REVIEW ARTICLE

Journal of Otorhinolaryngology and Facial Plastic Surgery 2024;10(1):1-7.
https://doi.org/10.22037/orlfps.v10i1.47100

Impacts of Extracorporeal Shockwave Therapy-Associated Noise: A Literature Review

Stephanie Quon[1], Sarah Zhou[2].

1. Faculty of Applied Science, University of British Columbia, Vancouver, British Columbia, Canada.
2. Faculty of Science, University of British Columbia, Vancouver, British Columbia, Canada.

Article Info

Article Note:
Received: November 2024
Accepted: December 2024
Publish Online: December 2024

Corresponding Author:
Dr. Stephanie Quon

Email:
stephaniesfquon@gmail.com

Keywords:
ESWT;
noise;
hearing loss;
complications;
occupational health

Abstract

Background: Extracorporeal Shockwave Therapy (ESWT) involves the application of impulse acoustic waves in a focused pattern to facilitate healing. While ESWT machines, classified as Class II medical devices, are widely used in urology and sometimes physical therapy, they produce impulse noise averaging 88 dB, raising concerns about potential auditory hazards for operators and clients. There is limited research and inconsistent recommendations regarding the need for hearing protection during ESWT.

Aim: This literature review aims to investigate the available evidence on the auditory impacts of ESWT-associated noise for both operators and clients, assessing the necessity for hearing protection.

Methods: A systematic search of studies on ESWT-associated noise was conducted, yielding 906 studies. After removing 131 duplicates and screening out 768 studies based on inclusion criteria, seven studies published in English were included in the review. The studies analyzed noise levels, hearing function outcomes, and recommendations for hearing protection.

Results: The findings on ESWT-associated noise and its auditory impacts were mixed. Four studies reported no significant detrimental effects on hearing function, while three studies indicated hazardous sound levels with potential risks for hearing loss. Operating manuals for ESWT devices reviewed recommend hearing protection for both operators and clients, although reported sound levels were often within regulatory safety limits.

Conclusions: There is inconsistent evidence regarding the auditory risks of ESWT-associated noise, with some studies identifying potential hazards, especially for operators exposed over extended periods. Operating manuals generally advise hearing protection, indicating a precautionary approach. Further research, such as randomized controlled trials, is needed to clarify the risks and develop evidence-based guidelines.

Conflicts of Interest: The Authors declare no conflicts of interest.
Please cite this article as: S. Quon, S. Zhou. Impacts of Extracorporeal Shockwave Therapy-Associated Noise: A Literature Review. J Otorhinolaryngol Facial Plast Surg 2024;10(1):1-7. https://doi.org/10.22037/orlfps.v10i1.47100

Introduction

Extracorporeal Shockwave Therapy (ESWT) is a therapeutic procedure where non-invasive, impulse acoustic waves are transmitted in a narrow or focused pattern to targeted body regions to facilitate healing (1). ESWT was first used in the 1980s for lithotripsy (2), and later expanded for use in pain management in orthopedic diseases in the 2000s (1). The application of ESWT for musculoskeletal disorders is primarily used in the treatment of overuse tendinopathies (3), and while the specific mechanisms of the treatment remain unclear, studies have shown that ESWT can break down sensory unmyelinated nerve fibers and stimulate neovascularization and collagen synthesis (4). As reported in systematic reviews, success rates for ESWT range from 65% to 91%, and some publications show positive and beneficial effects (5). However, recent reports of evidence vary; for example, there is evidence that ESWT has a negligible

Journal of Otorhinolaryngology and Facial Plastic Surgery 2024;10(1):1-7.
https://doi.org/10.22037/orlfps.v10i1.47100

impact on function and pain for patellar tendinopathy and Achilles tendinopathy (6). Overall, ESWT use has been increasing globally for a wide range of restorative treatments(7).

Operating principles

ESWT machines are classified as a Class II medical device by Health Canada, as defined in ISO 13485 Medical Devices Quality Management Systems (8). The source of ESWT wave generation includes electrohydraulic, electromagnetic, and piezoelectric principles (5). Operationally, ESWT works by generating a wave at the base of the head of the device by an electromagnetic acoustic source (2). When a high-voltage pulse from a capacitor discharge is transmitted, a current is induced in the aluminum membrane. The membrane is then repelled, which induces an acoustic wave. This wave often travels through a water or air-filled head to a focusing lens. Finally, the wave passes through the lens and into a coupling head (9).

Impacts of ESWT-associated noise

Sound is a vibration that propagates as an acoustic wave through a medium, and it is measured in decibels (dBA), while noise is defined as an unwanted or unpleasant sound. In the workplace, noise can be considered an occupational hazard that can have both short and long-term impacts on human health(10). Noise above 85 dBA over a prolonged period can begin to damage hearing(11), and as a whole, prolonged exposure to high noise levels can lead to hearing loss(12), tinnitus(13), and other auditory health issues. The National Institute for Occupational Safety and Health makes the conservative recommendation that hearing protection should be worn in the workplace whenever noise levels exceed 85 dBA, regardless of duration(14). While in use, ESWT devices produce acoustic emissions, resulting in noise that can range from moderate to high levels depending on the device's design and settings. The peak sound pressure of the device has been found to be around 90 dBA(15), while holding an average of 88 dBA(16). The device may be used at a wide range of durations based on the treatment type and application. In addition, sound exposure can be constant or in the form of impulses, and ESWT falls into the category of impulse noise. The ear has an acoustic reflex protection mechanism to protect against loud noises, where the contraction of the stapedius muscle helps to dampen the sound transmitted to the cochlea (17). As this protective mechanism is not as effective for impulse noise (15), this further draws attention to how long-term exposure to ESWT-noise could be potentially harmful. While some studies have explored the impacts of ESWT-related noise exposure on people receiving treatment (15), few fully explore the impact of the noise on operators of the machines, despite how operators of ESWT machines are exposed to the noise generated by the device for extended periods. While the majority of studies on ESWT find no significant adverse effects during or after the treatment for people receiving treatment (1) and no severe adverse effects are associated with ESWT(18), studies do not directly explore the impacts of the machine's associated noise, but rather focus on the impacts of the treatment itself on the body.

Purpose of literature review

Given the lack of clear evidence surrounding the impacts of ESWT-related noise and the necessity for hearing protection, the purpose of this literature review is to collate and review the available evidence and research on the impacts of ESWT-related noise on both operators and people receiving treatment. To date, no other literature review has been conducted on this topic.

Methods

Search strategy

The literature review was conducted using Google Scholar, CINAHL Complete, Embase, Ovid Medline, PubMed, and BASE. The search included keywords in two areas: ESWT (ESWT, Extracorporeal shockwave therapy,

Journal of Otorhinolaryngology and Facial Plastic Surgery 2024;10(1):1-7.
https://doi.org/10.22037/orlfps.v10i1.47100

Shockwave Therapy, lithotripsy) and noise (noise, sound, hearing, acoustic emissions). Articles related to ESWT, ESWT impacts, and ESWT-related noise were identified. The reference lists of relevant articles were also searched individually for additional articles.

Study selection

The reviewers (SQ, SZ) used Covidence to facilitate the literature review. The titles and abstracts of all citations were screened using the inclusion criteria, and discrepancies during screening were discussed between the reviewers. The final studies identified underwent a full-text screening by the reviewers. Inclusion criteria for the search were (1) completed studies, (2) written in English, and (3) described impacts of ESWT-associated noise. ESWT for use in both urology and physical therapy practice were included. Given the narrow inclusion criteria, there was no further exclusion criteria.

Results

From the initial search, 906 studies were identified and initially included into the review. From there, 131 duplicates were removed, and 775 articles were screened. Then, 764 articles were excluded based on the inclusion criteria, leaving eleven studies for a full-text review. Finally, the search revealed seven studies within the search criteria. The articles reviewed were published between 1987 and 2019. The final included studies are summarized in Table 1

Table 1. Overview of included articles, including article title, author, year, study type, and summary of main findings.

Title of Paper	Author, Year	Study Type	Relevant Findings
Does radial extracorporeal shockwave therapy impair hearing function in patients with plantar fasciitis?	Cobden et al., 2019	Randomized Control Trial	ESWT use for clients with chronic plantar fasciitis had no detrimental effect on hearing function after fifteen minutes of use.
Report on the Use of Extracorporeal Shockwave Therapy in Orthopaedic Conditions.	Anthony, 2018	Report	A report on the SONOCUR Basic ESWT device found that surface sound pressure levels were measured to be below the Occupational Safety and Health Administration standards for exposure.
Does lithotripsy cause hearing loss?	Dawson et al., 1994	Experimental Study	A study using the Dornier MPL9000 ESWT device found that the device did not have a significant effect on the hearing of clients or operators.
Identification of the auditory hazards of extracorporeal shock wave lithotripsy.	Naguib et al., 2002	Experimental Study	ESWT for lithotripsy had potentially hazardous effects on hearing, with operators experiencing higher rates of hearing loss.
Hazardous sound levels produced by extracorporeal shock wave lithotripsy.	Lusk & Tyler, 1987	Experimental Study	A study of the Dornier system GmbH machine identified hazardous sound levels for both clients and operators.
Prolonged exposure to extracorporeal shock wave lithotripsy and noise induced hearing damage.	Kraus & Weidner, 2001	Case Report	Report of a urologist who regularly administered five ESWT sessions per week experiencing long-term hearing loss.

Journal of Otorhinolaryngology and Facial Plastic Surgery 2024;10(1):1-7.
https://doi.org/10.22037/orlfps.v10i1.47100

A contemporary evaluation of the auditory hazard of extracorporeal shock wave lithotripsy.	Terlecki & Triest, 2007	Experimental Study	Contemporary ESWT found to not pose a significant auditory hazard to clients or operators by Occupational Safety and Health Administration standards.

From the seven studies identified, results were mixed as to whether or not ESWT-associated noise can cause hearing loss or pose as an auditory hazard. Four studies found that ESWT machines did not have a detrimental effect on hearing function(15, 16, 19, 20) , while three studies found that ESWT machines produced hazardous sound levels(21-23). In addition, four studies assessed the impacts of ESWT-associated noise on both clients and operators(16, 20, 21, 23), while two studies only assessed impacts on operators(19, 22) and one study only assessed impacts on clients receiving treatment(15).

Discussion

Studies reporting a lack of hazardous impacts on hearing

Overall, regarding the specific impacts of ESWT-associated noise, there has been mixed evidence regarding whether or not the noise can cause hearing loss. The study by Cobden et al. (2019) explored the impacts of ESWT on hearing function for clients with plantar fasciitis. This was the first prospective controlled study that evaluated hazardous effects on auditory functions for clients with recalcitrant plantar fasciitis treated with ESWT. The study found that impulse noise may have harmful effects on cochlear function depending on the level of discharge energy, the number of exposures, sound intensity and time between impulses. However, overall, ESWT use for clients with chronic plantar fasciitis had no detrimental effect on hearing function after fifteen minutes of use. A limitation of this study is that it used pure tone audiometry, which is a subjective test, and the specificity of ototoxicity detection was low. The results also indicated that hearing loss could occur after two sessions of ESWT as the study only measured impacts after one session, and the study did not evaluate the impacts on hearing function for operators who experience repeated exposure(15).

A report on the use of ESWT machines for orthopedic conditions conducted in Canada summarized the noise level tests of the SONOCUR Basic ESWT device(19). Testing data from the SONOCUR Basic was referenced from its original safety and effectiveness FDA-required testing conducted in 2002 (Siemens). The amplitude of the noise generated by the head of the SONOCUR Basic system was measured with a Larson Davis sound meter, and the equipment was designed to conform to Class I requirements according to IEC 804(24). The sound measurements were performed at a distance of 1m from the SONOCUR Basic unit, testing with all energy level settings and minimum and maximum repetition frequency from 1 to 4 Hz. The surface sound pressure levels were measured to be below the Occupational Safety and Health Administration standards for exposure times from 0.5 to 8 hours per day, at a distance of 1 meter from the ESWT device(19). In addition, a study conducted using the Dornier MPL9000 ESWT device was found to not have a significant effect on the hearing of clients and operators. This was evaluated using pure tone audiometry, with clients receiving one hour of use and operators assessed after three months of repeated exposure(20).

Studies reporting hazardous impacts on hearing

Limited research on the effects of ESWT for lithotripsy reveal that ESWT has potentially hazardous effects on hearing, which are often reported under temporary subjective hearing loss and tinnitus, again depending on the frequency and duration of exposure(23). Naguib et al.(23) investigated the effect of

Journal of Otorhinolaryngology and Facial Plastic Surgery 2024;10(1):1-7.
https://doi.org/10.22037/orlfps.v10i1.47100

exposure time by measuring the hearing levels of operators and clients before and after use, and found that operators experienced more hearing loss because they were exposed to noise for longer periods. Hazardous sound levels produced by ESWT lithotripsy were also reported in a study conducted with the Dornier system GmbH machine(21). In addition, a case report showed that a urologist who regularly administered five ESWT sessions per week experienced long-term hearing loss(22). Lastly, a study reported that the mean sound level produced by an ESWT machine is 88 dBA(16), which is above the threshold of 85 dBA for the risk of hearing loss by repeated exposure(11).

To measure hearing changes, the studies by Naguib et al.(23) and Lusk & Tyler(21) primarily utilized pure tone audiometry to assess changes in hearing levels before and after ESWT exposure. Temporary threshold shifts (TTS) were assessed by comparing pure tone audiometry results taken immediately before and after exposure to ESWT noise. However, the methodology for distinguishing TTS from permanent threshold shifts was not thoroughly explained. The timing of hearing evaluations also varied across studies. In Naguib et al.(23), hearing levels were measured immediately before and after ESWT sessions, however, in Kraus & Weidner(22), precise intervals of evaluation were not specified.

Operating manual recommendations

Another point of contention is that while there is conflicting evidence surrounding the impacts of ESWT-associated noise, operating manuals of ESWT devices often recommend the use of hearing protection. The operating manual for the Chattanooga Intelect F-SW recommends that operators and clients wear suitable hearing protection and that clients should be offered hearing protection(25). The operating manual for the Orbasone ESWT machine recommends the use of earplugs or hearing protection devices by clients, operators, and observers(26). The operating manual for the HMT Ossatron ESWT machine recommends the use of hearing protection for operators and clients to reduce the risk of hearing impairment(27). The operating manual for the MASTERPULS® Ultra MP200 reports that noise level during machine use is within safe limits, though suitable ear protection is still recommended to minimize noise exposure(28). The Chattanooga Intelect F-SW, Orbasone, HMT Ossatron, and MASTERPULS® Ultra MP200 are all classified and regulated as Class II MD FDA-defined ESWT Machines under the FDA(29). In addition, Subpart E 878.4685 of the FDA's regulations for defined ESWT Machines requires device labeling to include instructions for preventing hearing loss through the use of hearing protection(29).

Limitations

Limitations of this study include a too narrow inclusion criteria for papers and the method of review, both of which may have caused the exclusion of some relevant articles. Given the research approach of a literature review, the choice of articles may also have been subjective and impacted by selection bias. As the studies included were also published between 1987 and 2019, some of the older articles may also be outdated. There was also a lack of specificity in evaluating ESWT-related noise from machines used in both urology and orthopedic practice, as their uses can be very different(5, 30). The studies included did not specifically explore sex-based differences in susceptibility to hearing impacts from ESWT, and also did not specify age ranges and only resorted to describing them as adults.

Conclusion

While there is limited empirical evidence supporting the necessity of hearing protection for operators and clients in the use of ESWT, identified risks and recommendations from manufacturers suggest that both operators and clients could benefit from being offered the option of suitable hearing protection to avoid preventable hearing loss. Suitable hearing protection options such as properly fitted

Journal of Otorhinolaryngology and Facial Plastic Surgery 2024;10(1):1-7.
https://doi.org/10.22037/orlfps.v10i1.47100

expandable foam ear plugs, canal caps, earmuffs, and impulse noise protection earmuffs may be appropriate options to increase user and client safety. In addition, establishing a hierarchy of engineering and administrative controls can be used in conjunction with hearing protection to reduce exposure to the lowest achievable levels. Operators of ESWT may also choose to inform the recipients of the treatment on the potential risks associated with noise exposure from ESWT. Future research could involve more focused studies, such as a randomized control trial, on the impacts of ESWT-associated noise on both operators and clients.

Acknowledgments

Thank you to Brandon Sum for your role in conceptualizing and reviewing this work.

Conflicts of Interest

The authors declare no conflicts of interest.

Financial Support

Hearing Disorders Research Center, Loghman Hakim Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran, financially supported this work.

Author Declarations

SQ wrote the majority of the manuscript. SZ edited the manuscript. The manuscript has been read and approved by all named authors. The authors have no conflicts to disclose.

Data Availability

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

Authors ORCIDs

Dr Stephanie Quon
https://orcid.org/0000-0001-9188-8380
Sarah Zhou
https://orcid.org/0000-0002-9351-8487

References

1.De la Corte-Rodríguez H, Román-Belmonte JM, Rodríguez-Damiani BA, Vázquez-Sasot A, Rodríguez-Merchán EC, editors. Extracorporeal shock wave therapy for the treatment of musculoskeletal pain: a narrative review. Healthcare; 2023: MDPI.

2.Simplicio CL, Purita J, Murrell W, Santos GS, Dos Santos RG, Lana JFSD. Extracorporeal shock wave therapy mechanisms in musculoskeletal regenerative medicine. Journal of Clinical Orthopaedics and Trauma. 2020;11:S309-S18.

3.Aicale R, Oliviero A, Maffulli N. Management of Achilles and patellar tendinopathy: what we know, what we can do. Journal of foot and ankle research. 2020;13:1-10.

4.Sun J, Gao F, Wang Y, Sun W, Jiang B, Li Z. Extracorporeal shock wave therapy is effective in treating chronic plantar fasciitis: A meta-analysis of RCTs. Medicine. 2017;96(15):e6621.

5.Wang C-J. Extracorporeal shockwave therapy in musculoskeletal disorders. Journal of orthopaedic surgery and research. 2012;7:1-8.

6.Charles R, Fang L, Zhu R, Wang J. The effectiveness of shockwave therapy on patellar tendinopathy, Achilles tendinopathy, and plantar fasciitis: a systematic review and meta-analysis. Frontiers in Immunology. 2023;14:1193835.

7.Zhang X, Ma Y. Global trends in research on extracorporeal shock wave therapy (ESWT) from 2000 to 2021. BMC Musculoskeletal Disorders. 2023;24(1):312.

8.Bos G. ISO 13485: 2003/2016—Medical devices—Quality management systems—Requirements for regulatory purposes. Handbook of Medical Device Regulatory Affairs in Asia: Jenny Stanford Publishing; 2018. p. 153-74.

9.Act C. Summary of safety and effectiveness. 2011.

10.Themann CL, Masterson EA. Occupational noise exposure: A review of its effects, epidemiology, and impact with recommendations for reducing its burden. The Journal of the acoustical society of America. 2019;146(5):3879-905.

11. Natarajan N, Batts S, Stankovic KM. Noise-induced hearing loss. Journal of clinical medicine. 2023;12(6):2347.

12.Aarhus L, Engdahl B. Occupational noise exposure and asymmetric hearing loss: results from

Journal of Otorhinolaryngology and Facial Plastic Surgery 2024;10(1):1-7.
https://doi.org/10.22037/orlfps.v10i1.47100

the HUNT population study in Norway. American Journal of Industrial Medicine. 2020;63(6):535-42.
13.Molaug I, Aarhus L, Mehlum IS, Stokholm ZA, Kolstad HA, Engdahl B. Occupational noise exposure and tinnitus: the HUNT Study. International Journal of Audiology. 2024;63(11):917-24.
14.Chan HS. Occupational noise exposure; criteria for a recommended standard. 1998.
15.Cobden SB, Cobden A, Camurcu Y, Duman S, Ucpunar H, Dagistan H. Does radial extracorporeal shockwave therapy impair hearing function in patients with plantar fasciitis? Noise and Health. 2019;21(101):169-72.
16.Terlecki RP, Triest JA. A contemporary evaluation of the auditory hazard of extracorporeal shock wave lithotripsy. Urology. 2007;70(5):898-9.
17.Kryter KD. Impairment to hearing from exposure to noise. The Journal of the Acoustical Society of America. 1973;53(5):1211-34.
18.Guo P, Gao F, Zhao T, Sun W, Wang B, Li Z. Positive effects of extracorporeal shock wave therapy on spasticity in poststroke patients: a meta-analysis. Journal of Stroke and Cerebrovascular Diseases. 2017;26(11):2470-6.
19.Anthony J. Report on the use of extracorporeal shockwave therapy in orthopaedic conditions. 2018.
20.Dawson C, Chilcott-Jones A, Corry D, Cohen N, Williams H, Nockler I, et al. Does lithotripsy cause hearing loss? British journal of urology. 1994;73(2):129-35.
21.Lusk RP, Tyler RS. Hazardous sound levels produced by extracorporeal shock wave lithotripsy. The Journal of urology. 1987;137(6):1113-4.
22.Kraus S, Weidner W. Prolonged exposure to extracorporeal shock wave lithotripsy and noise induced hearing damage. The Journal of urology. 2001;165(6 Pt 1):1984.
23.Naguib MB, Badr-El Din M, Madian YT, Iskander NM. Identification of the auditory hazards of extracorporeal shock wave lithotripsy. The Journal of Laryngology & Otology. 2002;116(1):1-5.
24.Wallis A, Hill R, editors. A new technique for long term noise surveys. INTER-NOISE and NOISE-CON Congress and Conference Proceedings; 1990: Institute of Noise Control Engineering.
25.(n.d.) C. Operating Manual Chattanooga Intelect F-SW.
26.Orbasone. Orbasone Pain Relief System Operator Manual.2005.
27.(n.d.) H. Ossatron Operating Manual.
28.Medical. S. MASTERPULS® MP200 Operating Manual.2016.
29.Regulations CoF. Extracorporeal shock wave device for treatment of chronic wounds2018.
30.Tenforde AS, Borgstrom HE, DeLuca S, McCormack M, Singh M, Hoo JS, et al. Best practices for extracorporeal shockwave therapy in musculoskeletal medicine: Clinical application and training consideration. Pm & R. 2022;14(5):611.