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A New Micromanipulator System for Middle Ear Surgery

Thomas Maier, Gero Strauss, Mathias Hofer, Tobias Kraus, Annette Runge, Roland Stenzel, Jan Gumprecht, Thomas Berger, Andreas Dietz, and Tim C. Lueth, *Member, IEEE*

***Abstract*—In this article, a new Micromanipulator System (MMS-II) for middle ear surgery is presented. The purpose of this work was to develop a simple but effective manipulator that would enable the surgeon to move standard surgical instruments in a precise way even under non-ergonomic conditions. The MMS-II is lightweight, small, and easy to use; it requires no PC, besides a small microcontroller-based joystick console. Such features, together with a practicable sterilization concept and the availability of a multiplicity of surgical instruments, allow the system to be used in standard surgical procedures.**

I. INTRODUCTION

Microsurgical interventions at the middle ear are dominated by the small size of the structures that are operated on, such as the malleus, the incus, and the stapes. Hence, the interventions are done with the aid of an operating microscope and of special microinstruments, which are moved manually. The stapedotomy, for example, is an intervention where the stapes is partly removed, a small hole (Ø 0.4 mm) is pierced into the stapes footplate, and a tiny prosthesis (Piston) is inserted (Fig. 1). Under optimal conditions, the human hand reaches a precision of about 0.1 mm [1]. However, the hand's performance is limited by different factors during a middle ear intervention. This includes, for example, limited access to the operational field, adverse hand posture, unsuitable leverage (e.g., large distance between the region of interest and the surgeon's hand), high manipulating forces, instrument weight, [1] and a limited view of the region of interest [2]. Some of the options to compensate for these deficiencies are as follows: a) uninvolved tissue has to be removed, b) optimal trajectory has to be abandoned, and c) complete visual control has to be given up.

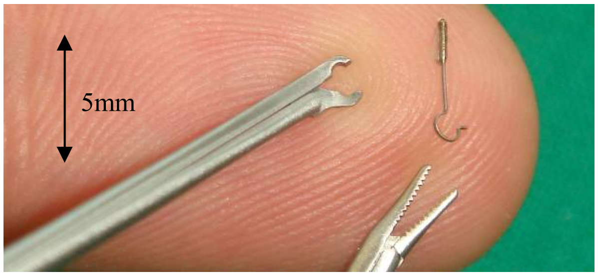

Fig. 1. Stapes prosthesis with forceps for middle ear surgery on fingertip (prosthesis: KURZ, Germany; instruments: Karl Storz, Germany).

Under such difficult ergonomic conditions, the requirements for surgeon's dexterity are especially stringent [3]. Several research approaches assume that mechatronic systems have the ability to improve the current gold standard in microsurgery concerning precision or spatial limitations [3][4]. Robotic systems are discussed in this manner as a possible remedy. For ear surgery, systems based on industrial robots have been developed. Also, experience has been gained with complex manipulators - such as DaVinci (Intuitive Surgical, Inc., USA) [4]-[6]. A microsurgical teleoperated robot (MSR-1), with a virtual environment for, e.g., eye surgery, has been developed by Hunter et al. [7]. In [8]-[10] a microsurgical master-slave manipulator (RAMS) with 6 degrees of freedom (DOF) is presented. With the steady-hand concept introduced by Taylor et al. [11], the surgical tool is held simultaneously both by the surgeon's hand and by a force-sensing robotic arm. The first version had 7 DOF (four linear, three rotational) and was first designed for retinal surgery. In a second version [12], the amount of DOF was reduced to 5, and the system was adapted to the surgical environment. In a study, the steady-hand concept was also used to fenestrate the stapes footplate [13]. Salcudean and Yan [14] and Ku and Salcudean [15] presented a teleoperated, piezoelectric-driven microgripper. Wei et al. [16][17] presented the theoretical design for a two-armed robotic system for ophthalmic surgery with 16 DOF, each based on a 6-DOF parallel robot (Stewart-Gough platform). It has a tip with 2 DOF based on a pre-shaped nickel-titanium (shape-memory alloy) tube. Nakano et al. [18] have developed a miniature parallel robot for eye surgery with 6 DOF. An active hand-held instrument to compensate tremor, based on piezoelectric actuators, was described in [19]. Miroir et al. [20] presented a theoretical approach for a telemanipulation system for middle ear surgery. Three manipulator arms, each with 6 DOF, are

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T. Maier is with the Institute of Micro Technology and Medical Device Technology (MiMed) at the Technische Universität München, Boltzmannstr. 15, 85748 Garching b. München, Germany (phone: +49-89-28915189; fax: +49-89-28915190; e-mail: thomas.maier@tum.de).

T. Kraus, R. Stenzel, J. Gumprecht, and T.C. Lueth are with the Institute of Micro Technology and Medical Device Technology (MiMed) at the Technische Universität München, Germany.

G. Strauss, A. Dietz, M. Hofer, A. Runge, and T. Berger are with the Department of ENT, University Hospital Leipzig, and with BMBF-Innovation Center Computer Assisted Surgery (ICCAS), University Leipzig, Germany.

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supposed to operate simultaneously at the middle ear. The authors assume that a maximum manipulation force of 3N is sufficient in middle ear surgery.

The existing approaches attach great importance to the highest degree of precision in the area of micrometers, especially in systems designed for eye surgery. Although most of these systems are focused on eye surgery, several authors plan to apply them in middle ear surgery too. In middle ear surgery, human-hand precision is generally sufficient; it is, however, partly limited by non-ergonomic conditions. A manipulator used in middle ear surgery potentially does not need a highly complex structure with force feedback, or micrometer accuracy, or a multiplicity of DOF to be effective. A disadvantage of existing systems is the limited availability of different surgical instruments. For the clinical acceptance of a mechatronic system, it is also advantageous if the operational procedures involved do not have to be changed. Hand-held instruments with tremor filter can increase precision but do not change the ergonomic problems. The Micromanipulator System II (MMS-II) was developed to provide the surgeon with a teleoperated instrument. The surgeon's usual dexterity should be assured even under adverse conditions. The system was designed to be helpful in certain clinical tasks and was not meant to execute large parts of the intervention. This limitation reduces the technical complexity to a minimum. The use of standard instruments, the small size of the manipulator, and a feasible sterilization concept facilitate the system's integration into existing surgical procedures.

A. *Current Surgical Setup in Middle Ear Surgery*

Fig. 2 shows an example of a surgical setup in middle ear surgery. The surgeon (Dr. Strauss, Leipzig) (2) sits in front of the patient's (1) head, using a special chair with elbow rest and a microscope (3). On the other side of the operating-room table (OR-table), a surgical nurse (4) and the anaesthetist (5) are sitting.

II. SYSTEM DESCRIPTION

The MMS-II consists of a small manipulator with 4 DOF and a control console with two joysticks. Other than these two components, no additional hardware, like computers, is needed. The overall system specifications are given in Table I.

A. *Positioning in the Surgical Setup*

An important development objective was to offer the possibility of integrating the MMS-II into the existing surgical environment and the usual surgical procedures. Small size is crucially important for the manipulator and controller in view of the limited space on the operating table. The manipulator is mounted next to the surgeon's right or left hand. Alternatively, an installation at a ceiling arm would be possible but has not yet been implemented, for reasons of flexibility. Fig. 3 shows the surgical setup with the manipulator. The surgeon sits at the OR table and observes the operating field through the microscope. The manipulator is attached to the table with a standard clamp. The controller is attached directly in front of the surgeon.

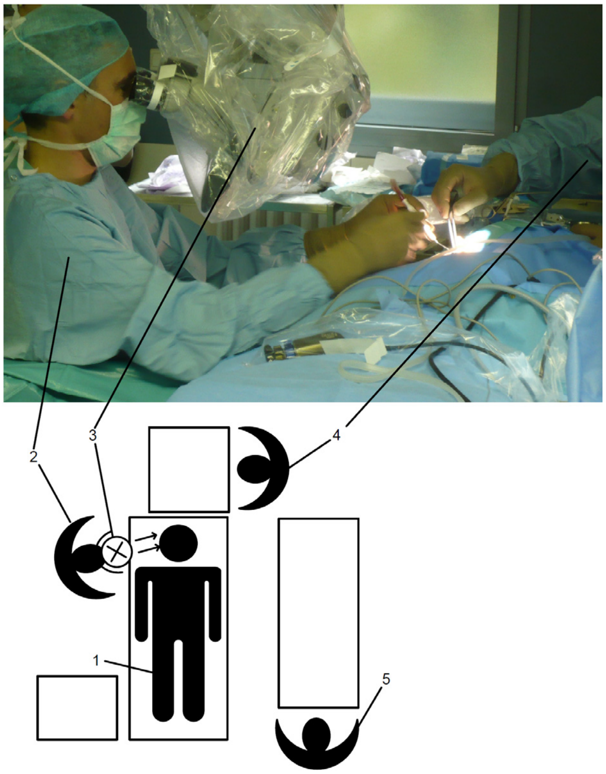

Fig. 2. Example of a surgical setup in middle-ear surgery.

Fig. 3. Surgical setup in middle ear surgery and placement of the MMS-II on the side rail of the OR table.

B. *The Manipulator*

The manipulator consists of an XY-table with a thin vertical Z-axis, a mechanical articulated arm, and an axis for opening and closing an attached forceps. The dovetail guides are made of plastic with the tribological pairing PE-HD and POM for the XY-table and PEEK-POM for the Z-axis. These tribological pairings show a minor stick-slip effect and can be operated under dry condition. The overall setup was designed for small weight. This allows the use of motors with limited performance. An alternative version of the manipulator, made of titan, is currently under construction.

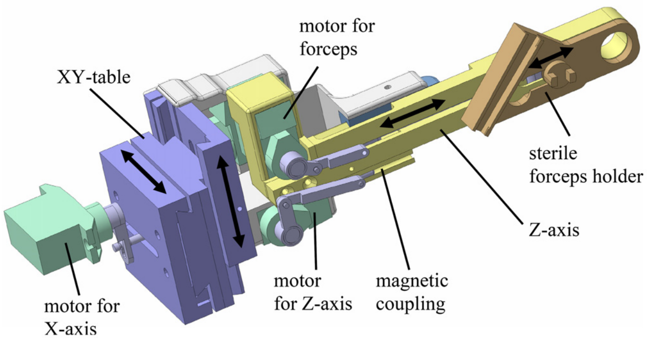

Fig. 4. MMS-II manipulator (without articulated arm, cover and sterile foil).

TABLE I
MMS-II CHARACTERSISTICS

XYZ motion	mm	20
Incremental motion Z	mm	0.029
Incremental motion XY	mm	0.044
Forceps motion θ	degrees	15°
Maximal force XY	N	4
Maximal force Z	N	3
Maximal torque forceps	cNm	20
Top speed XYZ	mm/s	40
Scaling factor	-	1:3.5
Length	mm	200
Base diameter	mm	80
Mass manipulator	kg	1
Mass joystick control	kg	1.5

The guides provide a 20-mm range of operation, which is about equivalent to the scale of the operating field. Servomotors (ACE, Taiwan) are used as drives. The position control of the actuator is carried out internally by an analog servomotor controller (Agamem Microelectronics, Inc., Taiwan). The motor is controlled through a PWM signal. The PWM signal is generated by the joystick console and is transmitted to the manipulator together with the supply voltage. The transformation of the motors' rotary motion into linear motion is done by lever arms. At the XY-table, this is done by a four-link mechanism. Fig. 5 shows the main structure of the kinematics. The motors are placed above or underneath the XY-table in order to minimize the manipulator's diameter. As to the Z-axis, the rotary motion is transmitted through a slider-crank mechanism (Fig. 6). The movement of the Z-axis for the motor angle α is as follows:

$$z = \cos\alpha \cdot l_1 + \cos\beta \cdot l_2 \qquad (1)$$

where

$$\beta = \arcsin\left(\frac{h - l_1 \cdot \sin\alpha}{l_2}\right) \quad , \quad \alpha \in \left]0;180\right[\qquad (2)$$

The movement of the X-axis and of the Y-axis is as follows:

$$x = j \cdot (\tan(90-\gamma))^{-1} \quad , \quad \gamma \in \left]0;180\right[\qquad (3)$$

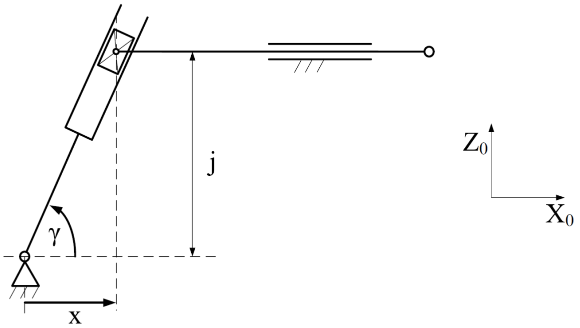

Fig. 5. Four-link mechanism for X- and Y-axis.

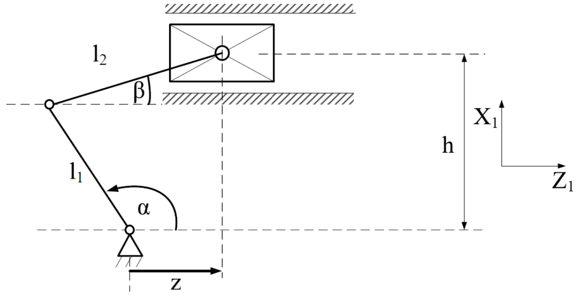

Fig. 6. Slider-crank mechanism for Z-axis and forceps.

Both lever mechanisms provide mostly a linear movement that render compensation unnecessary if the system is used only for telemanipulation (Figs. 7 and 8). The levers are made of slip modified PEEK plastic. The incremental movement of the Z-axis is of 0.029 mm; for the XY-table it is of 0.044 mm, which has proven to be sufficient for the requirements mentioned above. A standard articulated arm (NOGA, Israel) has been used in order to manually align the kinematics with the patient. The articulated arm has 5 DOF, which can be fixed with a central retaining screw. The fixation of the articulated arm at the OR-table rail allows further vertical displacement and rotation.

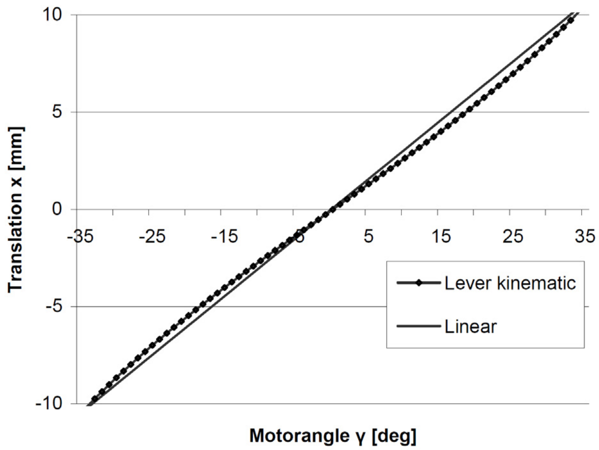

Fig. 7. Movement of the X- and Y-axis.

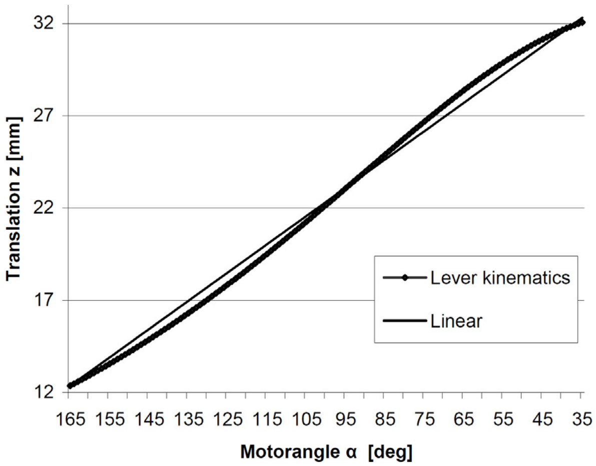

Fig. 8. Movement of the Z-axis.

To open and close the forceps, a movable slider is placed in the Z-axis. The slider is connected to a motor via a driving rod. Again, a three-hinge structure is responsible for the transmission of the motor's rotary motion. The movable part of the sterilizable forceps holder is pressed into the slider through a sterile foil. Thus, it is possible to open and close inserted forceps (Fig. 9).

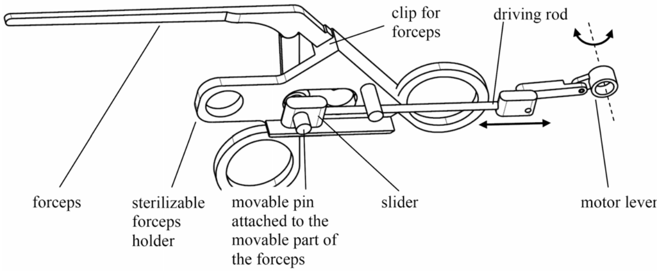

Fig. 9. Slider-crank mechanism with motor lever, connected to the sterilizable forceps holder. The movable pin is pressed through the sterile foil (not shown) into the slider.

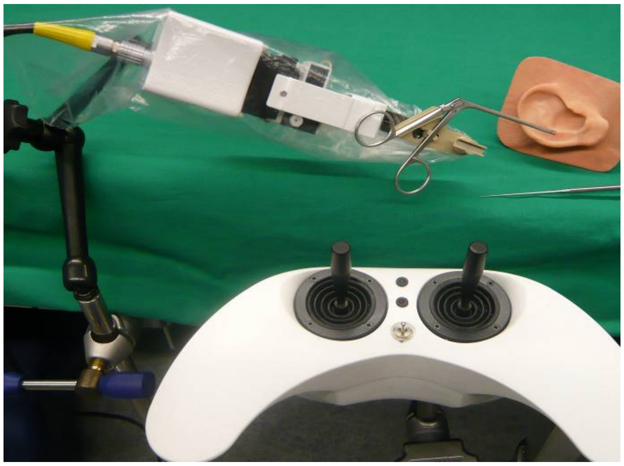

Fig. 10. MMS-II manipulator and controller with inserted forceps at an ear model.

C. Controller

The controller consists of two industrial joysticks, an ergonomic housing with hand rest, a microcontroller, and two medical power supplies. The joysticks (Megatron, Germany) have an electrical rotation angle of 50° at ±1% linearity and have been chosen for their robustness and compactness. A microcontroller (ATMega 2560, 8Bit, 16 MHz, Atmel, USA) was used as a central control unit. The microcontroller has the following functions, among others: watchdog, brownout detection, 10-bit analog-to-digital converters (ADC), pulse-width modulation (PWM) generators, and 8-bit and 16-bit timer. The microcontroller and the motors are supplied with external medical power supplies (SINPRO, Taiwan). A switch located on top of the controller allows the motors to be shut down. The microcontroller reads in the joystick voltages via four 10-bit ADCs, calculates the moving average (with the last four values) to improve accuracy, and proportionally calculates the motor positions. Each joystick axis thereby relates directly to one degree of freedom of the manipulator. Thus, and by avoiding a linearization of the lever mechanism, the computation is very simple. The motors are controlled by pulse-width modulation, and their positions are refreshed at 50Hz. The joysticks' range of motion at the surgeon's fingers and the range of motion of the manipulator axes result in a motion downscaling of currently 1 to 3.5. A 7-mm movement at the joysticks results in a 2-mm movement of the manipulator. An on-chip brownout detection (BOD) circuit controls the microcontroller's power supply and resets it in case of too low voltage. As a result of that, the program sequence is permanently stopped. To prevent system hang-up in case of runaway code, a watchdog is activated. The watchdog has a separate, 128-kHz oscillator and must be updated every 32 milliseconds - otherwise the microcontroller is also reset (Fig. 11).

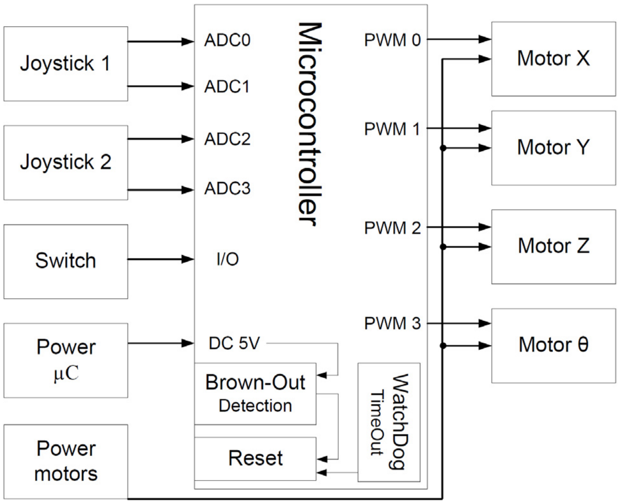

Fig. 11. Control block diagram.

Each joystick position is related to exactly one motor position. If the joysticks are moved while the motors are switched off, for safety reasons the motors must not move to the new position, when the motors are switched on again. To prevent unexpected movements, the motor is moved only if the joystick position and the motor position are matched. Otherwise the surgeon has to move the joysticks to the position where the manipulator is located. There, the axes again click into place. This does not usually occur and has not yet been considered a problem.

D. Sterilization concept and instrument holders

There are two options for using mechatronic systems in the operating room—where the operating field, the surgeon, or other sterile objects could get in contact with them. One option is to cover unsterile systems with sterile foils. In that case, sterile adapters are needed to connect sterile instruments to the system. Another possibility is to make the majority of parts of the mechatronic system sterilizable (sterilizable DC motors and encoders are available). Single-use parts are often sterilized with gas or radiation by the manufacturer. In the clinics, the most common sterilization method for reusable parts is steam autoclavation, whereby the inserted parts are sterilized through several cycles of different pressures and temperatures at saturated steam (e.g., 134°C, 3 bar). Disadvantageous are the high thermal, and thus mechanical, stress of the components and the increased development effort. In our group, a steam autoclaveable robot was presented in [21][22]. To reduce the MMS-II complexity, we decided to use sterile foils to the extent possible and to design only a few sterilizable parts with instrument contact.

At the beginning of the intervention, the MMS-II's manipulator and controller are covered with standard sterile foils. Two sterilizable adapters (instrument holder and forceps holder), made of PEEK plastic, have been developed to hold rod-shaped microinstruments and forceps (by Storz, Germany). The instruments can simply be clipped on. Pins located on the bottom side of the holders are pressed trough the foil (0.05-mm thickness) into holes on the manipulator's Z-axis. The pins and holes are designed so as to cup rather than punch the foil (Fig. 12). The difference in diameter between the hole and the pin defines the holding force. The forceps holder has two 3.93-mm pins, which are pressed into 4-mm holes. This results in an overall holding force of 14N. The instrument holder has one 9.75-mm pin, which is pressed into a 10.00-mm hole, which results in a holding force of 15N. The forceps holder consists of two parts: a stationary basis and a movable slider therein. This allows the opening and closing of the forceps through the sterile foil by a motor attached to the Z-axis.

E. Available Instruments

In all areas of surgery, one can find a huge variety of instruments that have long proven to be valuable. These instruments require practically no optimization of quality, size, or allowable load, particularly since surgeons have become accustomed to them. Therefore, our approach was to make use of standard instruments. As a starting point, we used a set of middle ear surgery instruments manufactured by Storz (Germany). Fig. 13 shows an assortment of instruments for the MMS-II. Currently, these are rod-shaped instruments, such as probes, knifes, and perforators as well as forceps and scissors.

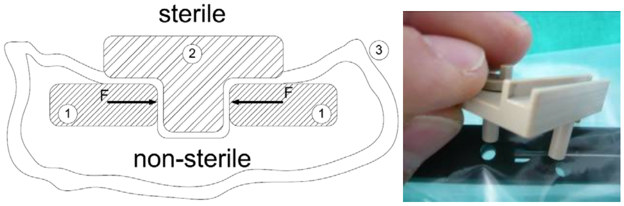

Fig. 12. Mounting of the forceps holder (2) in the holes of the non-sterile manipulator (1) by cupping the sterile foil (3).

Fig. 13. Assortment of available instruments for the MMS-II.

F. Surgical Workflow

Easy integration into existing surgical workflows of middle ear surgery is an important feature of the MMS-II. This implies a sterilization concept, a workflow that has been evaluated within the hospital, an easy user interface, and the ability for rapid change between manual and teleoperated instrument guidance. The first step in using the MMS-II consists in mounting the controller and the manipulator on the side rail of the standard OR table. The light weight of the manipulator enables a single individual to rapidly do this. After that, the sterile medical assistant covers both components with a sterile foil. The foil, covering the joysticks, is fixed with a sterile tape for ease of use. Then, both instrument holders are pressed onto the manipulator's Z-axis. These, together with the set of instruments, have previously been sterilized with a steam autoclave. First, the manipulator is swung out from the surgeon's workspace by the articulated arm. The surgeon exposes the middle ear as usual (access through temporal bone behind the ear or through the external auditory channel). To access a teleoperated instrument, the surgeon clips the required instrument onto the manipulator's holders and aligns the manipulator with the operating field, using the articulated arm. The manipulator is ready for use and can be controlled with the joysticks immediately upon being switched on. That takes only a few seconds. The manipulator's small size enables it to work manually and to be teleoperated in parallel—for example, if a third hand is needed. At anytime the manipulator can be swung in or out, as needed, during the intervention. This takes just a few seconds also. After the operation, the instrument and forceps holder are detached; the sterile foils are removed; and the MMS-II is dismounted.

G. Safety Features

Switching off the manipulator stops it immediately, on account of its little weight and its high gear-transmission ratio. Besides, low-power motors have been used, which limits the maximum forces. In addition, the small weight causes only slight mechanical impulses, even at higher speeds. If needed, the manipulator can be removed from the operating field with no loosening of the articulated arm's locking screw. A force of 15 N is necessary for that. Also, the workspace is just big enough for the required task. Using a microcontroller has significantly reduced the number and complexity of the electronic components. The correct functioning of the microcontroller is checked via watchdog and brownout detection. Besides, the software logically verifies sensor signals. The main risk was the Z-axis when using pointed instruments. Therefore, a magnetic coupling has been integrated into the Z-axis, which mechanically disconnects the motor at high applied loads. The maximum applicable load is set to 3 N. If the Joystick is set backward after the magnetic coupling has released, the Z-axis latches automatically again onto the motor.

III. CONCLUSION

In this article, a new Micromanipulator System (MMS-II) for telemanipulating middle ear surgery instruments has been presented. The goal was to develop a manipulator with low complexity, which would allow the surgeon to move instruments with precision even in non-ergonomic situations. We have described how the system can be integrated into existing surgical procedures. The main features are the use of standard instruments, like perforators or forceps, and the fact that the manipulator is controlled by a microcontroller-based joystick console but requires no additional computers. The system described is small, lightweight, inexpensive to produce, and has a practicable sterilization concept. We are currently working on an active controller with motorized joysticks.

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