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Micromanipulator for enhancing surgeon's dexterity in cochlear atraumatic surgery

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Abstract—**The hybrid stimulation in cochlear implants requires changes in the design of electrode arrays. A new generation of flat electrode arrays that does not damage the cochlea is being developed. For the insertion of these flat array electrodes a groove must be milled in the antero-inferior area of the round window niche. Even for the most experienced surgeon, it is very difficult to carry out this operation without damaging the cochlea. That is why external help is needed.**

For helping the surgeon to mill the groove, a compliant mechanism based micromanipulator has been designed, manufactured and tested. A surgical milling tool is attached to a specially designed compliant mechanism and positioned properly along the auditory canal. The compliant mechanism guides the motion of the surgical tool, keeping tactile feedback and enhancing the dexterity of the surgeon for an accurate milling of the groove.

I. Introduction

A cochlear implant [1, 2] is a surgically implanted electronic device that treats severe to profound sensorineural hearing loss by stimulating the auditory nerve. The use of the cochlear implants in humans dates from the late sixties with single electrode technology. However, it is in 1978 when a person receives for the first time a multi-channel cochlear implant. Since then, the approximately 100,000 devices implanted worldwide have proved the benefits of this technique.

A new strategy to improve the performance of the cochlear implants is the hybrid or electro-acoustic stimulation [3]. It consists in combining the electric stimulation of the auditory system with the significant residual low-frequency hearing in some patients. It has been tested that this kind of stimulation improves the musical and speech reception in noise for patients with low frequency residual hearing [4, 5].

The insertion of conventional electrodes has high risks to generate irreversible harm to the cochlea, losing residual hearing [6]. The cochlear surgery for the insertion of implantable devices, without causing significant damage to the cochlea is called atraumatic surgery and requires changes in the design of the electrode arrays and in the insertion techniques as well. Thus, a new generation of flat electrode arrays (figure 1) that preserves this residual hearing function has been developed. This electrode array is inserted between the bone and the spiral ligament, located in the lateral wall of the cochlea.

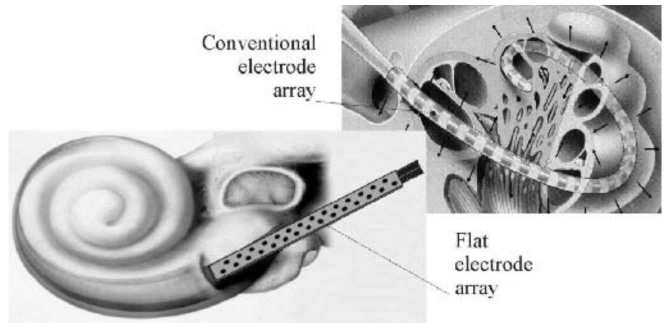

Figure 1. The new flat electrode array vs. the conventional one. The conventional electrode array is inserted along the scala tympani with high risk of causing irreversible harm to the cochlea. The flat array electrode must be inserted between the bone and the lateral wall of the cochlea, preserving patient's residual hearing.

For the insertion of the new flat electrode arrays a cochleostomy must be performed in the antero-inferior area of the round window niche, without damaging the cochlear tissue close to the bone. A long thin necked milling tool with a diamond bur on its tip (figure 2) must be inserted through the auditory canal and a little groove must be milled (2 mm deep, 5 mm long and 2 mm wide approximately). This operation is very complicated even for the most experienced surgeon.

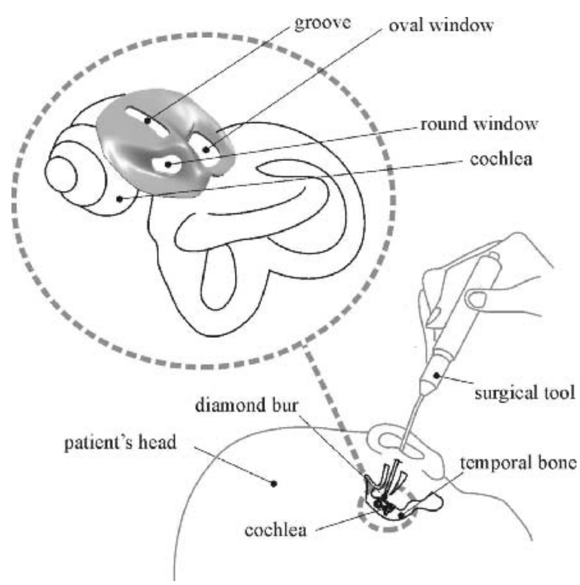

Figure 2. Ubication of the groove that must be milled. The milling tool is inserted along the auditory canal. The eardrum is put aside during the operation and it is put back in place again in the end of the operation.

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In a first approach to solve the problem of milling the groove, floor-mounted robot assisted surgery can be found. The advantages of the robot assisted surgery, devices like Zeus or Da Vinci [7], are: reduction of surgeon's hand tremor, higher accuracy, remotely manipulation, force feedback, scalable motion or preplanned image-based programming. However, these systems are big, bulky devices that take up too much room space, they are very expensive and being floor-mounted, patient and robot do not share the same reference system, so the patient must be immobilized or their relative motion compensated by real time tracking.

Surgical devices that can be patient-mounted near operation zone offer big advantages respect to the floor mounted ones [8]. They can be attached to the patient's bony anatomy, so there is no need of immobilizing the patient or motion tracking. Compact designs can be achieved, adapted to the workspace required and they are easier to manage. The price is also dramatically reduced.

A simple and fast method for milling the groove is desired, so the concept of a *haptic smart joint* (HSJ) is introduced: a steady support for handling the milling tool attached to the cranial surface of the temporal bone. It must guide the surgeon's hand in the direction of the groove and avoiding motion in the rest directions. Furthermore, tremor is eliminated, as the HSJ works as a support, providing the surgeon the precision needed, without losing tactile feedback. The HSJ must enhance the surgeon's dexterity for milling the groove.

II. Haptic Smart Joint

For working as a HSJ, a compliant mechanism [9, 10] has been chosen. A compliant mechanism gains all or part of its mobility from relative flexibility of its members. Compliant mechanisms have not backlash, neither there is wear or need for lubrication. The number of parts is reduced dramatically compared with rigid-bodies mechanisms, the assembly process is simplified and the cost of the mechanisms decreases.

Figure 3 shows the designed compliant mechanism. The motion is achieved thanks to the circular deformable thin walls called flexure hinges. This mechanism has three degrees of freedom (figure 3). The working reference system is defined as follows: the Z axis is parallel to the auditory canal axis, X is parallel to the groove that must be milled and Y is perpendicular to Z and X. The central part of the mechanism, where the tool is attached, can be displaced in X and Z axis and it can be rotated in Y axis. The compliant mechanism guides the motion of the surgical tool along the cited directions, while avoiding motion in the rest directions for a proper milling of the groove.

When no load is applied, the mechanism must be located in such a way that the tip of the surgical tool is a few millimeters above the place where the groove must be milled, as shown in figure 3, due to the limited range of motion of the compliant mechanism. When the surgeon softly applies load in the mechanism through the surgical tool, it deforms and the tip of the tool approaches the bone to mill. The compliant mechanism allows the surgeon to control the motion of the surgical tool accurately. Once the surgeon finishes applying load, the mechanism returns elastically to the initial position.

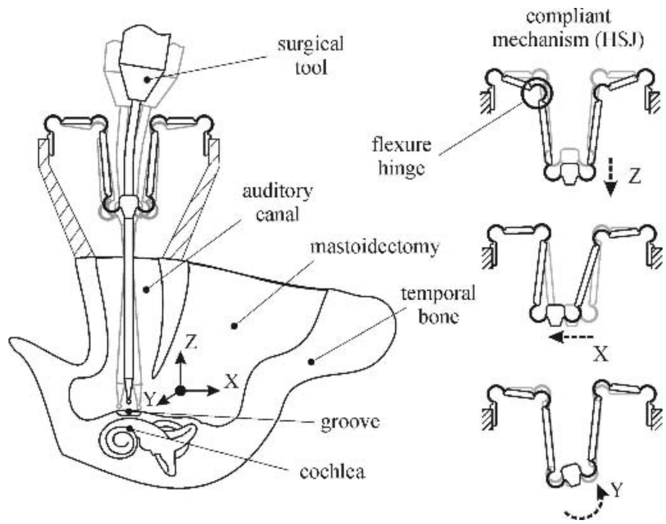

Figure 3. Motion of the compliant mechanism and the surgical tool for milling of the groove and degrees of freedom of the designed compliant mechanism: displacement in Z and X axis and rotation around Y axis.

The compliant mechanism has been manufactured by Wire Electro Discharge Machine in aluminum 7075 for the laboratory trials because of its high yield strength (Sy=500 MPa) to Young's Modulus ratio (E=72 GPa) and affordable price. This material should be substituted in the future by titanium or super elastic nitinol [11] for biocompability.

III. Micromanipulator for Cochlear atraumatic surgery

As told before, for a proper work of the compliant mechanism, it must be positioned a few millimeters above the place where the groove must be milled. That is why the whole mechanical system must provide the ability of attaching the HSJ to the temporal bone and positioning it in the space. The whole mechanical system will be called micromanipulator.

The micromanipulator is composed of two bodies: a lower body attached to the bone with two degrees of freedom for positioning the compliant mechanism; and an upper body that comprises four degrees of freedom for positioning, the compliant mechanism and the milling tool. Figure 4 shows the micromanipulator in two different configurations: coupled (a) and decoupled (b). The decoupled configuration shows the two aforementioned bodies and it is useful for the surgeon for visual inspection or for changing the diamond bur. The upper body slides into the lower one down to the coupled position. The coupled configuration is the working position for milling the groove.

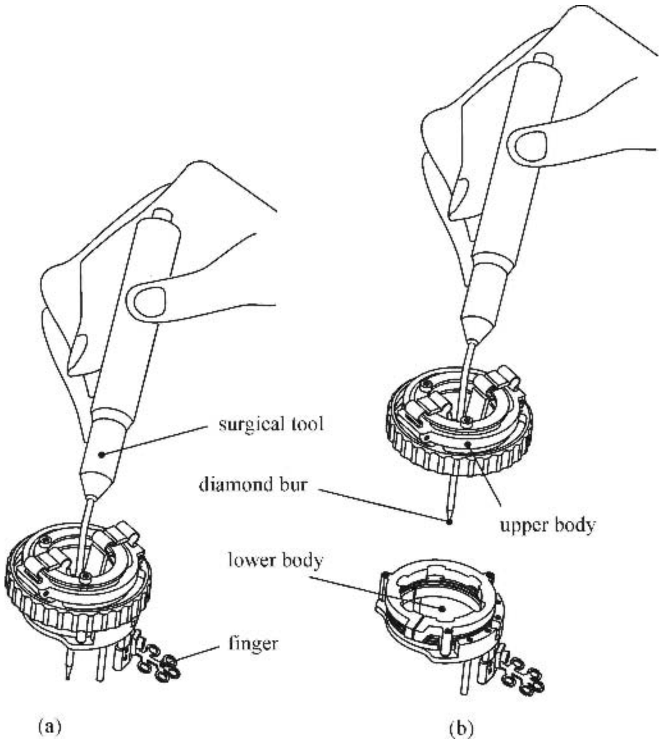

Figure 4. Micromanipulator in coupled (a) and decoupled (b) positions. Decoupling the upper body is very useful for changing the diameter of the diamond bur on the tip of the tool or for visual inspection.

The micromanipulator is attached to the cranial surface of the temporal bone, with its axis close to be coincident with the one of the auditory canal. For this purpose a special part designate as *finger* (figure 5) comprises several holes in which a titanium screw can be introduced for fastening the finger to the bone. It is possible to displace the finger in vertical direction and also to rotate it around the axis of the bolt. The two long bolts shown in figure 5 can be displaced vertically down to leaning on the temporal bone. The finger and the long bolts are used to attach the system to the temporal bone, in order to provide the necessary stability and stiffness, not to achieve a fine regulation.

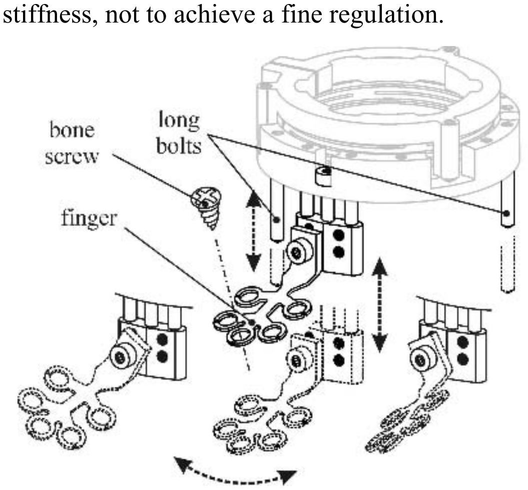

Figure 5. The finger is used for attaching the system to the bone. The long bolts lean on the bone providing the system stability and stiffness.

Once the system is attached to the bone, the HSJ must be positioned in six degrees of freedom. Two degrees of freedom are located in the lower body. The reference system used here is the same as shown in figure 3. The compliant coupling in figure 6.a provides two orientations: rotation around X and Y axis. Figure 6.b shows how translations in X and Y axis and rotation around Z are achieved, simply sliding the *holder* on a *washer* Once the desired position is achieved, the holder is blocked with two bolts. Vertical displacement is controlled by the nut in figure 6.c. A complete turn of the nut means a vertical displacement of 1 mm of the compliant mechanism. This fine vertical motion allows an accurate positioning of the tip of the tool a few millimeters above the bone surface where the groove is to be milled. The thread is left-handed since this way the surgeon finds the displacement of the tool more intuitive: when the nut is turned clockwise, the HSJ is displaced downward.

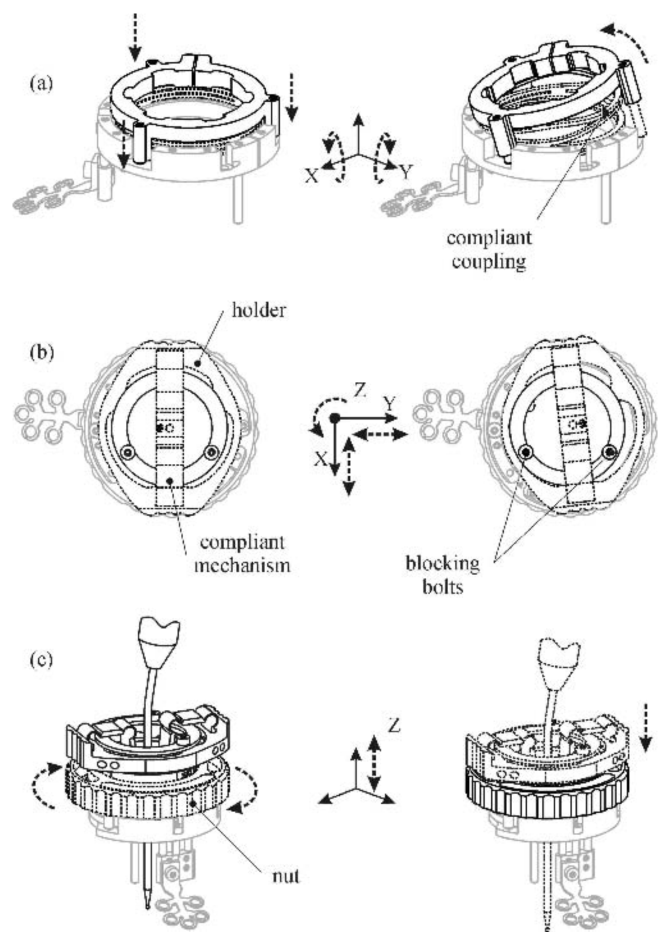

Figure 6. The compliant coupling in the lower body provides two orientations (a). Two displacements and one rotation are achieved sliding the holder on the washer (b). The left-handed fine pitch nut provides precise vertical displacement (c).

IV. Laboratory Trials

The complete system has been tested in the Otorhinolaryngology Department of the University of Navarra Medical School in ten formalin-preserved human temporal bones. Before the promontorial milling to expose the spiral ligament, a mastoidectomy, a posterior tympanotomy and a transcanal exploratory tympanotomy were performed; the micromanipulator was placed over the cranial surface in the temporal bone (figure 7.b).

(a) (b)

Figure 7. Micromanipulator prototype in decoupled configuration (a). Micromanipulator over temporal bone during laboratory trials (b).

The process of attaching the micromanipulator to the temporal bone, positioning the HSJ, milling the groove and removing the system takes less than ten minutes. One of the initial requirements was to achieve a fast and easy way for milling the groove, and this time is considered suitable for a surgical procedure by the surgeon.

The milling of the groove assisted by the micromanipulator was performed accurately. After the milling process, the spiral ligament in the lateral wall of the cochlea was visually inspected under surgical microscope vision to assess its integrity (figure 8).

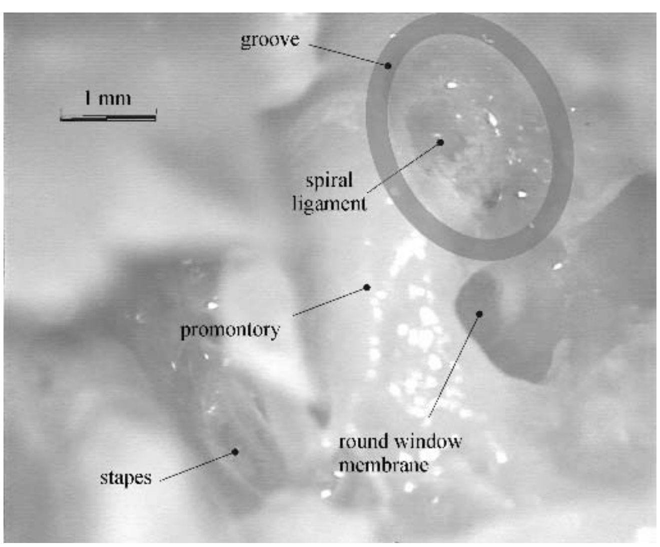

Figure 8. Microscopic image of the temporal bone showing the performed groove near the basal turn of the cochlea, necessary for the insertion of the flat electrode array.

Only one of the ten temporal bones studied suffered a small fracture in the lateral wall of the cochlea. No continuity solutions were observed for the other nine cases after having carried out a visual inspection through the microscope.

V. Conclusions

A micromanipulator for atraumatic cochlear surgery has been designed, manufactured and tested. It has been used for increasing the surgeon skill to mill a groove in the antero-inferior area of the round window niche. This makes possible the insertion of a new generation of flat electrode arrays for cochlear implants. After ruling out more sophisticated solutions, it was decided to apply the compliant mechanisms theory to solve the problem. A compliant mechanism has been specially designed for this purpose. This compliant mechanism works as a haptic smart joint that supports the surgical tool improving the precision of the surgeon.

The first laboratory trials in ten formalin-preserved human temporal bones have been very satisfactory, proving the utility of the designed micromanipulator in order to mill groove.

This philosophy of simply and effective micromanipulator based on compliant mechanisms can be exported to other kind of surgical operations where high precision and tactile feedback are needed, in order to enhance the surgeon's dexterity.

VI. References

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