal of the processus uncinatus (■ Fig. 3a). Medial turbinectomy was then performed bilaterally in order to obtain a wide access to the skull base. The functionally relevant bone of the inferior turbinate was preserved. In one case, the medial turbinates were spared for skull base reconstruction by local turbinate flaps as previously described by

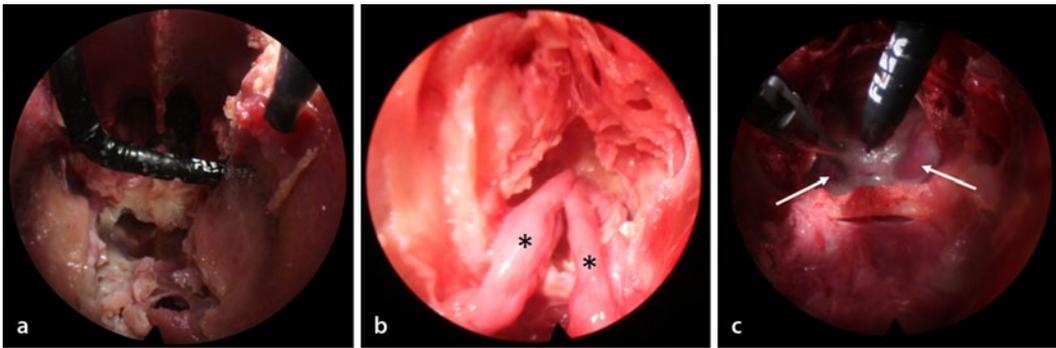


Fig. 3 ▲ **a** After resection of the nasal septum and the middle turbinates, the compatible flexible instruments are easily introduced into the right maxillary sinus via its natural opening. **b** In one case, both inferior turbinates are spared for skull base reconstruction by local turbinate flaps. During the surgical procedure the turbinate tissue was re-located into the nasopharynx. **c** Anatomical variation of the sphenoid sinus. A flexible Maryland dissector (*left*) and a flexible needle knife (*right*) are introduced into the sphenoid sinus after resection of the bony sphenoid septum. In this cadaver, both internal carotid arteries are freely visible (*arrows*). The bony cover in the lateral wall of the sphenoid sinus is not developed

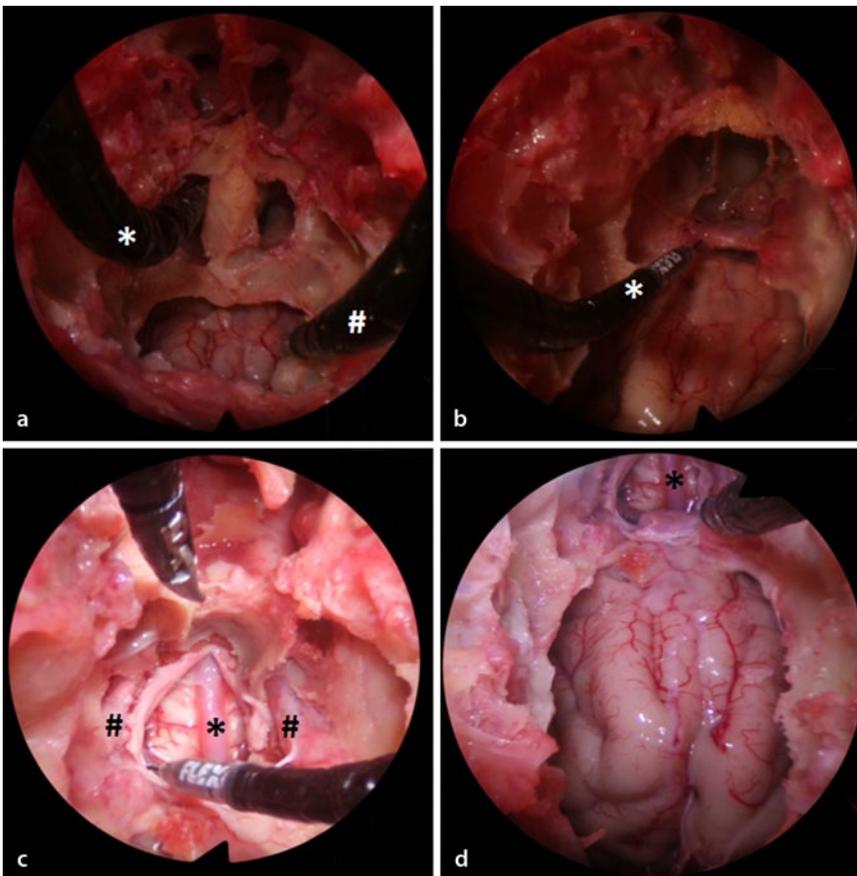


Fig. 4 ▲ Stepwise resection of the skull base. **a** After complete ethmoidectomy, the sphenoid sinus is opened up and the left sphenoid cavity is entered by a flexible grasper (*). The second flexible tool (#) touches the right frontal lobe of the brain after partial removal of the skull base. **b** The roof of the sphenoid sinus is completely removed offering free view of the pituitary gland touched by the tip of a flexible needle knife tool (*). **c** After resection of the clival bone and vertical incision of the dura mater, the basilar artery (*) passes over the brain stem. The internal carotid arteries (#) are located to each side of the brain stem. Instruments touch the floor of the sphenoid sinus and the dura mater on the left side. **d** The frontal lobe including superficial vessel formation is seen after resection of the complete skull base. The basilar artery (*) is displayed at the *top*

Yip et al. ([25], **Fig. 3b**). After complete ethmoidectomy, one cadaver displayed a rarely observed unprotected inner carotid artery missing the lateral bony walls in the sphenoid sinus (**Fig. 3c**). In other cases, complete ethmoidectomy was followed by bilateral sphenoidectomy through the natural sphenoid ostium (**Fig. 4a**). The anterior skull base and the roof of the sphenoid sinus were then carefully removed displaying the pituitary gland and the underlying optic chiasm (**Fig. 4b**). Finally, the posterior cranial fossa was approached after removal of the clivus displaying the basilar artery and the caudal sections of the inner carotid arteries (**Fig. 4c**). The frontal lobe including superficial vessel formation was seen after resection of the complete skull base (**Fig. 4d**). For proof of principle, all described structures were reached and touched by compatible flexible instruments. All relevant anatomic landmarks of the skull base were in comfortable reach of the compatible flexible instruments. Also, despite their small diameter of 3.5 mm, all flexible instruments were very reliable and user-friendly. However, it should be mentioned that the removal of the sinus and skull base structures was performed with rigid nonrobotic instruments as will be further discussed. (**Fig. 5** shows the set-up of the system.)

Discussion

The surgical techniques in skull base surgery have improved immensely in the last decade. In particular, the arrival of endo-



Fig. 5 ◀ Set-up of the complete system in a clinical setting. The console is positioned at the patient's left side, while the flexible endoscope itself is placed over the patient's torso. The surgeon is positioned at the patient's head

scopic instruments in combination with HD screen displays as well as refined procedures for closure of skull base defects by a variety of local and free tissue flaps should be highlighted [7, 18]. However, despite these beneficial developments, a series of pathologies in the sinus system and the skull base are still not accessible by standard approaches and often require an alternative surgical approach, e.g., supraorbital for lateral frontal sinus surgery or retrosigmoid for anterior brain stem surgery. These approaches display certain disadvantages in terms of significantly reduced working space or cosmetic outcome. Development and approval of new surgical tools and techniques with clinical relevance are therefore greatly supported.

The present human cadaver studies evaluated the handling of the Flex® System for endoscopic skull base surgery. In a series of specimens, improved visualization of the skull base was demonstrated, and all relevant anatomical landmarks were shown to be in reach of the compatible flexible instruments. The new HD camera system, which was recently introduced in the Flex® System, produces high-quality imaging that is acceptable even for delicate manipulation in the surgical area. Of note, this work focuses on the new technique and its potential for future skull base surgery. It does not aim to describe a new, readily available, surgical approach.

Currently, there are a variety of compatible instruments available for use in the Flex® System, including Maryland dissector, fenestrated grasper, needle holder, monopolar spatula, and monopolar nee-

dle knife. However, these instruments have been developed for use in the oral cavity and the larynx. They are, therefore, not yet optimized for skull base surgery. In many instances, the dimension of the instrument effectors appears to be too large, and due to the flexible nature of the instrument shaft, support of the instruments seems to be insufficient for bone work. Also, physical limitations seem to interfere with the development of a flexible drill tool. On the other hand, haptic feedback of the instruments is available throughout the surgical procedure, which is a major advantage in comparison to other currently available robotic systems. Whether the level of haptic feedback is sufficient for delicate skull base surgery needs to be determined. However, it should be underlined that despite their very small diameter of 3.5 mm all instruments are highly reliable in their function and are very user-friendly.

Several endoscopic mounts have been specifically designed for skull base surgery [6, 8, 10, 20]. As compared to these pure endoscope mountings, the Flex® System has the advantage that it also serves as a guide for flexible instrument delivery. Since the whole surgical procedure is no longer restricted to the "line of sight," not only the visual field of the surgeon is clearly increased, but also the area that can be reached by surgical tools is greatly extended. Taken together, these advantages enable the surgeon to safely treat several skull base pathologies.

The authors are aware of the fact that the currently used approach to the skull

base by midfacial degloving and partial removal of the septum is quite traumatic and probably not suitable for most surgical procedures. However, the present data are collected from a preclinical study exploring the future potential of a physician-controlled flexible endoscope system for skull base surgery. The observations of this study will help to further develop and improve the Flex® System aiming for clinical application even at highly vulnerable areas, e.g., the skull base. Importantly, despite the temporary partial resection of the nasal septum, a complete reconstruction of the nose is feasible after the surgical procedure is finished. Especially for approaches to the skull base, the complications of bleeding caused by surgical manipulation should be considered when choosing the appropriate instrumentation. Bleeding should be avoided by all means, as simple compression is not a feasible management at this site, but asks for subtle use of coagulation and the use of hemostatic material [21].

Conclusion

The present study underlines the advantages of a computer-assisted flexible endoscope system for clinical skull base surgery. Already today, the Flex® System can improve the visualization of the surgical area by its flexible viewing angle, and all important anatomic landmarks are in reach of the compatible flexible instruments. Extension of the available tool collection and further refinement of the system, which until now was solely developed for larynx surgery, will greatly enhance its use also for skull base surgery.

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Compliance with ethical guidelines

Conflict of interest. P.J. Schuler, M. Scheithauer, N. Rotter, J. Veit, U. Duvvuri, and T.K. Hoffmann state that there are no conflicts of interest.

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Rezeptor VLGR1 ist für Usher-Syndrom relevant

Im Rahmen einer neuen Forschungsgruppe der Deutschen Forschungsgemeinschaft (DFG) untersuchen Zellbiologen der Universität Mainz die Funktionsweise des größten Rezeptors unseres Körpers, des Very Large G protein-coupled Receptor-1 (VLGR1). Der G-Protein-gekoppelte Rezeptor (GPCR) zählt bislang zu der wenig untersuchten Familie der Adhäsions-GPCRs. Während die Funktion klassischer GPCRs bereits recht gut verstanden ist, ist über die Mechanismen, wie in dieser Rezeptorklasse die Adhäsionseigenschaften mit der Aktivierung integriert werden, bisher weit weniger bekannt.

Das Team um Univ.-Prof. Dr. Uwe Wolfrum vom Institut für Zoologie wird die physiologische Rolle von VLGR1 an der Zelloberfläche untersuchen. Dabei sollen die Mechanismen, die zur Aktivierung von VLGR1 führen, sowie die Wege der Signalweiterleitung in der Zelle entschlüsselt werden. Zudem soll die spezielle Funktion von VLGR1 in sensorischen Zilien in Auge und Ohr aufgeklärt werden. Mutationen im VLGR1-Gen führen zum Usher-Syndrom des Menschen, der häufigsten Form erblich bedingter Taub-Blindheit.

Sprecher der Forschungsgruppe "FOR 2149: Elucidation of Adhesion-GPCR signaling" ist Dr. Tobias Langenhahn von der Universität Würzburg. Des Weiteren sind Wissenschaftler der Universität Leipzig, der Universität Erlangen-Nürnberg, der Universität Mainz und der Universität Amsterdam in den Niederlanden beteiligt.

Quelle:

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