

ARTICLE



Impact noise of prostate biopsy devices

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ABSTRACT

Objective: To analyse the impact noise generated by prostate biopsy devices.

Materials and methods: In a laboratory setting, repeated impact noise was recorded at distances of 50 cm and 100 cm using five brands of device on chicken meat, an apple and an empty target. In a clinical setting, the impact noise levels of prostate biopsy devices were recorded in 40 real patient cases using three brands of device.

Results: In the laboratory setting, the average SPL (sound pressure level) peak level ranged from 104.3 to 121.3 dB. The highest impact noise levels were measured with the Monopty device, ranging from 114.8 to 122.4 dB. In the clinical setting, there were no statistical differences between repeated SPL values for each specific target. Also, the noise levels were equal when the same device brand was used at 50 cm and 100 cm. The highest SPLs were recorded with the Monopty device, which ranged from 110 to 127 dB. The corresponding values for the Max-Core and Multicore were from 106 to 122.5 dB and from 108 to 116.5 dB, respectively.

Conclusions: Biopsy devices generate high peak levels of impact noise. Personnel performing biopsies are advised to consider using hearing protection, even though the impact noise may not induce permanent hearing loss.

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Introduction

Prostate biopsy is a typical procedure performed in urology. Usually, 10–12 biopsies are taken per patient, with some urologists taking more than a hundred biopsies per day. In our preliminary clinical measurements, we found that these devices emit high impulse noise up to 120 dB in peak sound pressure level (SPL). To our knowledge, no publications or recommendations are currently available on this subject. Exposure to high noise levels may cause permanent cochlear damage resulting in sensorineural hearing loss and/or tinnitus [1].

Impact or impulse noise has acoustic characteristics of very short duration and high peak SPL. Impact noise may be created by the collision of hard objects, whereas impulse noise may be generated by a phenomenon such as an explosion [2]. Impact noise is known to cause the same cochlear damage as impulse noise, because the ear responds to the total energy of the noise exposure or the higher peak level of impact, which can induce direct mechanical damage leading to hearing loss [2]. The extent of hearing damage caused by such noise exposure depends on the duration of exposure, the sound energy of the impulse or impact, and individual susceptibility [3]. Impact noise has been suggested to induce less hearing loss than continuous noise at an emission level of less than 115 A-weighted dB (dBA). However, the exposure becomes more hazardous to hearing at emission levels higher than 115 dBA [4]. A gunshot is a well-known example of impulse

noise. Exposure to various impact noises occurring in daily activities is nevertheless more common.

In a biopsy device, the impact noise is created by the release of two consecutive preloaded strings that hit the hard wall of the device. The force of the strings releases two subsequently moving needles into the tissue taking the biopsy. For example, studies of impact noise have revealed that the maximum peak SPL generated by a titanium head golf driver is more than 120 dB [5]. The object of our study was to analyse the impact noise levels of prostate biopsy devices both in clinical and laboratory settings.

Methods

Clinical setting

Three brands of prostate biopsy device were used in a routine clinical setting: Max-Core[®], Monopty[®] (Bard Biopsy, 1415 West Third Street Tempe, Arizona 85281, USA) and Multicore[®] (SteryLab S.r.l. via Magneta 77/6, 20017 Rho-Milan, Italy). Transrectal ultrasound-guided biopsies were taken in 40 patients with suspicion of prostate cancer. We used the Max-Core[®] in 14, the Monopty[®] in 23, and the Multicore in 3 patients. Systematic biopsies were performed in 17 patients and fusion biopsies in 23 patients. Impact noises were recorded using a B&K Integrating Sound Level Metre, type 2225, holding the microphone close to the right ear, keeping an equal distance to the biopsy device.



Figure 1. Set-up for laboratory measurements. The biopsy device and target were hand-held during the biopsies. The distance from the microphone was measured with the ruler on the table.

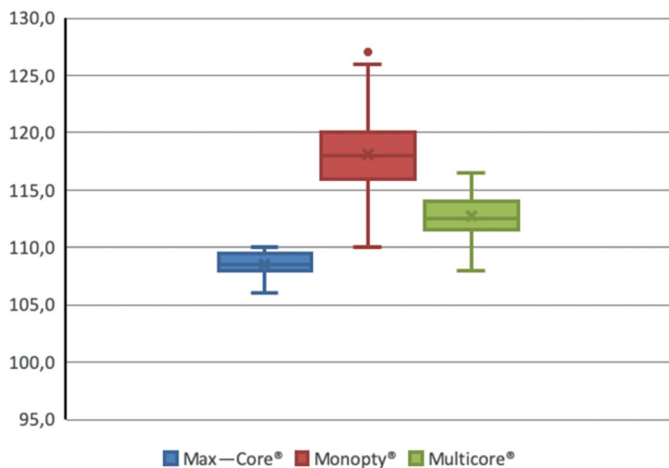


Figure 2. Measurements of impact noise (dB) generated by prostate biopsy devices in a clinical setting. The diagram shows the median value, standard error and range with outliers.

Laboratory setting

Further analyses of the biopsy devices were carried out in a laboratory setting (Figure 1) using five brands: Max-Core®, Monopty®, Multicore®, Tru-Core® (Argon Medical Devices, 2600 Dallas, Parkway, Suite 440, Frisco, TX 75034, USA) and Achieve® (CareFusion, 1500 Waukegan Road, McGaw Park, IL, 60085 USA). We used an apple, chicken meat and an empty target to mimic the resistance of the prostatic tissue. The biopsies were repeated three times with the same device, and repeated with a second device of the same brand to obtain six measurements at distances of 50 cm and 100 cm. The sound was recorded using a calibrated sound level metre (Norsonic Precision Sound Analyser Nor140) by linking its output to a computer-connected sound card (MOTU MicroBook

USB). The concrete walls of the lab had acoustic panels with similar acoustic characteristics as the room in the clinical biopsy measurements. The biopsy devices and targets were hand-held during the shots. This study was approved by a local ethical committee of Helsinki University Hospital.

Results

Clinical prostate biopsy measurements

The sound measurements totalled 291 in number. The average SPL peak of the prostate biopsy devices generated while taking biopsies ranged from 106 to 127 dB. The highest SPLs were with the Bard Monopty® device, mean value of 118 dB (range 110 to 127 dB, SD 3.2 dB). The second-highest SPLs were with the Max-Core®, mean value of 111.6 (range 106 to 122.5 dB, SD 3.5 dB) and the least noise was generated by the Multicore®, mean value of 112.7 (range 108 to 116.5 dB, SD 1.7 dB) (Figure 2).

Laboratory tests

The SPLs ranged from 104.3 to 121.3 dB at 50 distance and from 102.7 to 116.51 dB at 100 cm distance. There were no statistical differences ($p < .05$) between repeated SPL values for each specific target duration, which describes impulse duration up to the point where SPL decreases by 20 dB from peak level, mean 40 ms (range 34 to 47 ms).

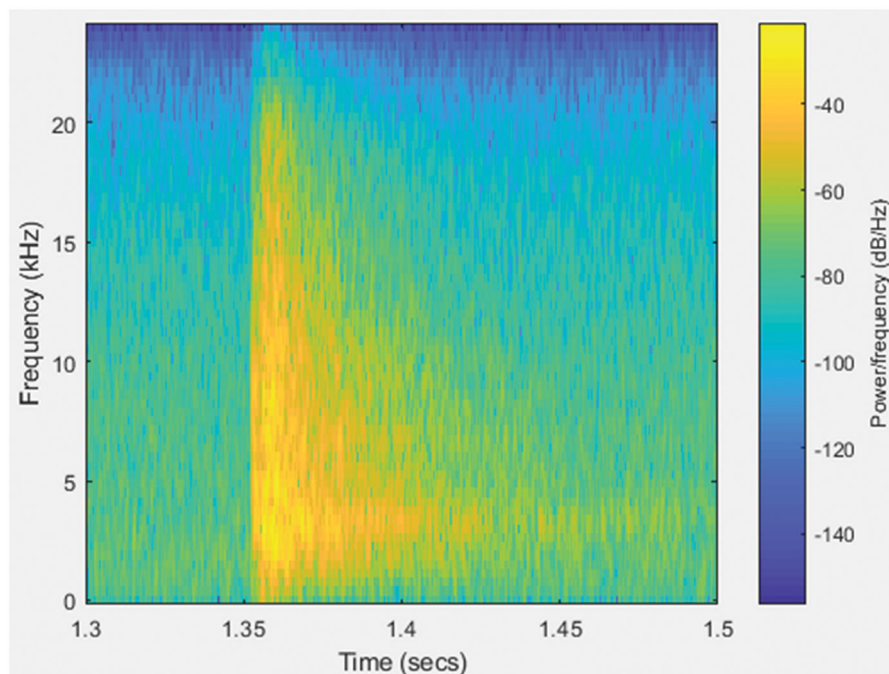
The lowest SPL was measured with the Max-Core® device and the highest with the Bard Monopty® device (range 114.8 to 122.4 dB). Measurements at 100 cm were obtained only with the Max-Core®, Monopty® and Multicore® devices. The noise levels were approximately 5 dB lower at 100 cm

Table 1. Lab test results of dB level of impact noise at 50 cm.

Biopsy device	Target	SPL (dB, average)	Min	Max	Sd	B-durations (ms, average)
Achieve®	muscle	111.4008	110.39	112.04	0.89	0.042
	apple	113.2951	110.94	115.05	2.12	0.037
	empty	114.8884	113.44	116.53	1.55	0.041
Tru-Core®	muscle	115.3716	114.84	115.64	0.46	0.037
	apple	115.5130	113.46	117.72	2.14	0.036
	empty	117.8756	116.50	118.90	1.24	0.043
Max-Core®	muscle	109.8359	108.17	111.35	1.16	0.036
	apple	109.4102	105.89	111.46	2.04	0.037
	empty	110.8494	110.43	111.81	0.55	0.040
Monopty®	muscle	121.3981	118.47	122.43	1.59	0.034
	apple	120.6903	114.86	121.91	2.73	0.037
	empty	120.0245	117.93	120.71	1.02	0.037
Multicore®	muscle	112.5972	110.63	113.73	1.11	0.035
	apple	111.1677	110.00	113.30	1.23	0.035
	empty	112.5940	112.37	114.85	0.90	0.037

Table 2. Lab test results of dB level of impact noise at 100 cm.

Biopsy device	Target	SPL (dB, average)	Min	Max	Sd	B-durations (ms, average)
Max-Core®	muscle	104.3680	102.07	106.48	1.47	0.041
	apple	106.1923	102.45	107.89	1.98	0.041
	empty	106.3744	104.84	108.87	1.35	0.047
Monopty®	muscle	114.7482	112.91	115.70	1.11	0.040
	apple	113.9123	109.83	115.52	2.13	0.038
	empty	115.5645	114.78	116.51	0.67	0.041
Multicore®	muscle	107.8215	104.64	109.31	1.54	0.041
	apple	105.1812	104.26	106.75	1.05	0.043
	empty	107.2410	106.20	108.39	0.71	0.045

**Figure 3.** Analysis of the impulse sound sample after performing a biopsy on chicken meat using an Achieve device. The spectrogram reveals a broad spectrum of sound during the first 30 to 40 ms. marked here in yellow.

compared to that at 50 cm when the same device brand was used. The SPL ranged from 104.3 to 115.6 dB (mean value of 109.0). The SPLs were equal between two samples of devices of the same brand. **Tables 1** and **2** show the results in detail.

The impulse noise of the Achieve device performing biopsies on chicken meat was analysed in detail, as shown in **Figure 3**. The spectrogram reveals a broad spectrum of sound during the first 30 to 40 ms.

Discussion

Individuals exposed to impact or impulse noises can experience tinnitus or hyperacusis and may suffer residual hearing loss at long-term follow-up [6,7]. The dip in the audiogram is typically at 3 – 6 kHz regardless of the spectrum of the exposure noise, since the ear is most sensitive at these frequencies. The heavier and/or longer-lasting the noise

exposure is, the wider the spectrum of the hearing loss is and the worse the hearing thresholds are. The sound generated by the prostate biopsy device is very short in duration and the SPL is comparable to that of an airgun. In practice, 50 cm is the approximate working distance at which patient biopsies are taken. The laboratory tests accordingly represent the SPLs typically measured at 50 cm in the clinical settings.

European Directive 10/2003/EC sets forth minimum requirements for the protection of workers exposed to noise [8]. The limit value for impulse noise is 140 C-weighted dB (dBC), and the upper and lower action values are 137 dBC, and 135 dBC, respectively. Thus, it seems that the SPLs generated by prostate biopsy devices should represent no major risk for occupational noise-induced hearing loss. However, the biopsy noise may be harmful for individuals with tinnitus, since about a third of patients suffering from tinnitus experience a worsening of their condition after noise exposure [9]. The present study has some limitations. In patient measurements, the direction of the biopsy device seemed to have an impact on the dB level, since the sound level was reduced by 1–2 dB when the biopsy device was turned downwards. In addition, the groups were not equal in size. The wall materials, size of the room and dimensions of the acoustic space might all have an effect on sound levels, but these differences are unlikely to affect the overall risk profile.

Preventing damage caused by noise exposure is more important than treating it afterwards. Urologists taking frequent prostate biopsies should be advised to use hearing protective devices. In addition, further development of silent biopsy devices with improved noise damping and absorption properties is also needed. A further factor to be noted is that core biopsy devices are used in many other specialities as well.

Conclusion

Biopsy devices generate high peak levels of impact noise of very short duration. Unprotected, prolonged and repeated exposure to this impact noise should be limited, even if it

may not induce permanent hearing loss. Exposure to impact noise should be restricted if personnel find it uncomfortable. We encourage the manufacturers to work on developing more silent prostate biopsy devices. Until then, personnel taking biopsies should consider using hearing protection.

Disclosure statement

No potential conflict of interest was reported by the authors.

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