Extracorporeal Shock Wave Therapy (ESWT) in Orthopaedics and Traumatology

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1 ESWT, the powerful approach to musculoskeletal diseases

Extracorporeally generated shock waves were first used for kidney stone fragmentation in the early eighties. The treatment modality revolutionized urological stone management and developed into today's method of choice. Since the mid nineties shock waves are also used for several kinds of musculoskeletal applications such as tennis elbow, calcified shoulder, heel spur and non-unions. Analgesic effects as well as healing effects due to enhanced metabolism, circulation and revascularization are reported. Astonishingly, significant improvements up to complete reduction of pain even in chronic complaints and stable reunion of non-unions are gained. Using basically the same technology as for stone fragmentation, extracorporeal shock wave therapy (ESWT) stands for shock wave application in general, with a specific impact on orthopaedic indications, both, non-unions and tendopathies as well as others.

Even in sports medicine ESWT becomes a valuable new therapeutic treatment modality. In 1996, for the first time, an orthopaedic shock wave device was used by the German team during the Olympics in Atlanta. Instead of stone disintegration it was applied to several types of tendopathies and persistent close to bone soft tissue pain. Again at the World Cup 1998 in France, three of the participating teams including the winner France made use of shock wave machines (MINILITH SL1, STORZ MEDICAL AG, Switzerland) to keep the athletes on their top performance level on time. Today several sports teams make use of ESWT on a regular basis.

2 Shock waves for medicinal use

Shock waves in medicine are focussed high pressure acoustical waves of very short time duration. They are transmitted through soft tissue without major losses and reflected at interfaces of different organs. Shock waves are pulsed acoustic waves characterized by short time duration (< 1 microsecond) very high pressure amplitudes of several 10 - 100 MPa (100 -1000 bar) and relatively low tensile wave components (approx. 10% of maximum pressure).

Shock waves are generated outside the human body in water and transmitted widely spread over a large skin transmission area onto the target region where the acoustic energy is concentrated to a focal area of 2 – 8 mm in diameter. Modern ESWT devices make use of coupling cushions instead of an open water bath to couple the shock waves into the body without significant losses. Targeting of the treatment region is done either by an isocentrically attached co-axial ultraound transducer or by a flouroscopic localization device such as mobile C-arms.

Treatment of the affected tissue region is done by a sequence of 1000 – 4000 shock wave pulses fired with a repetition frequency of 1 – 4 pulses per second. The whole treatment lasts 15 –30 minutes and is usually performed without or under consumption of very little local anaesthetic drugs.

3 Shock wave generation technology

Within the last two decades several different methods of shock wave generation have been developed. There is no question, that electro-hydraulic, piezo-electric and electro-magnetic techniques can generate shock waves for medicinal applications. There are technical benefits and some disadvantages of the accordingly generated shock waves, however, there is no "magic" feature which would qualify only one of the systems being effective. Possible differences in rise time of pressure increase are washed out by passing through living tissue, thus being of no relevance with respect to efficacy of the specific modality. Nevertheless, significant technical differences make certain systems more favourable than others.

3.1 Electro-hydraulic – ellipsoidal reflector, the historic method

The electro-hydraulic principle makes use of a spark plug like electrode configuration. A rapidly expanding plasma bubble heated by the spark

channel repels the surrounding water volume. The thereby developing spherical shock wave is focussed by aid of a semi rotational ellipsoidal reflector. The first kidney stone lithotripter was based on this historic principle, first invented for soft tissue treatment 50 years ago (Fig. 1). This type of shock wave generator is still in use, however, it features some significant drawbacks compared to modern shock wave devices such as costly wear of electrodes, extraordinary noise level, non-uniform energy delivery etc.

3.2 Electro magnetic cylinder - parabolic reflector, present state of the art

The state of the art configuration of a shock wave device utilizes a cylindrical coil arrangement of an electro-magnetic generator with a parabolic reflector (Fig. 2). The cylindrical coil system provides significant improvements over flat coil arrangements with lens focussing. The cylindrical wave front is focussed virtually without energy loss by a rotational parabolic reflector. Simultaneously, it provides the appropriate space on the central axis for implementation of either inline X-ray localization or inline ultrasound transducers.

Whatever technique of shock wave generation is used, to date, shock waves are always generated outside the human body, transmitted via a large skin area and concentrated by means of focussing reflectors to the area of interest within the selected tissue. In order to target the energy precisely to the desired location, imaging devices (ultrasound and/or X-ray) are used. The most precise method utilizes co-axially arranged (inline) configurations of imaging modalities and shock wave devices. Offline configurations (transducer outside the shock wave application head) suffer from reduced accuracy due to different tissue to be passed by shock waves and imaging energies.

Due to the technical benefits such as power, reproducibility, dynamic range and lifetime the electro-magnetic principle and i.e. the electro-magnetic cylinder source with a parabolic reflector becomes more and more standard in high quality ESWT devices because of the additional benefit of inline localization features as discussed below.

4 Orthopaedic shock wave devices

Although side effects of ESWT are usually negligible high energy shock waves may cause harm to certain organs if not applied properly. Precise targeting and avoiding critical tissue are mandatory. Apart from certain other organs especially lung tissue is sensitive to potential shock wave lesions and bony tissue may obstruct shock wave propagation. ESWT devices, therefore, require some kind of localization modality such as ultrasound and/or X-ray in order to clearly control the shock wave propagation pathway through the human body. Different device configuration are commercially offered with inline or offline arrangements of shock wave applicator and localization modality.

A second tool to increase therapeutic shock wave efficiency is to concentrate the shock wave energy to a well confined treatment area and keeping the energy density as low as possible anywhere else. This simple but efficient idea simultaneously reduces potential side effects. Technically, the goal is to use large aperture angels of the focussing device which also provide high energy concentration (therapeutic effect) and low energy density (low pain and tissue lesions) in the coupling area and anywhere else.

Due to the large variety of indications, the shock wave applicator needs to be coupled to a number of distinct areas of the human body from top to toe. This requires a high degree of mechanical flexibility of the shock wave head which usually cannot be provided by ordinary lithotripsy machines for urinary stone fragmentation. Several companies developed specific orthopaedic devices with a flexible support of the shock wave head with or without inline ultrasound or X-ray targeting configurations.

Modern ESWT devices have all the beneficial features required by the specific needs of musculoskeletal indications. The latest generation also offers sufficient power and penetration depth up to 15 cm to fragmentize all kinds of human calculi. Such interdisciplinary devices as for example the MODULITH SLK Storz Medical, Switzerland (Fig 3.) contribute to significant cost reduction due to multiple use in different medicinal specialties.

5 Medicinal aspects

After its introduction in 1994, more than 100'000 shock wave treatments were successfully performed on various indications. Approximately 70 to 80% of the treated patients gained significant improvements of their complaints although - and this is worth to mention - their chronic disease was unsuccessfully treated before by several conservative treatment methods. Many thousands of patients could thus be released from their complaints without open surgery which would have been the next available treatment choice, also promising a limited success rate only.

Apart from treating chronic diseases after several months and years of frustrane conservative treatment approaches an interesting subgroup of indications is identified within sports medicine. Top athletes need to be fit on time and do not like to undergo time consuming conservative therapies unless absolutely required. ESWT offers a simple, fast and effective therapeutic procedure which allows continuation of sports activities usually the following day after treatment. ESWT is a non-invasive therapy without significant side effects. Often immediate pain relief and muscle relaxation enables continuation of training and participation in sports events.

The situation for other than top athletes turned out to be different. Since some of the below listed indications may be successfully treated by conservative measures such as injections, massages etc. at lower costs the shock wave treatment was only applied after frustrane treatments (minimum 6 month) by conservative methods. Such persistent chronic pain indications feature the negative and most difficult selection of patients only suitable for open surgery. Even surgical methods promise an improvement in only 70 to 80% of the patients. Extracorporeal shock wave treatments are successful in a similar percentage of patients with the extraordinary advantage of being completely non-invasive. Most important also is the fact that patients may continue to work as usual the following day. Taking into account the significant reduction of the inability to work and the short healing time not only compared to open surgery, ESWT is generally cheaper than several months of conservative treatment efforts.

6 Indication Range

The therapeutic potential of ESWT is by far not yet fully known. The working mechanism is still under discussion. Improvement of circulation and metabolism seems to be one of the most stringent mechanism responsible for muscle relaxation, pain reduction and enhanced heeling processes in case of non-unions.

The following four indications are considered well established due to thousands of successful treatments all over the world.

- Non-unions
- Tendinosis calcarea
- Plantar and dorsal heel spur
- Tennis elbow

All those indications are successfully treated by ESWT predominately in chronic stage. This does not mean that treatment in the acute phase will be less efficient. However, simple conservative treatment strategies may gain equally good results at lower costs. For financial reasons doctors restrict themselves to use ESWT only for the previously frustrane treated chronic diseases.

Further indications such as hip necrosis and others are under investigation. Preliminary results are promising.

7 Financial Aspects

Due to the high success rate and the almost complete lack of side effects ESWT became a frequently used treatment alternative for tennis elbow, heel spur, tendinosis calcarea and others. Surprisingly, this seems to be the reason for preventing a wide acceptance of the method in some countries.

In spite of all over excellent medicinal success, published in several hundreds of papers, statistically proven evidence supported by prospective double blind studies is still lacking. Several studies are currently performed and FDA approval for several different indications is pending in the US. Interestingly, most of all other accepted conservative and reimbursed medicinal procedures are also lacking statistically proven evidence. At the first glance, ESWT seems to be costly due to expensive technical equipment. In times of lack of financial resources and cost explosion in medicinal care, this is an extremely sensitive issue. Whenever a fixed amount of

money is shifted from one medicinal speciality to another concerns and growing suspicion of the affected medicinal group and health care authorities are generated. Taking into account not only reimbursement costs of public health care systems, but all recovery costs including convalescence time, the financial benefit is obvious.

8 Conclusion

ESWT has proven to be a new and very effective treatment modality based on the shock wave technology established since 20 years in urological stone therapy. In addition to its fragmentation power shock waves turned out to provide significant therapeutic effects in various musculoskeletal diseases. There is no doubt about final acceptance of this technology by the medicinal community even if financial restrictions and inertia of health care systems presently prevent ESWT from being as well accepted as it deserves to be.

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