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US ARMY MEDICAL RESEARCH LABORATORY

FORT KNOX, KENTUCKY

REPORT NO. 610

EFFECTS OF HIGH INTENSITY IMPULSE NOISE AND RAPID CHANGES IN PRESSURE UPON STAPEDECTOMIZED MONKEYS

Major John L. Fletcher, MSC
Captain George D. Roberson, MC
Michel Loeb, Ph. D.

UNITED STATES ARMY
MEDICAL RESEARCH AND DEVELOPMENT COMMAND

21 August 1964

Report Submitted 12 August 1964

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The animals used in this study were handled in accordance with the "Principles of Laboratory Animal Care" established by the National Society for Medical Research.

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21 August 1964

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Military Psychophysiological Studies
DA Project No. 3A012001A800

USAMRL Report No. 610
DA Project No. 3A012001A800

ABSTRACT

EFFECTS OF HIGH INTENSITY IMPULSE NOISE AND RAPID CHANGES IN PRESSURE UPON STAPEDECTOMIZED MONKEYS

OBJECT

To determine the effect of high intensity impulse noise and of rapid changes in pressure upon stapedectomized patients.

RESULTS

No experimental disarticulation of the prostheses was observed, nor were any behavioral manifestations of vestibular involvement seen. No significant difference between the two types of prostheses used was found.

CONCLUSIONS

There is no valid evidence in this study to support drastic duty limitation for stapedectomized personnel. No operational basis for choice between the polyethylene and vein graft procedure as opposed to the stainless steel piston could be found.

APPROVED: George S. Harker
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EFFECTS OF HIGH INTENSITY IMPULSE NOISE AND RAPID CHANGES IN PRESSURE UPON STAPEDECTOMIZED MONKEYS

Today we find the stapedectomy procedure the treatment of choice in the management of otosclerosis. The widespread incidence of otosclerosis, plus the popularity of the stapedectomy procedure, have resulted in a great number of persons undergoing this operation. The relative newness of the procedures and the difficulties attendant upon research in this area in part account for the dearth of research on the subsequent effects of this procedure upon the hearing abilities and susceptibilities of those so treated. Investigations have been made of the susceptibility of stapedectomized patients to noise induced temporary threshold shifts (1, 2, 3). So far, the findings appear to indicate no heightened susceptibility to acoustic insult. However, at best many problems beset the researcher in this endeavor. One critical problem is that of securing a proper control group against which to compare a stapedectomized population. Ideally, the control group should differ from the experimental group only in that they have not been stapedectomized. Certainly, auditory acuity of the two groups should be the same, because auditory acuity is a limiting factor in noise induced temporary threshold shifts (4). This requirement is exceedingly difficult to meet, and as a result, extreme caution must be observed in evaluating the results of studies where this condition was not met.

Several problems should be considered in evaluating the hazards of the environment to the stapedectomized person. Impulse noise, with its precipitous rise time and typically high overpressure, would logically be thought to pose more of a problem than would continuous noise, not only because of the possibility of noise induced hearing loss, but also because of the possibility of the inertia of the prosthesis-ossicular chain interacting with the steep rise time of the impulse to result in disarticulation of the prosthesis, or more drastic damage. Andersen et al (5) measured the transmission of sound before and after insertion of stapedial prostheses in cadaver temporal bones. They found no prosthesis weight-frequency related effects. They did, however, note that exposure to "violent" sounds resulted in disarticulation of the prostheses. They also observed that at such high levels (in excess of 100 dB) the prosthesis did not follow the movement of the incus. Subjective reports are frequently encountered suggesting that changes in altitude, such as those found in unpressurized or suddenly de-pressurized airplane cabins, result in failure of the prostheses. However, one might think that if the patient were able to equalize the pressure, i.e., "clear" his ears, danger from this source would be minimized.

in order to minimize activity during exposure (such as fighting, jumping, and other activities that might produce deleterious effects).

Group II, also 12 animals, 24 ears, was placed in an altitude chamber and ascended to a pressure equivalent altitude of 30,000 feet, then descended, free-fall, to 1,200 feet. This was repeated three times with 2 min intervals between runs. No sedation or tranquilization was given this group as we were afraid such treatment might interfere with the animals' ability to equalize pressure.

Group III, 11 animals and 22 ears, was housed with the other animals, treated just like them, but not exposed to gunfire or pressure change.

Immediately after exposure, the animals in Groups I and II were anesthetized and had their tympanic membranes reflected in order to determine the effects of the exposure upon the tympanic membrane, ossicular chain-prosthesis, middle ear mucosa, and the oval window reaction. At a later date the animals of the control group, Group III, were similarly scrutinized.

RESULTS

The over-all results were surprisingly good from a clinical point of view, i.e., the prostheses were extremely resistant to disarticulation, so much so that none were experimentally interrupted. The observed reactions of the tympanic membrane, middle ear mucosa, and oval window were also remarkably mild. Both the PE + V and the SSP did well. The data do not seem to differentiate between the two as far as we can tell. Complete results of the experiment are presented in Tables 1, 2, 3, and 4. As can be seen, gunfire had no observable effect upon the prostheses and little observable effect upon the tympanic membrane, middle ear mucosa, and the oval window. Also, no behavioral effects of vestibular trauma were seen. Obviously, in view of the severity of the impulse noise to which these animals were exposed, more than a human would normally ever receive, we need not fear failure of the prostheses from this source. However, it is equally plain that we cannot, on the basis of this experiment, say anything about the damage to the hearing of the animal, only that the prostheses did not fail. In a further effort to promote failure of the prostheses by impulse noise, six animals of Group I were exposed to 12 rounds of gunfire from a 90 mm cannon. The average quasi-peak SPL, measured inside the cage, was in excess of 190 dB. Again, we failed to produce drastic results (see Table 4).

We could observe no significant basis for choice between the PE + V and SSP techniques. If basis for choice exists, it is surgical, not mechanical.

It is appropriate to mention here that more research is necessary before we can set exposure criteria for the patient's work environment. It will probably be some time before sufficient data are accumulated to enable us to evaluate the permanent effects of various noises upon the hearing of stapedectomized patients.

CONCLUSIONS

1. High intensity impulse noise and rapid changes in air pressure do not appear sufficient to cause significant prosthesis failure in stapedectomized monkeys.

2. Of the two variables tested, within the limits of this experiment, pressure changes appear to be more traumatic.

3. No apparent difference appears to exist between the reliability of the stainless steel piston and the polyethylene and vein techniques.

4. Solely on a basis of fear of prosthesis failure, no reason can be seen for any drastic limitation of duty of stapedectomized patients.

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1. Steffen, Ted N. and James C. Nixon. Stapedectomy and noise. The Laryngoscope, 73: 1044-1060, 1963.

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The Armed Forces are a particularly lucrative source of both problems and research possibilities with regard to stapedectomies. Gunfire noise exposure is, of course, typical of military personnel, and with the increasing use of aircraft of all kinds, and of airborne operations involving parachuting, a large number of persons are exposed to rapid changes in pressure. Problems of this nature suggested the research to be reported in the succeeding sections. Specifically, an investigation was made of the effects of impulse noise and sudden changes in pressure (simulating altitude changes) upon stapedectomized monkeys. Monkeys were used because of both the ethical and practical considerations involved.

METHOD

A total of 40 Cebus monkeys were procured and subjected to surgery. The Cebus monkey, a New World species, was used because its middle ear is quite accessible to surgery, unlike that of the Old World monkeys, and is markedly similar to that of man. Both ears of each animal were operated with the same type of prosthesis placed in each ear. Half the animals were treated with a modified Shea (6) technique utilizing a No. 90 polyethylene strut and vein graft (PE + V), while the other half had a stainless steel piston (SSP) made especially to fit the Cebus monkey. Five of the surgically completed animals expired subsequent to surgery from non-surgical causes so that our experiment was performed on a population of 35 animals. These animals were randomly divided into three groups. Group I was exposed to high intensity impulse noise on two occasions, to machine gun fire and to 90 mm cannon fire. Group II was exposed to rapid changes in pressure simulating changes in altitude, while Group III was the control group. They were operated, kept with and treated like the experimental groups except that they were not experimentally exposed to either of the variables.

Group I, which consisted of 12 animals (24 ears) was exposed to 2,000 rounds of fire from an M-73 7.62 cal machine gun. The fire was 5 sec bursts with a 5 sec interval between bursts. All animals exposed had had at least 2 months to recover from surgery. Firing was done on an open range in the field. The quasi-peak sound pressure level (SPL), measured inside the animal's retention cage, averaged 164 dB. Sound measurement was accomplished using a General Radio Model 1551-B sound level meter, a Massa 141-B microphone, and a General Radio Model 1556-B impact noise analyzer. Variability of the pressure was ± 2 dB. All animals were tranquilized 2 hours prior to exposure by injection of 1 mg/kg body weight of Seruylan (phencyclidine hydrochloride) in order to minimize activity during exposure (such as fighting, jumping, and other activities that might produce deleterious effects).

Group II, also 12 animals, 24 ears, was placed in an altitude chamber and ascended to a pressure equivalent altitude of 30,000 feet, then descended, free-fall, to 1,200 feet. This was repeated three times with 2 min intervals between runs. No sedation or tranquilization was given this group as we were afraid such treatment might interfere with the animals' ability to equalize pressure.

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The effects of altitude (pressure) as seen in Table 2, were somewhat more noticeable. For example, Table 1 shows that in Group I, the appearance of the tympanic membrane was normal for all subjects. In Group II, however, only eight of the membranes appeared normal; the rest varied from a slight to a generally injected appearance. Similarly, the middle ear mucosa was normal in Group I, while in Group II, only seven were normal, with the remaining 17 varying from a slight reaction to frank hemorrhage. The oval window reaction observed in the two groups was about the same. As we examine these data we are inescapably drawn to the conclusion that while neither of these experimental variables really wrecked havoc with the prostheses, the effects of the pressure change were considerably more marked. It is significant, we believe, that no failures of the prostheses were induced. The procedures are obviously highly reliable and quite resistant to forces considerably in excess of those one normally encounters in everyday life. This is not to say that failure will not occur, merely that we were unable to produce it. We desire to emphasize again, however, that these results related only to susceptibility of the prostheses to failure, and to tissue response, not to the effect of these variables upon the hearing of the stapedectomized animal.

We also believe that it is significant that no behavioral manifestations of vestibular damage could be observed. Any penetration of the vestibule by the prostheses should have produced immediate and observable behavioral changes. The fact that none were observed strongly suggests that no penetration occurred. Serial sections are being made of the temporal bones but results are not ready at this time.

Our results obviously do not support the findings of Andersen *et al* (5) who reported disarticulation of the prostheses at "violent" levels. This is not surprising, as their prosthesis was in an exposed dead temporal bone, while ours was in an intact living animal.

DISCUSSION

Based upon the results presented above, we can see no real need to drastically restrict the duty activities of stapedectomized persons after complete recovery from initial surgery. As always, common sense should be used but apparently the procedures are quite resistant to failure if successfully performed. However, as shown in Tables 1 and 2, original results of the insertion of the prostheses can be less than perfect, so that trauma could conceivably break down an initially imperfectly implanted prosthesis.

We could observe no significant basis for choice between the PE + V and SSP techniques. If basis for choice exists, it is surgical, not mechanical.

It is appropriate to mention here that more research is necessary before we can set exposure criteria for the patient's work environment. It will probably be some time before sufficient data are accumulated to enable us to evaluate the permanent effects of various noises upon the hearing of stapedectomized patients.

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LEGEND FOR TABLES

TM - Tympanic Membrane
MM - Middle Ear Mucosa
OW - Oval Window

Tympanic Membrane

Normal (N) - Self-explanatory.
Slight injury - Hyperemia in vascular strip area.
General injury - Entire tympanic membrane hyperemic.

Original Results

Self-explanatory.

Middle Ear Mucosa

No reaction (NR) - Self-explanatory.
Slight reaction - Generalized injection.
Moderate reaction - Some petechiae.
Frank hemorrhage - Self-explanatory.

Oval Window

Slight - Very little reaction in the drum or the vein around the prosthesis.
Moderate - Somewhat greater reaction around prosthesis.
Marked - Drum plastered to incus with much reaction around prosthesis.

TABLE 1

GROUP I - GUNFIRE

(Polyethylene Strut and Vein Graft)

Left Ear				Right Ear			
Post-Exposure Appearance of the TM	Original Results	Reaction of the MM	Reaction of the OW, Due to Surgery	Post-Exposure Appearance of the TM	Original Results	Reaction of the MM	Reaction of the OW, Due to Surgery
N	Originally slipped tube	NR	Slight	N	Good	NR	Slight
N	Good	NR	Moderate	N	Good	NR	Slight
N	Good	NR	Marked	N	Good	NR	Slight
N	Good	NR	Slight	N	Good	Moderate	Moderate
N	Gcod	NR	Slight	N	Good	NR	Slight
N	Good	NR	Slight	N	Good	NR	Slight

(Stainless Steel Piston)

Left Ear				Right Ear			
Post-Exposure Appearance of the TM	Original Results	Reaction of the MM	Reaction of the OW, Due to Surgery	Post-Exposure Appearance of the TM	Original Results	Reaction of the MM	Reaction of the OW, Due to Surgery
N	Good	NR	Slight	N	Good	NR	Slight
N	Good	NR	Slight	General injury	Good	Moderate Question of perilymph in middle ear	Moderate
N	Good (Poor crimp, no slipping)	NR	Slight	N	Good	NR	Moderate
N	Good	NR	Slight	N	Good	NR	Slight
N	Good	NR	Slight	N	Good	NR	Slight
N	Good	NR	Moderate	N	Good	NR	Slight

TABLE 2

GROUP II - ALTITUDE

(No Perforations Seen in Any Ears)
(Polyethylene Strut and Vein Graft)

Left Ear				Right Ear			
Post-Exposure Appearance of the TM	Original Results	Reaction of the MM	Reaction of the OW, Due to Surgery	Post-Exposure Appearance of the TM	Original Results	Reaction of the MM	Reaction of the OW, Due to Surgery
General injury	Good	Frank hem-orrhage	Slight	Slight	Good	Slight	Slight
N	Good	NR	Slight	Slight	Good	Slight	Slight
N	Good	NR	Slight	Slight	Good	Frank hem-orrhage	Slight
Slight	Good	Moderate	Slight	Slight	Good	NR	Slight
N	Good	NR	Slight	N	Slipped	NR	Slight
Slight	Slipped	Slight	Slight	Slight	Good	Frank hem-orrhage	Slight

(Stainless Steel Piston)

Slight	Good	Moderate	Slight	Slight	Good	Moderate	Moderate
Slight	Good	Moderate	Moderate	Slight	Good	NR	Moderate
Slight	Good	Frank hem-orrhage	Moderate	N	Poor crimp	NR	Slight
General injury	Good	Moderate	Moderate	Slight	Good	Moderate	Marked
Slight	Good	Moderate	Slight	N	Good	Slight	Slight
N	Good	Slight	Slight	N	Good	NR	Slight

TABLE 3

GROUP III - CONTROLS*

(Polyethylene Strut and Vein Graft)

Left Ear				Right Ear			
Post-Exposure Appearance of the TM	Original Results	Reaction of the MM	Reaction of the OW, Due to Surgery	Post-Exposure Appearance of the TM	Original Results	Reaction of the MM	Reaction of the OW, Due to Surgery
N	OK	OK	OK	N	OK	OK	OK
N	OK	OK	OK	N	Slipped immediately post-op	OK	OK
N	OK	Moderate	OK	N	OK	Moderate	OK
N	OK	OK	OK	N	Poor operative connection	OK	OK
N	OK	OK	Moderate	N	OK	OK	OK
N	OK	OK	Moderate	N	OK	OK	OK
N	OK	OK	OK	N	OK	OK	Moderate

(Stainless Steel Piston)

N	Good	NR	N	N	Riding high, poor crimp	NR	N
N	OK			N	OK	OK	OK
N	OK	OK	OK	N	OK	OK	OK
N	OK	OK	OK	N	OK	OK	OK

*Some surgically completed animals expired from non-surgical causes, so control group slighted to allow correct experimental groups.

TABLE 4

EXPERIMENTAL - GUNFIRE 2 (90 mm)

(Polyethylene Strut and Vein Graft)

Left Ear				Right Ear			
Post-Exposure Appearance of the TM	Original Results	Reaction of the MM	Reaction of the OW, Due to Surgery	Post-Exposure Appearance of the TM	Original Results	Reaction of the MM	Reaction of the OW, Due to Surgery
(Stainless Steel Piston)							
						Marked*	

*With this one exception, gunfire produced no observable effect.

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