Strojniški vestnik - Journal of Mechanical Engineering 52(2006)7-8, 470-476
UDK - UDC 681.7.068:612.85
Izvirni znanstveni prispevek - Original scientific paper (1.01)

Preučevanje in razvoj stekleno-vlaknenega vibrometra primernega za popolno vsadne slušne pripomočke

Investigation and Development of a Fiber-Optic Vibrometer for Use in Totally Implantable Hearing Aids

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V tem prispevku prikazujemo rezultate raziskave in razvoja stekleno-vlaknenega vibrometra, primernega za popolno vsadne slušne aparate (TIHA). Najpomembnejši del te raziskave so: opto-elektronična metoda za obdelavo signalov, opto-mehanično postavljanje zaznavnega vlakna, kirurško vsajanje ter biozdružljivost materialov. Izvedli smo in vitro in in vivo meritve tarče, ki je v našem primeru vibracija nakovala s podnanometrsko ločljivostjo na vsem slišnem zvočnem spektru in z uporabo nizkih in visokih koherenčnih tehnik. Velik preboj je narejen pri zmanjšanju porabe električne energije opto-elektronične in postopkovne enote na 2 mA@2,2 VDC z uporabo digitalne obdelave signalov imenovane tehnika DSP.

(Ključne besede: vibrometrija, vlakna optična, pripomočki slušni, vsadki, DSP)

In this paper we present the results of the research and development of a fiber-optic-based vibrometer for use in totally implantable hearing aids (TIHAs). We addressed the most important issues regarding the projected vibrometer: the optoelectronic measurement technique and signal processing, the optomechanical positioning of the sensing fiber, the surgical implantation technique and the material's biocompatibility. We performed in-vitro and in-vivo measurements of the target (e.g., incus) vibrations with a sub-nanometer resolution over the whole audio range, using low and/or high coherence techniques. A breakthrough is made by a dramatic reduction of the power consumption of the optoelectronic and signal-processing unit to about 2 mA at 2.2 VDC by introducing a digital signal processing (DSP) technique.

(Keywords: vibrometry, fiberoptics, hearing aids, implants, DSP)

0 INTRODUCTION

Hearing loss occurs to most people regardless of their age. There are some 31.5 million people in the USA (as of 2005) with hearing loss. Hearing loss is the single most common birth "defect" in America. There is a similar situation in Europe. Approximately one third of all seniors aged 75 years and older have significant hearing loss. About 14 percent of all people aged 45 to 64 years have demonstrable hearing loss. Hearing loss negatively impacts quality of life, personal relationships and of course, the ability to communicate. Some 90 to 95 percent of all cases of hearing loss can be corrected with hearing aids.

There are many types of conventional hearing aids (CHAs). They are electric, battery-operated devices that amplify and change sound to allow improved communication. Hearing aids receive sound through a microphone, which then converts the sound waves to electrical signals. The amplifier increases the loudness of the signals and then sends the sound to the ear through a speaker. However, they have a number of disadvantages, e.g., acoustic feedback, poor sound fidelity and the stigma of aging [1].

For these reasons there is a continuous effort in the scientific community to improve current hearing devices or even to develop new types of device. The most interesting approach is the development of partially or totally implanted hearing aids (TIHAs) ([2] and [3]). Basically, these devices are also composed of a microphone and actuators, just like conventional hearing aids. The largest problem still existing in implantable hearing aids is the lack of a reliable microphone to provide a long-lasting sensing functionality.

This paper is devoted to the research and development of a novel implantable microphone based on fiber-optic low- and high-coherence interferometry [4, 5]. The main properties outlined in the projected microphone are the ability for contact-less measurement of the middle-ear ossicles vibrations with sub-nanometer resolution across the full audio-frequency range. During this project we have had to investigate, in a parallel way, the optoelectronic sensing unit and signal processing, the optomechanical miniature stage for holding, adjusting and fixing the sensing fiber, and the surgical implantation and biocompatibility of the materials.

One of the prime goals of the project was to achieve a low-power vibrometer to be considered as a serious candidate for all kinds of currently used implantable hearing aids, including cochlear implants (CIs). Finally, a great breakthrough was made by dramatically reducing the power consumption from 70mA at 12 VDC to about 2 mA at 2.2 VDC of the entire sensing system. It was reached by introducing digital signal processing and a vertical cavity surface-emitting laser diode (VCSEL) as a light source.

1 METHODOLOGY

1.1 Principle of operation

The sensing principle is based on low- or high-coherence interferometry ([4] and [5]) performed by a fiber-optic interrogation set up, depicted in Fig.1. The core of the sensing system is a 3×3 single mode (4/125 μm) fiber-optic coupler [6], which provides two interferometric signals mutually shifted in phase by $2\pi/3$. The benefit of such an approach is the overcoming of signal fading, which usually occurs in classical interferometric schemes based on just a single 2×2 coupler.

Three input arms of the 3x3 coupler are connected with two receiving photodiodes and one light source, e.g., a laser diode or a superluminiscente diode. One outlet arm is immersed in index-matching gel to suppress the back-reflection from the fiber end. The second outlet arm is directed to the referencing mirror and the third arm, called the sensing arm, is directed toward the vibrating target, e.g., the incus in the middle ear. Beams reflected from the vibrating target, and beams reflected from the reference mirror are combined in the coupler generating the quadrature interferometric signal.

We stimulated the incus vibrations by generating sound pressure from a loudspeaker. We applied a sinusoidal pure tone with a frequency varying between 500 Hz and 5 kHz at a sound level between 70 and 90 dBA SPL. The sound was measured continuously by a Digital Sound Level

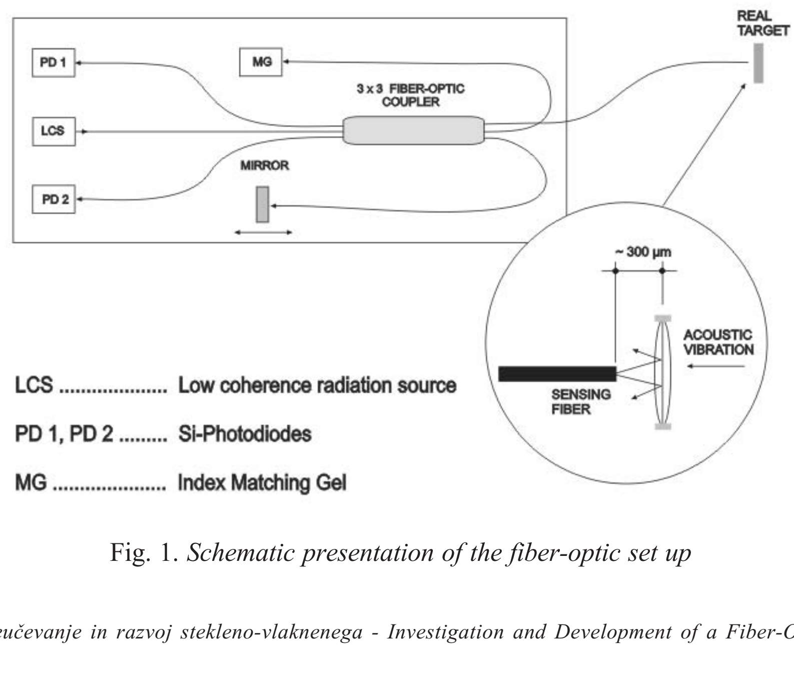

Fig. 1. *Schematic presentation of the fiber-optic set up*

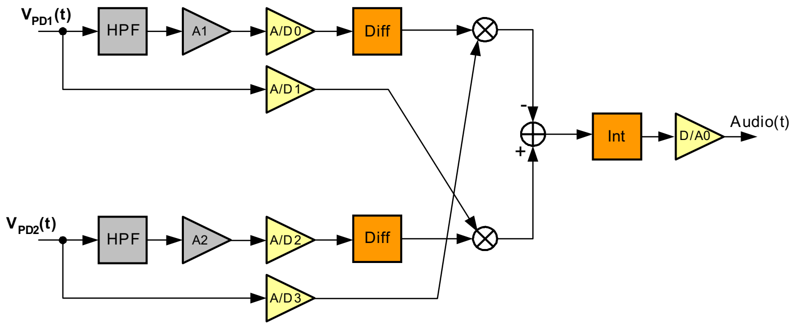

Fig. 2. *Block diagram of the DSP realization of the cross-multiply technique*

Meter RO-350 at about 10 cm distances from the rabbit ear.

1.2 Signal processing

Signal processing of the first model of the fiber-optic vibrometer was realized entirely by analog SMD technology [7]. The primary goal of the first model was to develop and to adopt an appropriate algorithm for signal processing, taking into account the mathematical description of the sensing principle [8]. Therefore, we did not take care so much about the power consumption and the overall dimensions of the model. However, in the last phase of the project we approached the requirements governed by the final usage of the microphone, low-power consumption and small overall dimensions of approximately 20x20x4 mm. The only way to fulfill these technical demands was the development of DSP.

Fig. 2 shows the DSP realization of the cross-multiply technique, which was previously realized in analog technology. Subtraction, addition and multiplication are supported in the MSP430 core by generic instruction or by a special on-chip hardware module. There are two DSP algorithms used in microphone design that are critical in time: discrete time differentiation and integration. The implementation of these functions mainly determines the sound quality and the low-power performance. However, quality and power are opposite requirements. Higher sound quality consumes more power, and lowering the power leads to decreasing sound quality.

1.3 Optomechanical stage

The main requirements for a miniature mechanical system aimed at holding, adjusting and final fixing of the sensing fiber are: fast and easy positioning of the sensing fiber toward the vibrating target and firm fixation of the fiber in the optimum position in terms of the maximum back-reflected signal. Additionally, all the materials as well as the sensing fiber must be biocompatible.

In order to fulfill the above requirements we developed several different miniature mechanical stages, starting with the simple one depicted in Fig. 3.

Fig. 3. *The first version of the titanium holder*

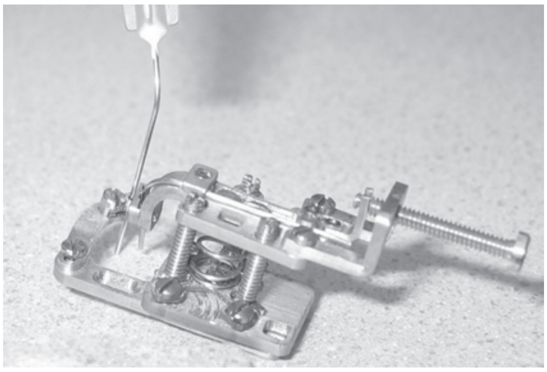

Fig. 4 *A prototype of the holder with the possibility for fine positioning*

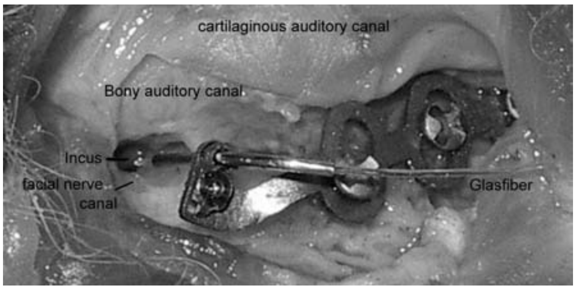

Fig. 5. *An implanted sensing fiber and Ti holder*

This model, made of titanium (Ti), could not provide stable fixation of the sensing fiber after the adjusting procedure, so we developed the model depicted in Fig. 4. This model has the possibility to adjust the fiber in the x-y-z directions as well as angular adjusting. The special feature of the model is an ability to lock the optimum fiber position and to keep it for a long period of time after the implantation. The model is made of brass.

1.4 Surgical technique

For *in-vivo* experiments the sensing fiber was implanted surgically and firmly fixed onto the rabbit scull using the first model of the titanium holder. Fig. 5 presents an implanted sensing fiber fixed by a titanium holder. Fig 6 is a close up of the same situation, showing how the real target looks, i.e., the rabbit incus.

For this purpose the middle ear was opened using a retro-auricular transmastoid recess approach. Care was taken to leave the ear channel and tympanic membrane intact as well as the original state of the whole auditory chain [9].

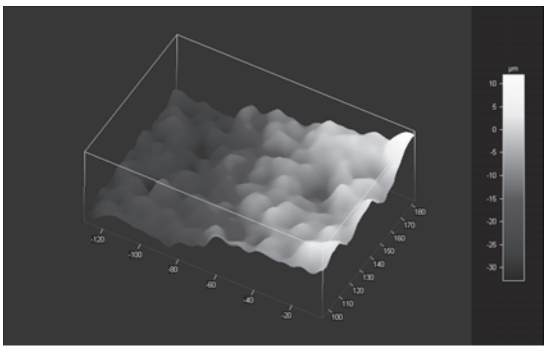

Fig. 7. *Roughness of a human incus bone taken by a fringe projection profilometer*

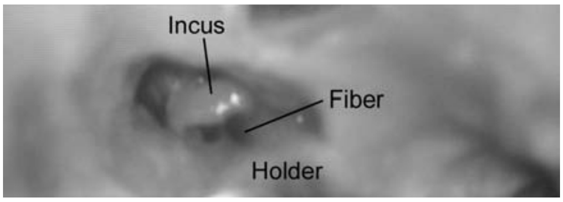

Fig. 6. *A close up of the real target, i.e., the rabbit incus*

1.5 Biocompatibility issue

The biocompatibility of the applied materials, the titanium and the glass optical fibers, were investigated by the preparation of histological specimens of the implanted fibers. We implanted the sensing fiber in two rabbits. They carried the implanted fibers and titanium holders for approximately two months. After this time we killed the rabbits and extracted the implants for the histological investigation. The main goals of the *in-vivo* experiments and the histological research were to determine whether the implanted devices can provoke an inflammation and to see if scar-tissue cells grow over the wall and the tip of the fiber.

2 RESULTS

In Fig. 7 we present the morphology of a relatively fresh human incus taken by a fringe projection profilometer. The roughness of the incus surface is about 15 µm peak-to-peak. A similar result was obtained from the investigation of the rabbit

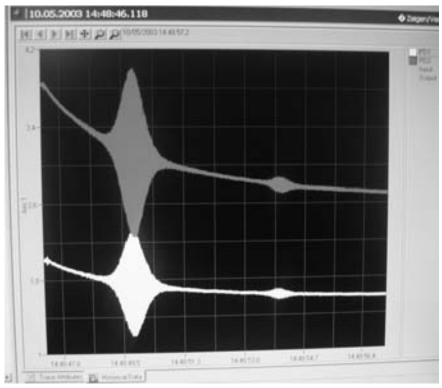

Fig. 8. *Coupling curves between the end of the sensing fiber and the incus surface captured by the two photodiodes PD1 and PD2 y-axis: signal, V; x-axis: time, sec*

incus. In both cases the incus surface behaves as a pure diffusive target with a relatively small reflectivity of about 2%.

Fig. 8 presents coupling curves between the sensing fiber and the incus obtained by simultaneously capture of the signals on PD1 and PD2. There are two typical low-coherence interferograms, the larger one coming from the end of the sensing fiber and smaller one coming from the incus surface.

After signal processing, made by the analogue electronic circuit, we obtained quadrature signals in the shape of the Lissajous figure presented in Fig. 9. The useful signal appeared as a moving part of a full ellipse. The length of the trace represents the amplitude of the incus vibration, approximately 7 nm peak-to-peak at 2 kHz and 70 dB SPL. The width of the trace roughly shows the noise level.

Fig. 10 presents the frequency response of the rabbit incus. The obtained frequency response has a typical shape characteristic for other animals as well as for human beings. We can see the occurrence of the resonant frequency somewhere around 2 kHz. Similar results regarding the amplitude of the vibrations of the ossicles in a human middle ear were obtained by Vlaming et al. [10].

In Fig. 11 we present the frequency response of the DSP based low-power fiber-optic vibrometer obtained by measuring the amplitude of the vibrating of an aluminum mirror. The mirror was stimulated to vibrate by a piezo transducer, previously calibrated with a Polytec laser vibrometer.

Fig. 12 presents a histological specimen of part of the middle ear containing the sensing fiber and the incus. The fiber-tip–incus separation in this case was no more than 50 μm. The overall incus dimensions are 1.5 × 2 mm.

3 DISCUSSION

The morphology of the incus, Fig. 7, originating either from the rabbit or human beings, is very developed with a lot of hills and valleys. For this reason we had a lot of troubles to find an appropriate facet that would be able to reflect the impinged light beam backward into the sensing fiber. The problem was even larger because of the very small reflection of about 2%. We found that the average overall dimensions of such a facet were about 15×15 μm. The beam coming out from the tip of the sensing fiber forms a dot of about 15 μm in diameter if the target-to-fiber tip separation is approximately 100 μm. This means we had to have a very fine adjusting system to meet the appropriate facet of the incus. It was achieved with the mechanical stage presented in Fig. 4.

The aiming of the sensing fiber toward the incus was followed up by monitoring the intensity of the back-reflected signals, captured by photodiodes PD1 and PD2, depicted in Fig. 8. The moment of the occurrence of the second interferogram meant that we obtained the back-reflected signal from the target. The separation between the first and second interferogram is equal to the separation between the sensing fiber tip and the incus surface. It is a very good method for adjusting the sensing fiber position to be sufficiently far away from the incus. It is of primary importance

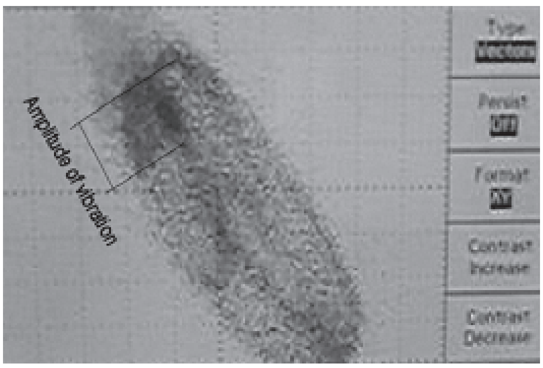

Fig. 9. *Quadrature signals presented as the Lissajous figure of the rabbit incus. The amplitude of vibration was about 7 nm peak-to-peak at 2 kHz and 70 dB SPL*

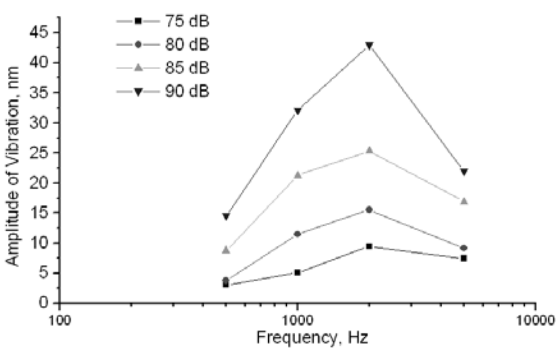

Fig. 10. *Experimentally obtained frequency response of the analog based fiber-optic vibrometer*

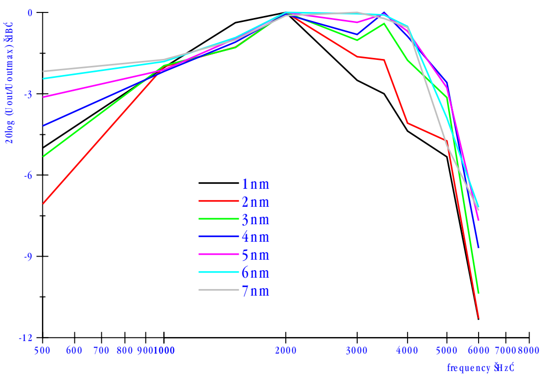

Fig. 11. *Experimentally obtained frequency response of the DSP based fiber-optic vibrometer*

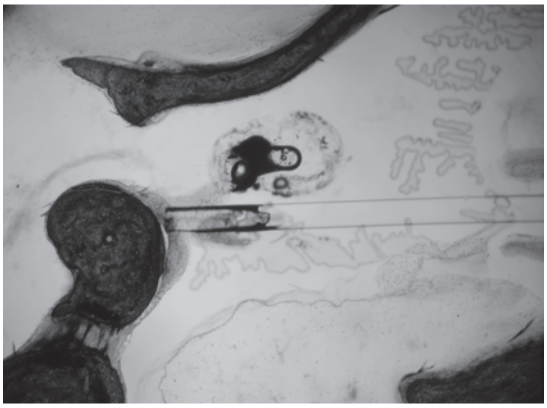

Fig. 12. *Histological cross-section of the middle ear containing an implanted sensing fiber vs incus*

to provide the sensing function of the microphone, even in the case of relatively large DC shifting of the auditory ossicles due to a change of atmospheric pressure. We set up the fiber-incus separation to be between 200 and 300 µm.

Fine adjustment of the mechanical stage was used to optimize the outlet signal, graphically presented as a Lissaojus figure, Fig. 9. The only small waking part of the full ellipse corresponds to the real amplitude of the incus vibration. There is a method [5] to reconstruct the amplitude of the vibrations using data presented in the Lissaojus figure.

Applying the above-mentioned procedure we obtained the frequency response of the fiber-optic vibrometer either for the analog or DSP-based version. However, the first one was made by low-coherence interferometry, and second one by high-coherence interfereometry. Both of them have some advantages and disadvantages. The first one provides high optical power, offers a more comfortable method for adjusting the fiber and the definition of the fiber-to-incus separation. However, the electrical power consumption is too high. For example, a laser diode polarized just below the threshold in order to work as LCS consumed approximately 70 mA without an electrical analog circuit. The final implantable microphone cannot tolerate such a high power consumption.

On the other hand, the high-interferometry based vibrometer provides a remarkably reduced power consumption of less than 2 mA at 2.2 VDC. This was achieved by introducing VCSEL as a light source, which consumed about 0.5 mA. The rest of the current was consumed by the digital signal processing. However, the price for this progress was a remarkable decrease in the optical power. For example, we measured just about 2 µW of the optical radiation emitted from the third (middle) outlet arm, later immersed in index-matching gel, Fig. 1. If we know that the incus reflection is about 2% it means that, in the best case, we had an incus-reflected light intensity of below 40 nW. However, even with such a modest optical power we got very good results. This was possible with a specially developed software package for signal processing based on the algorithm depicted in Fig. 2. The introduction of DSP into the optoelectronic interface of the vibrometer gave a great opportunity to miniaturize the whole device.

Finally, *in-vivo* experiments were performed on two rabbits for 2 months, and showed there were no inflammation effects onto the surrounding tissue of the animals. Histological investigation of the implanted sensing fibers showed there was no scar-tissue cell growth over the wall of the glass fiber. However, in one case, depicted in Fig. 12, we noted there was cell growth over the tip of the sensing fiber. It was caused by touching the incus surface with the end of the sensing fiber and creating a wound over the incus. During the healing phase the scar tissue covered the wound and even established a new connection with the not-so-distant fiber tip.

4 CONCLUSION

We can conclude that we established low- and high-interferometry techniques as a platform for the realization of one contact-less fiber-optic vibrometer suitable for application in TIHAs. We addressed the most important issues regarding the final implantable microphone: the optoelectronic circuit and signal processing, the optomechanical adjustment, and the surgical and biocompatibility problems. Because of that we performed an *in-vivo* investigation of the implanted sensing fiber and the mechanical holder.

We pointed out the most important result that we recently obtained by dramatically decreasing the power consumption (approximately 2 mA at 2.2VDC) of the whole sensing system introducing DSP and VCSEL as a light source.

The next steps in the investigation will be as follows: miniaturization and optimization of the optoelectronic unit, optimization of the optomechanical assembly for the fiber adjustment, and biocompatibility and encapsulation of the whole system ready to be implanted.

Acknowledgment

We would like to acknowledge Integrated Microsystem Austria (IMA), who supported this project.

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Prejeto:
Received: 2.11.2005

Sprejeto:
Accepted: 22.6.2006

Odprto za diskusijo: 1 leto
Open for discussion: 1 year