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Design of a Clinically Viable Pneumatic System for the Acquisition of Pressure Compensated Otoacoustic Emissions

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***Abstract*—Otoacoustic emission (OAE) screening is perhaps one of the most common diagnostic tools used on both adults and children alike to clinically asses hearing health. However small to moderate middle ear pressures (both positive and negative), which are quite prevalent among the general population, are known to significantly reduce the OAE response specifically among frequencies below 2kHz. This study focuses on the design and development of a software controlled syringe pump which will be used for the automatic compensation of middle ear pressure. This study reports validating test results which confirm the feasibility of using this system for future clinical trials.**

I. Introduction

Otoacoustic Emissions (OAEs) are sounds signal generated by an active process in the auditory system's cochlea. It has been widely accepted that the generation of OAEs is a precursor for healthy hearing. The measurement of evoked OAEs can be used to determine the general health of the cochlea and basilar membrane's response and sound transmission forward and backwards through the inner ear. OAEs are commonly used for newborn infant hearing screening where many middle ear pathologies are first detected. In most cases, secondary screening tests such as tympanometry, which aims at pinpointing middle ear transduction issues, are not conducted unless the patient has failed the OAE screening first. If no tympanometric measurements have been taken prior to OAE-based hearing screening, there is a larger probability that more false positives would be found in neonatal wards throughout Denver, CO (high altitude) than similar wards in Miami, FL (low altitude). Increases in ambient pressure have an almost identical effect on OAE recordings when compared to naturally occurring negative middle ear pressures (NMEPs), or significant NMEPs which occur from middle ear pathologies such as Eustachian tube dysfunction [2]. Thus arises the need for pressure compensated OAE screening. This study aims at reviewing the design of a self-compensating pressure system capable of generating steady meatal pressures during OAE diagnostics. Facets of system design including patient safety factors, software interaction, and initial test results will be presented.

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II. Research Background

A. Overview of the Hearing Mechanism

The human ear is divided into three main anatomical areas: (1) outer ear (2) middle ear and (3) inner ear. The outer ear comprises the cartilaginous pinna and the auditory canal or external acoustic meatus. The primary function of the external ear is to funnel in sound from an individual's environment and then transmit those acoustic signals down the conduit of the external acoustic meatus towards the tympanic membrane which is the opening of the middle ear.

Towards the end of auditory canal, sound comes into contact with the tympanic membrane. This elastic membrane is the primary component in the middle ear region which further consists of the ossicles, tensor tympani muscle, and stapedius muscle. The two core functions of the middle ear system are force amplification and sound transduction. Within the middle ear region there is also a pressure shunting branch via the Eustachian tube. This branch acts as pressure relief valve within the middle ear. However, it often does not function properly due to middle ear pathology resulting in a pressure imbalance.

The final region of the human hearing system is the inner ear. The interface between the middle and inner ears is the stapes and its physical connection with the oval window of the cochlea. The primary function of the inner ear is frequency resolution and neurological transduction of hydrodynamic motion into frequency coded impulses which ultimately act on the auditory cortex of the brain.

B. Basics of TEOAE

OAEs are low-level acoustic responses generated by the outer hair cells which are picked up by a sensitive low noise microphone placed within the auditory canal in the form of a probe. The OAE results from a natural active response from the cochlear amplifier and thus the lack of evoked OAEs can lead to the diagnosis of cochlear damage.

Transient evoked otoacoustic emissions (TEOAEs) derive their name from the method of which OAE stimulation is achieved. These emissions are elicited from the ear in response to a sudden acoustic stimulus, a click typically 75 μs in duration, in order to stimulate a broad range of the cochlea.

Approximately 20 ms of data are recorded post stimulation from the probe microphone in the ear canal. TEOAE recording systems implement an averaging technique with many rounds of click stimuli being elicited and their appropriate OAE recorded. Because the noise floor is ideally random the noise should in fact average out to zero

while the recorded OAE echo will remain or grow with respect to the noise floor due to its repetitive elicitation and recording. A spectral analysis of the response is conducted to determine frequency specific cochlear function information in order to identify potential regions of hearing loss.

C. Typical Effects of Pressure on the Recorded TEOAE

Through the use of animal models, it has already been demonstrated that pressure buildups within the middle ear have a direct effect on the physical characteristics of the tympanic membrane which allow for sound transmission into and out of the middle ear cavity. Lee and Rosowski reported the biomechanical effects of increased ear canal pressure on the middle ear structure of gerbils. Specifically the vibration velocity of both the pars tensa and pars flaccida, the two primary components of the tympanic membrane, were analyzed for varying amounts of artificially induced tympanometric pressure. Using laser Doppler velocimetry it was determined that non zero middle ear pressures (i.e. pressures not equal to the ambient surrounding pressure of the external ear canal) had the specific effect of reducing the velocity of both tympanic membrane components for stimulating frequencies less than or equal to 2000Hz [3]. This reduction of vibration velocity directly impacts the mechanical transduction of the ossicular chain and its impact on the oval window and thus the end stimulation of the basilar membrane and its hair cell structure.

The effects of static pressure on otoacoustic emissions have been recorded in several studies in the past. Naeve et al. (1992) recorded the effects of static pressure within the -200 to +200 daPa range. The transient OAE (TEOAE) responses of several volunteers were recorded under normal and induced pressures. Both positive and negative ear canal pressures induced the same outcome which was a reduction of low frequency components within the TEOAE signal. The response of the OAE signal to static pressure resembled the inherent characteristics of a high pass filter with cut off frequency of 2600Hz and a slope of 4dB per octave. The higher ear canal pressures brought the TEOAE signals to below the noise levels of the recording instrumentation thus suggesting that severe negative middle ear pressures, occurring naturally in patients, could result in false positives during an OAE screening session [4].

Trine et al. [5] performed a follow up study analyzing 14 patients who were specifically exhibiting tympanometric peak pressures (TPP) from -100 to -310 daPa. Unequalized ear results showed a dramatic attenuation effect at low frequencies (i.e. $\leq$ 1kHz). Pressure equalization via static negative ear canal pressure produced by the measurement probe brought upon increased TEOAE amplitudes as well as a higher rate of reproducibility in almost all patients. Perhaps the most dramatic result of the study was the TEOAE effect in two specific patients during equalization. With both of these patients, their initial, unequalized OAE screening yielded a FAIL result (i.e. reproducibility less than 50%) which indicated that they would be ideal candidates for middle ear pathology, thus additional testing would be needed. However, after pressure equalization, reproducibility rates improved from 42% to 83% in one patient and 49% to 78% in the other. This result clearly indicates that negative middle ear pressures have a direct correlation with false positive screenings in patients with mild to progressive NMEPs. This study also demonstrated that the best improvements are not proportional to the largest NMEP present. Therefore pressure equalization can have a very dramatic end effect on patients who may not even be aware of naturally occurring NMEPs. Pressure equalization also brought on an improvement of stimulus presentation within the ear canal with respect to stimulus ringing as measured by the instrumentation probe. The stimulus spectrum was also smoother, which could have contributed to the increase in TEOAE amplitudes, outside of the boost effect gained during admittance changes.

Similar low frequency attenuation effects were seen by Plinkert et al. in 1994 [6], who conducted research on the effect of middle ear pressure on both the TEOAE and DPOAE. Again static pressure within the ear canal was varied between -200 and +200 daPa. Both TEOAE and DPOAE signals were greatly reduced at frequencies less than or equal to 2 kHz.

III. Design Methodology

A. Mechanical Design Overview

A complete pump system capable of studying the benefits of compensated OAE screening consisted of two main parts: (1) OAE recording software complete with an off the shelf probe capable of recording low noise OAE emissions, and (2) a syringe pump which can be controlled and combined with the aforementioned probe and data acquisition software. The compensation system will be using Intelligent Hearing System's (IHS) SmartTrOAE DSP based software/ hardware platform. This OAE recording system is capable of performing standard click TEOAE testing and works with standard OAE probes such as the Etymotic 10D and 10B+. This platform was paired with a custom built, automated syringe pump in a master/slave configuration. During design special emphasis was given to syringe volume calculations, motor selection, aspects in reliability, position sensing, pressure monitoring, and patient safety.

In general, the pump system as shown in Fig. 1 comprises three stages: motor block stage, travel stage, and termination stage. The motor block stage is where the DC motor is mounted and where the front of the syringe is encased and clamped to the front stop. This section of the syringe pump also houses the start switch, an SPDT micro switch which when pressed by the travel plate relays the starting position of the syringe pump. The travel stage is a subassembly which houses the linear bearings which in turn travel along the alignment shafts during operation. This stage also retains the back end of the syringe during operation and is responsible for the operation of the pump. The termination stage is where the lead screw terminates and is supported by

a radial bearing as well as where the stop switch is housed, a secondary micro switch which operates identically to the start switch but relays the end position of linear travel.

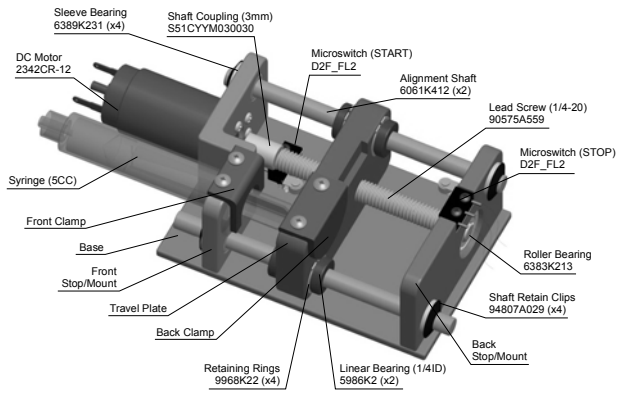

Fig. 1 Isometric view of syringe pump with component callout

The travel stage employs two precision linear bearings which run along two precision machined shafts supported on each end by the motor block stage and termination stage. The linear bearings aid in the reduction of system friction, while also maintaining strict linearity during the pump's motion. The benefit of such a design is increased motor efficiency and speed while decreasing friction.

The geometry of the syringe itself was also selected to ensure quick flow rates during operation. Typical tympanogram rates are typically around 200dAPA/s. Some assumptions were initially made regarding the linear speed of the pump system, such as the assumption that a minimal linear speed of 0.125in/s (or 3.2mm/s) should be specified so as to design a pressure system which would be as equally fast if not faster than commercially available systems. From this initial constraint we can develop an expression for volume displacement within the syringe as seen in (1).

$$V_{displaced} = L(\pi r^2) \tag{1}$$

Because the syringe we have chosen has a circular cross section, the volume displaced is characterized by the length the plunger travels (L), and the cross sectional radius of the syringe body (r). Equation (1) yielded 0.022in3, or 0.36cc. Thus if our linear actuation speed from the motor coupling to the lead screw remains at 0.125in/s, the pump will displace approximately 0.36cc per second. Boyle's law, which relates pressure and volume, was used to estimate the transitional relationship between this displaced volume and the resulting pressure change. It was determined that at the system's most optimal condition we could expect a pump speed with a rate of 786 daPa/s.

After accounting for boundary losses, even if the system were to perform at 40% efficiency, due to these losses, a pressurization rate of 314.4 dAPA/s would still outperform existing tympanometry screeners.

Linear speed is just one of many input variables which were used for the development of the syringe pump. Additional important design inputs included: motor supply reference voltage (Vdc), desired linear speed (s), rotational speed as seen at the shaft of the motor (n), plunger force (F), actuating screw lead (l), and efficiency (η_s), no-load motor current (I_o), and the motor's torque constant (k_m). From these input conditions three major motor parameters were calculated: (a) load torque (M), (b) power (P), and (c) loaded current draw (I). These relationships are characterized by equations 2-4. It must be noted that M must be converted into [oz-in] for equation (3) after calculating torque in equation (2).

$$M = \frac{Fl}{2\pi\eta_s} \tag{2}$$

$$P_{motor} = \frac{nM}{1350} \tag{3}$$

$$I = \frac{M}{k_m} + I_o \tag{4}$$

B. Electrical Design Overview

There are four major sections which comprise the syringe pump's hardware design: (A) digital I/O interface, (B) motor driver circuit, (3) pressure transducer circuit and (4) patient safety release valve circuit. The pump control system acts as a slave to the IHS digital acquisition system. The IHS system is a commercially available OAE diagnostic system. Custom software written expressly for the sake of obtaining pressure compensated OAEs. The IHS system provides power as well as input and output signals using a TI320c31 DSP. The DSP and control hardware is in turn connected using a USB interface to a Windows-based user control and data analysis software running on a PC.

The DSP system provides a total of five digital inputs which are driven through an octal buffer chip (SN74F541DW) into the pump control board providing control for various functions and triggers within the syringe pump's hardware. Table I describes all of the digital inputs and their functions.

TABLE I
DSP GENERATED DIGITAL INPUTS

Input	Description
D0	Motor control line (PWM, 1 = Forward, 0 = Reverse)
D3	Digital switch control (A/D, 1 = Pressure, 0 = Switches)
D4	Clock control line (CLK, 1 = Enabled, 0 = Disabled)
D5	Motor shut off (MTR, 1 = Off, 0 = On)
D6	Release Valve (RV, 1 = Open, 0 = Closed)

The syringe pump's DC motor is driven by a DMOS full bridge motor driver IC (A3950). DSP control lines D0, D4, and D5 control certain aspects of the motor driver chip. The IC controls DC motor function via pulse width modulation (PWM) and can work with supply voltages up to 36VDC.

The phase and enable lines control the motor's directionality as well as speed. The enable pin on the motor driver chip is controlled via an external clock signal.

The syringe pump uses a sophisticated dual port pressure transducer provided by Honeywell (ASDX001D44D). The transducer is a piezoresistive sensor, with amplified output and built in signal conditioning. The IC works from a +5VDC supply and acts as a differential gauge. In an atmospheric condition the analog output is about 2.5VDC. Positive pressure changes result in voltage increases until the transducer reaches 1PSI at which time the unit reaches its top most limit (5VDC). Negative pressure differences have the exact opposite effect whereas the bottom limit is 0VDC.

The core component responsible for delivering patient safety is the solenoid triggered release valve provided by LeeCo (LHDA053115H). The output pressure line from the syringe pump feeds directly into a T-coupling where one output feeds the main patient interface while the remainder of the pneumatic circuit connects to the input port of the pressure transducer and to the normally open port of the LHDA release valve.

Triggering of the release valve is initiated in one of three ways: (a) position switch triggering, (b) direct software trigger or (c) comparator output trigger. Position switch triggering occurs in two different events. The first is during initiation, when the pump finds its home position. The second is when the pump reaches the end of its stroke. The release valve is automatically triggered so as to purge any residual pressure. The other two potential triggering events would be a direct software trigger made available to the audiologist in the windows computer interface. This allows venting if the audiologist feels that a test should be stopped and is controlled via D6. A comparator circuit provides the final triggering event. A high and low pressure threshold can be set via POT adjustment of the circuit. This allows for very fine adjustment of the testing conditions and pressure ranges, and ensures that testing does not exceed the predetermined range.

IV. Results

After the system was properly calibrated (ref. ANSI S3.39-1987 section 10.2), the pressure compensation system was validated using two test qualifiers as deciding factors. A preliminary tympanogram was taken, and both a negative and positive pressure compensated OAE was compared to a standard OAE screening of the same volunteer. It should be noted that the results presented in this article are done so for the purpose of establishing the functionality of the newly designed pump system.

A. Preliminary Tympanogram

In order to validate the design of the pressure compensating system, a standard tympanogram was taken. The results of the tympanometric measure showed a very clearly defined peak pressure at 0daPA. The resulting tympanogram reflected the expected result as compared to the baseline tympanogram obtained using a commercially available tympanometric device.

B. Pressure Compensated OAE Testing

Three OAE tests were performed on the same volunteer: normal, positively compensated (+80daPA), and negatively compensated (-80daPA). Variations in recorded amplitudes were noticed to be significant for both pressure compensated tests. The results are shown in table II.

TABLE II
COMPARISON BETWEEN NORMAL AND PRESSURE COMPENSATED OAE AMPLITUDES

F [Hz]	Normal	Negative Pressure	Positive Pressure
1000	3.09	0.83	0.59
1500	-2.84	-6.55	-2.91
2000	-3.16	-6.87	-7.18
3000	-9.34	-11.57	-6.28
4000	-15.89	-18.02	-5.13

V. Conclusion

Based on these initial test results, the design of the pressure compensating OAE diagnostic system was deemed successful. The screening system will be used during a larger scale clinical study which will focus on the development of an accurate mathematical model showing the potential benefits of pressure compensated screening. This future study will also focus on the time domain signal analysis of pressure compensated OAEs, which has been previously found to be lacking.

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