Safety of SHOCKWAVE Therapy

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BACKGROUND
Shockwave originated in the 1960's and 70's for non-invasive treatment of kidney stones and gallstones (lithotripsy). Human and animal studies in the 1980's incidentally observed osteoblastic response patterns that generated an interest in additional therapeutic uses. Since that time, it has been used successfully for over 20 years to manage a variety of orthopedic conditions (Schmitz et al 2015).

TYPES OF SHOCKWAVE (Van der Worp et al 2013, Cleveland et al 2007, Furia et al 2010, Schmitz et al 2015)
Additional information sources:

- Shockwave therapy BC - http://www.shockwavetherapy.ca/about_eswt.htm - What is ESWT0 Accessed Dec 15, 2014.
- Shockwave therapy - http://www.shockwavetherapy.eu/ Accessed Dec 15, 2014.
- Shockwave Training – www.shockwavetraining.ca (Calgary, AB, Canada – March 17, 2019.)
- Shockwave theory - http://www.shockwavetherapy.education/index.php/theory/types-of-shockwave Accessed March 27, 2019.
- Electrotherapy on the Web: http://www.electrotherapy.org/modality/shockwave-therapies - Accessed March 25, 2019.
- Prouza O. 2013. Shockwave therapy in musculoskeletal treatment. http://skanlab.no/wp-content/uploads/2013/10/swt_part_1.pdf (accessed Mar 27, 2019).

There are two types of shockwave therapy. Focused shockwave therapy (FSWT) and radial shockwave therapy (RSWT).

FSWT
A pressure field is generated that converges in the adjustable focus at a selected depth in the body tissues, where the maximal pressure is reached. There are three methods for generation of a focused shockwave: electrohydraulic, electromagnetic and piezoelectric. All of these waves are generated in water (inside of the applicator), which allows for a more natural transference of the waves into the body, with limited reflection.

Electrohydraulic shockwaves are high-energy acoustic waves created by the underwater explosion with high-voltage electrode spark discharge. The waves are then focused with a reflector and targeted at the diseased area. It is a true shock wave at all settings.

Electromagnetic shockwaves are created by an electric current passing through a coil to produce a strong magnetic field. A lens is used to focus the waves, and the focal therapeutic point being defined by the length of the focus lens. The amplitude of the focused waves increases when the acoustic wave propagates towards the focal point. It is a true shock wave at high settings only.

Piezoelectric shockwaves involve a large number of piezocrystals mounted in a sphere that receives a rapid electrical discharge that induces a pressure pulse in the surrounding water that leads to a shockwave. The arrangement of the crystals causes self-focusing of the waves towards the target centre, which leads to a precise focusing and high-energy within a defined field. It is a true shock wave at high-energy settings only.

RSWT

Radial shock waves are produced by more recently developed pneumatic devices. The term 'radial' refers to the diverging pressure field of the RSWT devices, which reach a maximal pressure at the source of generation (as compared to a focal point away from the applicator). Accelerating a projectile, using compressed air through a tube on the end of which an applicator is placed, generates radial shockwaves. The projectile hits the applicator, which transmits the generated pressure wave into the body. (These waves are NOT generated in water).

INDICATIONS

Shockwave has been shown to be effective for the following select musculoskeletal disorders:

- Calcific tendons & tendinopathies (Kim et al 2014, Verstrelen et al 2014, Gerdesmeyer et al 2003, Cacchio et al 2006, Malliaropoulos et al 2017, Becker et al 2015, Gallagher et al 2012, Wang et al 2002, van der Worp et al 2014, Dedes et al 2018, Cacchio et al 2011, Ilieva et al 2012)
- Plantarfasciitis (Chang et al 2012, Crecco et al 2013, Ilieva 2013, Ibrahim et al 2010)
- Non—Union fractures (Birnbaum et al 2002, Furia et al 2010)
- Stress fractures (Moretti et al 2009, Rompe et al 2010))
- Osteoarthritis (Zhao et al 2012, Frisbie et al 2009, Kawcak et al 2011, Wang et al 2010, 2011, 2012, Dahlberg et al 2005, Mueller et al 2007, Souza et al 2016)
- Low back pain (Noarnicola et al 2018, Nedelka et al 2014)
- Sacroiliac joint pain (Moon et al 2017)
- Coccydynia (Marwan et al 2017)
- Myofascial trigger points (Ramon et al 2015, Walsh et al 2019)
- Necrosis of the femoral head (Wang CJ et al 2005, Wang L et al 2008)

CONTRAINDICATIONS

- Circulatory disorders where bleeding may be a concern (Desai et al 2017).
- Over malignant tumours. However, cancer itself in a removed area is not a contraindication (Crevenna et al 2019), and newer research is pointing towards shockwave as being an adjunct to cancer care due to its role in permeabilization of mammalian cell membranes (Lopez-Marin et al 2018). However, for now it remains a standard contraindication.

- Presence of infection – (Newer research however, is showing that shockwave may be helpful to reduce inflection in chronic wound cases – Zhang et al 2018).
- Shockwave is not generally applied to areas or locations overlying the abdomen or chest (where gas or air is present in the body) (Desai et al 2017, Sistermann & Kathagen 1998).
- Over the abdomen or lumbar spine in pregnant patients (Desai et al 2017).

Manufacturer-Promoted Contraindications without backing or contradiction in the literature

- Metabolic conditions whereby the bone may be fragile.
- Over major blood or nerve vessels too close to a treatment areas.
- Within 4 weeks of a cortisone injection to the area being treated. (The concern is that increased circulation may flush out the injected medication – No studies can be found to validate this contraindication)

Previously thought to be contraindications

- Nerve disorders - Shockwave is now being shown to be harmless to nerve and may improve nerve regeneration (Wu et al 2007, Mense & Hoheisel 2013)
- Over epiphyses in young patients - Newer reviews have stated that it is now considered safe (Lohrer et al 2016)
- Over metal implants – In the case of plated fractures, shockwave is still beneficial, with no adverse events related to the presence of a metal plate. (Wang et al 2001)
- In conjunction with corticosteroid treatment – Topic cortisone in conjunction with shockwave enhanced the effectiveness for plantar fasciitis. (Vahdatpour et al 2018) No studies could be found that compared effectiveness of shockwave therapy in conjunction with a corticosteroid injection.

ADVERSE EVENTS

Redness of the skin, bruising, petechiae, hematoma, and transient discomfort with treatment. (Bannuru et al 2014, Schmitz et al 2015)

CONCLUSIONS from a systematic review on efficacy and safety of Extracorporeal Shockwave Therapy (ESWT) (Schmitz et al 2015)

- ESWT is effective.
  88.5% of the RCTs (randomized controlled trials) on rESWT (radial) and 81.5% of all RCTs on fESWT (focused) had positive outcomes.
- ESWT is safe.
  There were no reports of serious adverse events in any of the studies included in this analysis
- For certain orthopedic conditions, RCTs on ESWT were the predominant type of RCT listed in the PEDro database and/or obtained the highest PEDro scores among all investigated treatment modalities.
  Type of RCT and highest PEDro scores (as compared to all other treatment modalities) were fulfilled for plantafasciopathy, non-calcific supraspinatus tendinopathy, and calcific tendonitis of the shoulder. RCTs for Achilles tendinopathy and lateral epicondylitis also

ranked high. There were not enough RCTs for ESWT to draw meaningful conclusions regarding greater trochanteric pain syndrome, patellar tendinopathy, knee osteoarthritis, long bone fracture, osteonecrosis of the femoral head, proximal hamstring tendinopathy, long bicipital tenosynovitis, myofascial pain syndrome, myogelosis of the masseter muscle, and spasticity.

- There was no difference in the 'quality' of RCTs on ESWT in PEDro with positive or negative outcomes.
- Application of local anesthesia adversely affects outcome of ESWT.
  The molecular mechanisms underlying this phenomenon are not yet fully understood, but substantial evidence points to a central role of the peripheral nervous system in mediating molecular and cellular effects of shock waves applied to the musculoskeletal system. These effects could be blocked by local anesthesia. Thus, it is now generally recommended to apply shock waves without local anesthesia to the musculoskeletal system.
- Application of insufficient energy adversely affects outcome of ESWT.
  RCTs that showed positive outcomes for rESWT & fESWT for calcifying tendonitis of the shoulder used 2.6x more energy flux density (EFD) than studies that showed a negative outcome. For plantarfasciopathy, positive studies used two times the EFD as negative RCTs. A similar finding was also made when comparing studies for Achilles tendinopathy.
  There is no scientific evidence in favour of either rESWT or fESWT with respect to treatment outcome.
  It appears that success is more dependent upon sufficient EFD (energy flux density – i.e. power) than with the type of ESWT.
- The distinction between radial ESWT as 'low-energy ESWT' and focused ESWT as 'high-energy ESWT' is not correct and should be abandoned.
  Different authors have used different thresholds for categorizing 'high' and 'low' energy. Because there is no consensus in the literature, this distinction appears arbitrary and should be abandoned.
- There is no evidence that a certain fESWT technology is superior to other technologies.
  Focused shock waves can be produced by electrohydraulic, electromagnetic, and piezoelectric shock wave generators. The RCTs on fESWT in PEDro do no indicate an advantage of a certain fESWT technology over other technologies.
- An optimum treatment protocol for ESWT appears to be three treatment sessions at 1-week intervals, with 2000 impulses per session and the highest EFD that can be applied. This recommendation is based on the average number of treatment sessions and the average interval between treatment sessions among all RCTs on ESWT in PEDro. With respect to the EFD of the impulses (to be as high as possible, i.e. what can be tolerated by the individual patient without application of local anesthesia), this recommendation is based on findings of one study on rESWT for plantar fasciopathy with positive outcome and another study on fESWT for calcifying tendonitis of the shoulder with positive outcome that 'more is better'. There is not a single RCT on ESWT in PEDro, contradicting this 'more is better' recommendation.

APPENDIX 2

SAFETY

Several review papers, meta-analyses, or randomized-controlled trials conclude that shockwave therapy is a safe modality for orthopedic conditions (Schmitz et al 2015), tendinopathies (Dedes et al 2018, Li et al 2017, Cacchio et al 2006), plantarfasciitis (Roerdink et al 2017), and osteoarthritis (Wang TS et al 2020).

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