Does the distance from a laser source to the ear influence the optoacoustic activation of the auditory system?

Beeinflusst der Abstand einer Laserlichtquelle zum Ohr die optoakustische Aktivierung des Hörsystems?

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Abstract

Hearing loss is the most frequent sensory deficit in humans with approximately 436 million affected people worldwide requiring treatment. If untreated, it can lead to social isolation and reduced quality of life for many individuals. Currently available auditory prostheses based on mechanical and electrical energy are not sufficiently supplying the hard of hearing patients, thus making novel stimulation strategies necessary. A new generation of hearing aids based on optoacoustic effects provide promising results for the future. For this purpose, we proposed to assess the effect of the distance between the laser source and the vibratory site at three different anatomical structures of the peripheral hearing organ. Therefore, the auditory threshold of anesthetized female albino guinea pigs was determined using click-evoked brainstem potentials of 0–80 dB SPL. 10 ns laser pulses at 532 nm wavelength and 10 Hz repetition rate with increasing intensity were then used to irradiate the tympanic membrane, the round window, and the otic capsule. For this, the laser fiber, with a 365 µm diameter, was positioned at 0.1, 2.6, 5.1 and 10.1 mm distance from the three anatomical sites. To assess the neuronal activity, optically induced acoustic brainstem potentials were recorded. The auditory threshold for each distance was estimated by the identification of the first recorded Jewett complex. The optical stimulation using a laser with 532 nm wavelength and 10 Hz repetition rate induced a progressively decreasing signal, the further the distance between the source and the target. The further the laser was placed from the target, the higher was the intensity of the laser pulse required to achieve an equivalent auditory activation threshold. In our experiment this effect was consistent at all the measured distances and for all the three targeted anatomical sites. As expected, the maximal activation was achieved in the position most proximal to the irradiated anatomical site. The distance between the laser source and the targeted anatomical structure demonstrated, therefore, an inverse correlation to the amplitude of the induced optoacoustic activation. The use of this result in new developments could allow for adjustment of the laser source in order to adapt to the anatomical characteristics and the specific pathology present in each case.

Keywords: hearing aids, optoacoustics, pulsed laser operation, optical evoked potentials

Zusammenfassung

Schwerhörigkeit ist die häufigste sensorische Beeinträchtigung des Menschen. Weltweit sind etwa 436 Millionen Menschen von einer behandlungsbedürftigen Schwerhörigkeit betroffen. Bleibt dieser Hörverlust unbehandelt, führt er bei vielen Betroffenen zu sozialer Isolation und verminderter Lebensqualität. Derzeit verfügbare Hörprothesen, die auf mechanischer oder elektrischer Energie basieren, bieten in vielen Fällen nur eine unzureichende Kompensation des Hörverlustes, so dass die

Entwicklung neuer Stimulationsstrategien erforderlich ist. In unseren Vorarbeiten konnten wir demonstrieren, dass die auf optoakustischer Stimulation des peripheren Hörsystems basierenden Hörgeräte vielversprechende Ergebnisse für die Zukunft bieten. Zu diesem Zweck analysierten wir nun die Auswirkungen des Abstands zwischen der Laserlichtquelle und des bestrahlten Gewebes an drei verschiedenen anatomischen Strukturen des peripheren Hörorgans. Die Hörschwelle von narkotisierten weiblichen Albino-Meerschweinchen wurde mit Hilfe von klick-evozierten Hirnstammpotenzialen von 0-80 dB SPL bestimmt. Anschließend wurden 10-ns-Laserpulse mit einer Wellenlänge von 532 nm und einer Wiederholungsrate von 10 Hz mit steigender Intensität verwendet, um das Trommelfell, das runde Fenster und die otische Kapsel zu bestrahlen. Zu diesem Zweck wurde die Laserfaser mit einem Durchmesser von 365 µm in einem Abstand von 0.1, 2,6, 5.1 und 10.1 mm zu den drei anatomischen Zielstrukturen positioniert. Für die Analyse der somit induzierten neuronalen Aktivität wurden optoakustisch induzierte Hirnstammpotenziale aufgezeichnet. Die Hörschwelle für jede Entfernung wurde festgelegt, sobald ein als solcher identifizierbarer Jewett-Komplex zu erkennen war. Die optoakustische Stimulation führte zu einem immer schwächeren Signal, je weiter die Quelle von der Zielstruktur entfernt war. Mit anderen Worten: Je größer der Abstand zwischen Laser und Zielstruktur, desto höher war die Intensität der Laserpulse, die erforderlich war, um die entsprechende auditive Aktivierungsschwelle zu erreichen. In unserem Experiment war dieser Effekt an allen Abständen und für alle drei anvisierten anatomischen Zielstrukturen zu beobachten. Wie erwartet, wurde die maximale Aktivierung in der proximalsten Position zum Hörorgan erreicht. Der Abstand zwischen der Laserquelle und der anvisierten anatomischen Struktur zeigte eine umgekehrte Korrelation mit der Amplitude der ausgelösten Aktivierung. Die Nutzung dieser Ergebnisse in neuen Entwicklungen könnte eine Anpassung der Laserquelle an die anatomischen Merkmale und die individuelle Pathologie im Einzelfall ermöglichen.

Schlüsselwörter: Hörgeräte, Optoakustik, Laser, optoakustisch evozierte Potenziale

1 Introduction

Approximately 430 million people worldwide suffer from severe hearing loss of over 35 dB requiring treatment. Around 80% of these individuals live in low to middle income countries. Roughly 25% of all over 60-year-olds are affected. Untreated severe hearing loss leads to social isolation and reduced quality of life for many individuals [1]. Despite the rapid development and innovation within the field of auditory prostheses, many affected individuals remain inadequately treated in the sense of not receiving the needed auditory device. On top of this, many do not wear their hearing aids regularly or some of them do not wear them at all, for various reasons. Some of these reasons include design-related issues such as: the susceptibility to acoustic feedback with insufficient amplification ability, poor speech clarity especially in background noise, an inadequate frequency resolution, insufficient frequency filtering – especially in loud environments, uncomfortable fit and potential resulting ear canal irritation [2]. To combat these problems and meet the individual needs of hard of hearing people, a new strategy to stimulate the ear more precisely and with reduced or no adverse reaction is needed. A new generation of hearing aids, based on the optoacoustic effects, shows promise as they should improve the hearing quality using a contactless, specific, and due to using light instead of soundwaves – a technique that propagates the needed information faster, without blocking the ear canal. The optoacoustic effect is currently being used in the fields of spectroscopy and imaging [3], [4]. The absorption of pulsed light waves causes the receiving medium to expand and contract, creating oscillations which can generate an acoustic impulse [5]. Activation of the hearing organ using photons was firstly described by Bell in 1880 [6], and in earlier experiments by Fridberger in 2006 [7]. In 2009, Wenzel et al. demonstrated a contactless, controlled activation of the inner ear [8], [9]. One year later they showed that this method can be effectively applied to different locations ranging from the ear drum to the inner ear [10]. Subsequently, a more frequency-specific method of stimulation was developed [11] and the biocompatibility of the radiation examined [12], [13]. Collectively these studies have shown the optoacoustic stimulation method to have great potential in the development of a new auditory prosthesis. To assess the most effective positions for such an auditory device, the effect of different distances between the light source and the vibratory structure of the auditory system on the induced electrophysiological effect needs to be investigated. We therefore present herein our study analyzing this effect at different distances between the laser source and the target medium, in an animal model.

2 Materials and methods

2.1 Animal model

In our study, 13 female albino guinea pigs weighing between 350 and 720 g (Breeder: Charles River Laboratories, Research Models and Services, Germany GmbH) were examined. The studies were approved by the Animal Welfare Office of the University of Saarland and by the Central Veterinary Office of Saarland (TV44/2017). All procedures were completed under general anesthesia performed with an intramuscular injection of 100 mg/kg Ketamine (Ketamine hydrochloride (100 mg/ml, Urostamin Serumwerk Bernburg AG) and 14 mg/kg Xylazine (Rompun Bayer Vital GmbH, Leverkusen). For sedation maintenance, 30 mg/kg ketamine and 0.6 mg/kg xylazine were administered approximately every 30 minutes, based upon the animal's breathing rate and any pain reaction. The guinea pigs also received between 1 and 2.5 ml NaCl 0.9% (B. Braun Melsungen AG, Melsungen) subcutaneously for hydration, depending on the weight of the guinea pig and the duration of the experiment. For further analgesia, a subcutaneous infiltration of Prilocainhydrochlorid 1% (Xylonest, Serumwerk Bernburg AG) was applied to the operation field. To prevent hypothermia, the guinea pig was positioned on a heating pad at approximately 37–38 °C during the procedure.

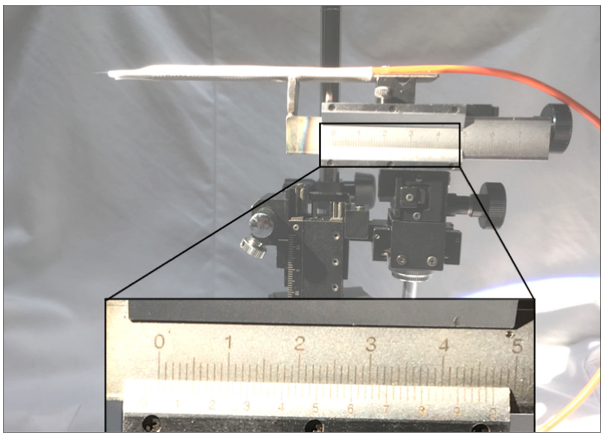

Figure 1: Micromanipulator with Nonius scale, allowing accuracies up to 20 µm.

2.2 Surgical approach

Firstly, a retroauricular-transossary incision was made. Using microsurgical techniques, access to the tympanic membrane, round window, and otic capsule was achieved. A laser fiber measuring 365 µm in diameter was positioned into the ear using a micromanipulator and a custom-made device (Figure 1). This system allowed the irradiation of the three anatomical structures (umbo/tympanic membrane, round window, otic capsule) at distances between 0.1 and 10.1 mm.

2.3 Acoustic stimulation

To monitor the function of the hearing organ, acoustic auditory brainstem responses (AABR) were recorded prior to and after each optoacoustic stimulation at each targeted position in a soundproof room. The animals were exposed to acoustic click stimuli of increasing intensity, generated with a digital signal processing system (Agilent 33500 B Series True Waveform Generator, Keysight Technologies GmbH, Germany) and presented through a free field loudspeaker (custom made from a DT-911, Beyerdynamic GmbH & Co. KG, Germany) calibrated for a 10-cm distance to the left ear. The clicks were 100-microsecond duration rectangular pulses repeated 256 times at a sampling rate of 20 kHz. The click stimuli increased in 10 dB SPL steps, from 0 to 60 dB SPL as described in our previous work [8]. The resulting auditory evoked potentials were recorded using 4 needle electrodes positioned subdermally at the cranial vertex, right mastoid, left mastoid and on the back (Figure 2). The response thresholds were defined by the lowest intensity with the first appearance of reproducible ABR waves.

2.4. Optoacoustic stimulation

The laser irradiation at each position was performed using a Neodymium-doped yttrium orthovanadate (Nd: YVO4)-Laser with an emission wavelength of 532 nm within the sound-proof room. The 365 µm diameter multimode laser fiber was placed orthogonal to the targeted tissue and 10 ns Laser pulses with a repetition rate of 10 Hz were used for stimulation (*Agilent 33500 B* Keysight Technologies GmbH). Optoacoustically induced brainstem auditory evoked potentials (OABR) were consequently recorded. To identify the optoacoustically induced auditory threshold, the intensity of the laser pulses was increased in the following steps: 0, 1, 2, 3, 4, 5, 7, 10, 16, 20, 23 µJ/pulse. The acoustic and optoacoustic auditory threshold was defined for each distance by the first appearance of reproducible ABR waves. The irradiation was performed on the following structures: Tympanic membrane – umbo, round window – membrane, otic capsule (Figure 3). The laser filament was positioned at 0.1, 2.6, 5.1 and 10.1 mm from the target to allow for identification of a possible trend relating to the distance between source and target. The sequence for one test series is shown in Figure 3.

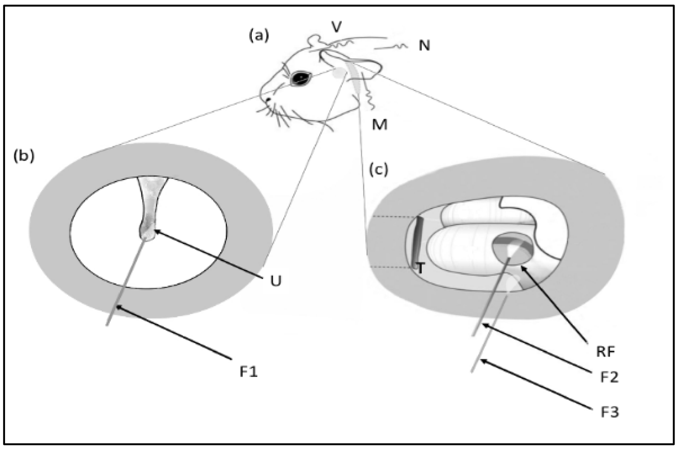

Figure 2: Experiment schematic adapted from Wenzel et al. [10]. (a) Expansion of the external acoustic meatus, retroauricular incision and positioning of the electrodes on the mastoids (M), vertex (V) and neutral (N). (b) Detailed view of the extended meatus with view of the tympanic membrane, the umbo (U) and the positioning of the laser fiber (F1). (c) Detailed view of the retroauricular incision with view of the tympanic membrane (T), the round window (RF) and the laser filament positioned towards the round window (F2) and the otic capsule (F3) [10].

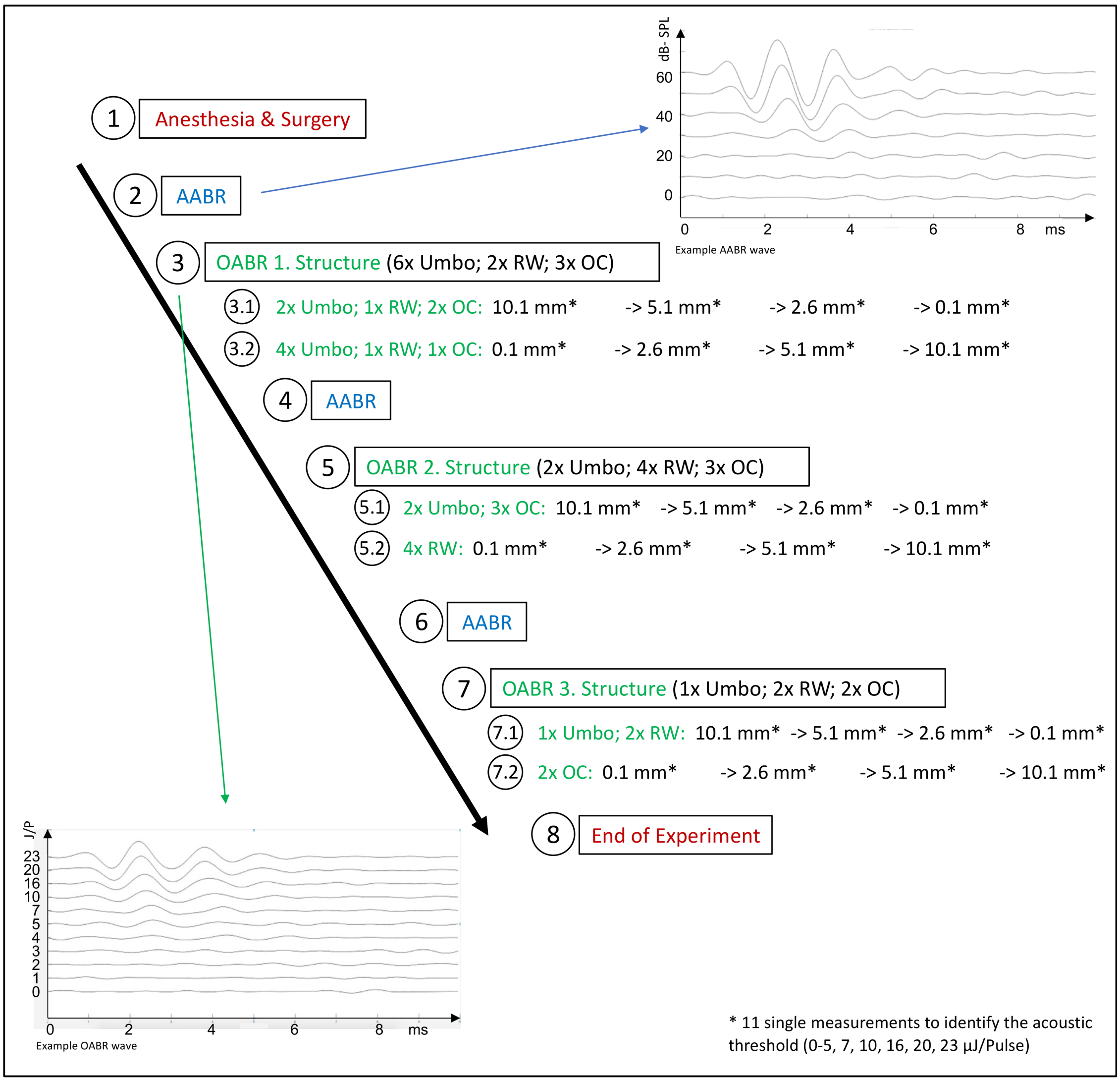

Figure 3: Temporal sequence of the individual steps in one test series. Insets represent examples (top right corner) for AABR series induced by different sound pressure level and (bottom left corner) OABR series induced by different light intensity levels.

2.5 Statistics

The data was evaluated using the statistical software Origin2020b from OriginLab Corporation (USA). The statistical significance level for all the tests was set at 5%. To establish a baseline, the difference between the auditory thresholds in µJ/P for 0.1–2.6 mm (first gap), 0.1–5.1 mm (second gap) and 0.1–10.1 mm (third gap) was taken. This allowed for the comparison of the results between the animals and the minimization of outliers.
The data was analyzed using Friedmann ANOVA, with the Shapiro-Wilk test being used to exclude a normal distribution.

3 Results

3.1 Influence of the distance between laser and target

The distance of the laser filament to the target material was found to have a significant influence on the laser beam. Upon exiting the filament, the laser beam diverges approximately 12°. This results in a reduction of the laser intensity on the target surface with increasing gap distance. For orthogonally placed laser filaments, the irradiation diameter can be calculated as seen in Figure 4.
The laser spot can be calculated using the following formula (x being the distance, d being the diameter of the fiber (0,365 mm) and α being the opening angle (12°)):

$$A = \pi \times \left[0.5 \times \left(d + 2(\tan(\alpha) \times x)\right)\right]^2$$

The relationship between the laser spot area and the gap between the laser filament and target area is presented in Figure 5.

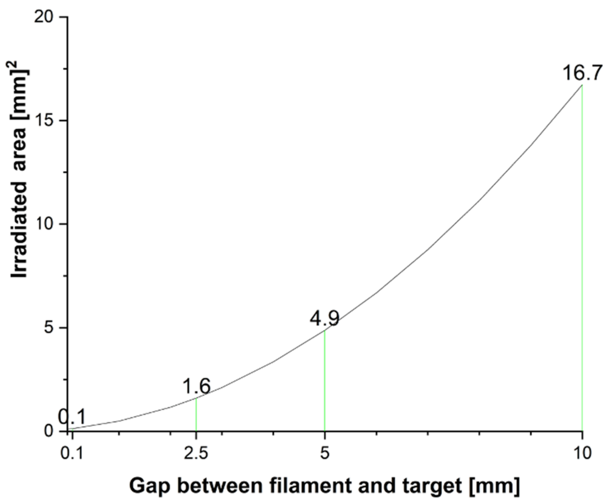

Figure 5: The relationship between the irradiated area (A) and the gap between the laser filament and the target area (χ).

3.2 Influence of the distance between laser filament and the tympanic membrane – umbo

The recorded data as described in section 2.5 is displayed in box plots to allow for better clarity and comparison. Irradiation of the umbo/tympanic membrane at different distances (Figure 6) demonstrated an increase in the auditory threshold with increasing distance from the laser source to target. The auditory thresholds at 0.1–2.6 mm and 0.1–5.1 mm (p=0.03*) as well as 0.1–2.6 mm and 0.1–10.1 mm (p=0.001***) were statistically significantly different. The difference between 0.1–5.1 mm and 0.1–10.1 mm presented a slight increase in median and mean, however the differences were not statistically significant (p=0.54). It is important to note that an outlier was identified in the 0.1–5.1 mm measurements. In this particular experiment there is no consistent explanation for the outlier, however due to the small sample numbers (n=9), this outlier could have skewed the results. These experiments will be repeated once the final wavelength for the prototype has been decided.

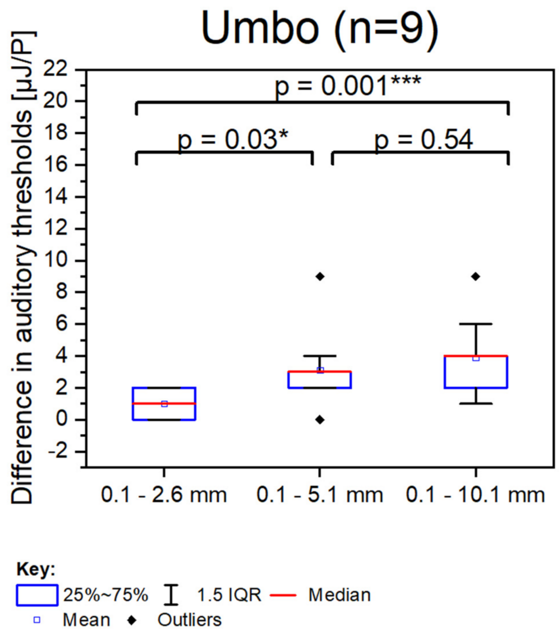

Figure 6: Auditory threshold at the tympanic membrane – umbo at different distances.

3.3 Influence of the distance between laser filament and the round window membrane

The results from the irradiation of the round window membrane at different distances also showed that with increasing distance from the laser, the auditory threshold increased (Figure 7). At this location the difference between 0.1–2.6 mm and 0.1–5.1 mm did not prove to be statistically significant (p= 0.37). The mean and median demonstrated an attenuation of the induced auditory

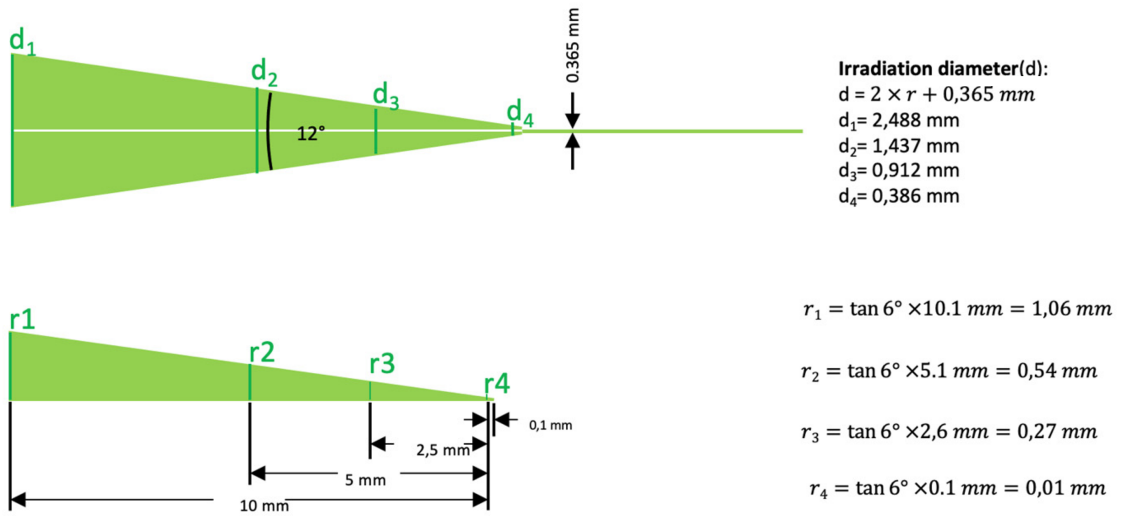

Figure 4: Graphic representation of the irradiation diameter orthogonal to the target surface area at the distances of 0.1, 2.6, 5.1 and 10.1 mm from the target surface.

signal at 0.1–5.1 mm. The auditory thresholds of 0.1–5.1 mm and 0.1–10.1 mm presented a trend towards a decrease in the induced signals (mean: second distance 4.43 µJ/P, third distance 9.14 µJ/P; median: 0.1–5.1 mm: 4 µJ/P, 0.1–10.1 mm: 8 µJ/P, however this was not statistically significant (p=0.08). The comparison between 0.1–2.6 mm and 0.1–10.1 mm distances showed a statistically significant difference (p=0.001***). The data from this location also demonstrates the previous trend that with increasing distance the activation of the hearing organ decreases.

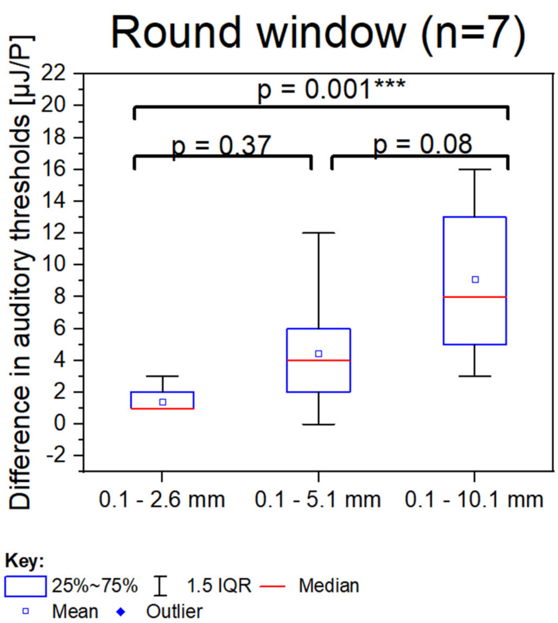

Figure 7: Auditory threshold at the round window membrane at different distances.

3.4. Influence of the distance between laser filament and the otic capsule

The OABR results induced through the laser irradiation of the otic capsule at different distances (Figure 8) had the highest variability compared to the other anatomical irradiation sites. The same trend of increasing auditory threshold with increasing laser distance to target is, however, still apparent. At this location the mean auditory threshold at 0.1–2.6 mm was 0.75 µJ/P, at 0.1–5.1 mm: 2.88 µJ/P and at 0.1–10.1 mm: 3.63 µJ/P. The differences between the auditory threshold at 0.1–2.6 mm and 0.1–5.1 mm are statistically significant (p=0.03*). The auditory thresholds at 0.1–5.1 mm and 0.1–10.1 mm showed weaker mean values (mean: 0.1–5.1 mm: 4.43 µJ/P, 0.1–10.1 mm: 9.14 µJ/P). The differences were, however, not statistically significant (p=0.99). The larger distance, comparing the differences between 0.1–2.6 mm and 0.1–10.1 mm, showed a statistically significant difference (p=0.04*).

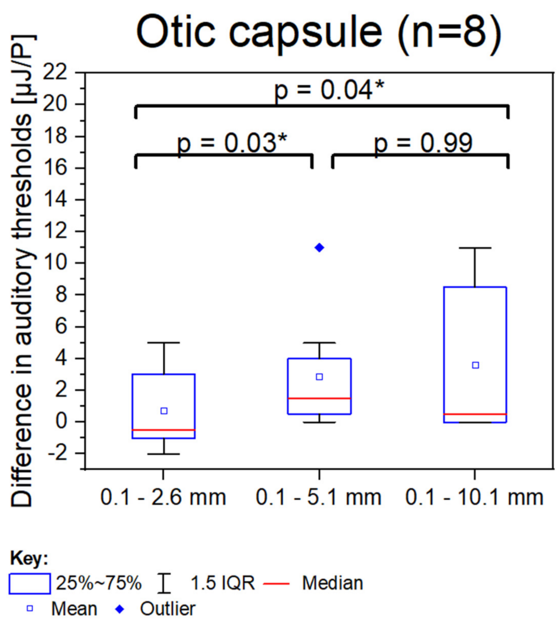

Figure 8: Auditory threshold at the otic capsule at different distances.

4 Discussion

Light can be applied in a more focused manner to targeted structures compared to other energy forms used currently in auditory prostheses and promises to be an alternative for the improved accuracy in the activation of the peripheral auditory system [8], [11]. The accuracy of such a novel stimulation technique, however, needs to be defined before considering the implementation of this technique in a prototype suitable for human application. Previous work has focused on the stimulation with laser pulses in very close proximity to the targeted tissue [8], [11], [13]. Different controlled distances to the vibratory structures needed therefore to be analyzed for the design of a novel auditory prosthesis.

Our study demonstrates that with an increasing distance between the laser filament and the target organ, a higher intensity of the laser pulses is required to reach the auditory threshold. This effect is demonstrated with varying intensities at the different anatomical sites investigated. One possible explanation for this is the aforementioned laser beam divergence of approximately 12° (section 3.1). The divergence of the laser beam together with the varying bone thickness and/or bone quality within the otic capsule, as anatomically known [14], may explain the high variability in radiation results at this anatomical site (section 3.4). Our collected data suggests that the most promising anatomical site currently for translation would be the tympanic membrane. This could be due to the amplification effects of the membrane, however further causes cannot be excluded and further experiments need to be performed to confirm the optimal anatomical site. We also consider systems that would be able to be adapted to individual anatomies especially for patients with changed anatomy after middle ear surgeries. Another possibility for the diminished effectivity of the optoacoustic stimulation with increasing distance is increasing light dissipation with the larger laser beam surface area resulting in lower photon density at the irradiation focus, with concomitant decreased energy transfer into key structures. The amplitude of the induced vibrations would therefore be decreased, as well as the intensity of activation translated in our experiments in OABR amplitudes. Therefore, higher light intensities would be needed to reach the threshold. Using a light collimator at the end of the filament might be a solution to be considered in future for this issue. Additionally, further analysis is required to determine if concomitant irradiation of the neighboring anatomical structures would influence the efficacy of the optoacoustic effect.

From a further, purely physical point of view, the vibrations induced are dependent on the mass, stiffness and damping of the targeted structure. E.g., the otic capsule is anchored in the temporal bone and would need an increased energy level to be set in vibrations compared to the tympanic membrane. In our study, we tried to reduce this variability by analyzing the differences within each targeted structure, and not their absolute value (Figure 6, Figure 7, Figure 8). In the designing process of the optoacoustic hearing devices, this significant detail must be taken into account. An individualized stimulation of each patient according to his or her anatomical condition will have to be provided

Another important consideration is the biocompatibility of the laser irradiation with respect to the auditory function and histological analysis. Sorg et al. demonstrated in their study that depending on the intensity of radiation, a negative effect of optical stimulation could be detected in mice [13]. In our experiment, the sequence of distances tested, and the order in which the locations were irradiated, varied between animals, reducing the impact of potential radiation effects. Further studies on biocompatibility are in process.

Green laser light (532 nm) was originally chosen for this study as visible light promised very good biocompatibility. However, in the meantime, the study performed by Heimann et al. demonstrated that multiple other wavelengths can, and should, be considered to increase the efficiency of the optoacoustic stimulation of the auditory organ [15]. These studies are also ongoing.

And finally, the use of an absorbing silicon film [16] gives this novel system a further chance to improve standardization of the optoacoustic stimulation method by reducing the variability of the interindividual differences in absorption characteristics of the targeted vibratory structures and amplifying the induced vibrations. All this is to allow for optimization and miniaturization of the system and improve the energy consumption so that it can be tested in clinical trials.

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