Summary of the sound wave phenomenon

Shockwaves are acoustic waves, i.e. sound pulses, that carry high energy, characterized by a particular waveform (rapid peak of positive pressure followed by a rapid phase of negative pressure), able to produce direct mechanical stimulation. Generated in an aqueous medium and conveyed on a defined point referred to as “focus” (or target), they transmit a measurable amount of energy, able to provide precise therapeutic effects.

How they work
When the shockwave travels through living tissues (through appropriate energy levels for the treatment site and desired therapeutic effect), said tissues undergo a beneficial “micro hydro massage”, able to promote a series of biochemical and cellular reactions, which are ultimately responsible for the therapeutic effect.

With calcific formations, which often occur in inflamed tendons and ligaments, what leads to their disappearance after treatment with shockwaves (not in all treated cases though), is not linked to a direct mechanical action (of “breaking”) but to their dissolution, through the activation of local biochemical processes.
What is ShockWave Dual Power

SHOCKWAVE DUAL POWER is the evolution of "monomodal" shockwave devices based on the concept that it is necessary to generate sound waves to be applied to tissues to obtain appreciable results in therapeutic or aesthetic terms.

The "multi-mode" approach of SHOCKWAVE DUAL POWER is the first great innovation in the field of shock waves after decades of technological immobility, so much so that it is covered by an international patent.

The concept underlying SHOCKWAVE DUAL POWER can be explained with a simple, yet effective example: if you have the key of a door it is perfectly useless to break it down with your shoulder.

The R&D Department and the Scientific Division of Winform have worked for a long time looking for this "key", and found it in the possibility of generating tissue modifications that allow the sound wave to propagate effectively, without the need to use extremely high pressure as in traditional systems.

This effect was achieved thanks to the synergy of devices capable of preparing the "road" for a uniform wave, propagated by a high reaction piezoelectric system with fast rise ramp pulses.

The shock pressure generated by this system is calibrated to be able to effectively penetrate tissues bio-stimulated by SHOCKWAVE DUAL POWER, reaching the therapeutic target in a quick and controlled manner.

All that is summed up as being able to keep the effectiveness of traditional shockwave systems but in a more comfortable and safer manner for the patient, who does not perceive any pain or discomfort during treatment.

SHOCKWAVE DUAL POWER, the modern concept of shockwave.
ShockWave Dual Power: to use synergy for a revolutionary shockwave concept

1. TECAR: GEL-SOL transition of the extracellular matrix
2. SHOCKWAVE: implosion of water molecules and release of energy (cavitation effect)
3. TRANSDERMAL VEHICULATION: oxygenation of the tissue with LifeGel

SYNERGIC WAVE SHOCKWAVE DUAL POWER OF WINFORM
Wiform has developed and patented a complex and effective system that, thanks to the synergy of TECAR and Transdermal Vehiculation, opens the door to and allows the shockwave to penetrate with no more need for very high pressure and above all, without causing any pain to the patient.
What is the Tecar method

It is the application of a radio-frequency energy emission system, applied to the human body as a curative method, which controls and quantifies the quality and quantity of energy accumulated by the organism.

Therefore, Tecar is also a medical device that uses the energy applied to registered therapeutic processes.

Premise: to obtain these assumptions with a physical principle of endogenous radio-frequency the human body must play the leading role, so that the principle adapts in real time and respects the biological and clinical processes of the organism.

How Tecar works

It is a generator that uses the physical principle of the high frequency capacitor, it creates an electromagnetic field between the active and negative electrodes, involving the human body in a hyperactivity of movement through the shifting of electrolytic charges found in the organism. All these elements work when the circuits close, creating an electric differential that generates the energy and creates a shifting of charges equal to the number of pulses that the generator emits.

The electric differential is measured like a voltage source. The human body is a second class armature and has the function of a conductor with resistances that can be superficial and deep.

All this explains why all those tissues between the active electrode and the counter electrode are affected, in fact forcing us to take into account not only the cutaneous impedance but also the impedances that develop inside the organism in the various tissues crossed by the energy. Therefore the unit of measurement cannot be limited to voltage alone, but necessarily the electrical conductivity with all surface and deep resistance parameters.

If the physical principle, that is the generator, is finally able to control both voltage and current and the resistance, we will be able to control the thermal effect that does not perform a curative action, but can become, if control is ever lost, a contraindication.

All of this finally determines the possibility of quantifying the absorbed energy in Joules per cm², allowing the health care operator to quantify the suitable energy dosage to apply for the required treatment, with the typical selectivity of emission frequency, making it possible to create a treatment protocol that is objective rather than subjective.

All of this allows three fundamental factors:

Greater efficacy, provided by the optimal energy dose

Lesser contraindications and certainties of the result, eliminating energy overdose.

This technology creates an epochal change by placing different parameters on the use and application of the physical principles of radiofrequency applied to the organism for a therapeutic process.
What is the method
Transdermal Delivery

It's a painless method with no side effects. It allows the transdermal vehiculation of active ingredients with high molecular weight in cell interstitial spaces without the intermediation of blood circulation in the first phase (e.g. drugs, homeopathic products, plant protection products).

The system uses low frequency electrical pulses as a carrier (electroporation). The stimulation electric wave is produced by a direct current generator, that is able to assess variations in skin resistance in stable and reproducible conditions.

With an appropriate variation of the electrical parameters, this method makes it possible the transcutaneous vehiculation of substances without altering the tissues and reaching optimal depth.

The Transdermal Vehiculation method radically and effectively changes the way of administering both low and high molecular weight active substances, like hyaluronic acid, fibrinolytics, etc.

Penetration
The skin's main "barrier" function resides almost entirely in the stratum corneum. The very low permeability of this layer to water-soluble substances is due to the extracellular lipid matrix comprised of ceramides, cholesterol, long-chain fatty acids in a defined molar ratio, critical and functional to the integrity of the barrier.

The penetration of a substance applied to the skin can occur:

through glandular annexes
(pilosebaceous apparatus and eccrine glands)

transepidermally
(intercellular and/or transcellular route)
Interactions
shockwave and tissues
biological

Shockwaves have been used in the medical field for over forty years: initially their use was identified as a therapeutic tool able to intervene on the structure of kidney stones, shattering them and reducing their size so as to facilitate their elimination. The lithotripsy proved to be a method so effective, safe and highly repeatable that it quickly became the gold standard for the treatment of renal and urethral lithiasis. But the real breakthrough in the orthopaedic and rehabilitation field occurred in 1986, when the first experimental studies on the influence of shock waves on bone tissue began, as it was feared that the lysis effect on the renal calculus would also affect the iliac and femur bones, damaging them.

Graff et al. study showed that the bone tissue of the treated animals had not reported macroscopic changes, but through histological investigation we could observe some microcracks which, after 2-3 weeks from exposure, had completely regenerated, with the presence of new bone tissue (osteogenesis). The slight changes observed by the authors on the bone exposed to treatment were not a contraindication to the lithotripsy, leaving instead room for a wide scientific debate on the new therapeutic horizons of the method.

Haupt picked up the correct intuition of Graff and his collaborators and began a series of experiments (in particular on animal models) to evaluate the biostimulation potential of shock waves, both in the regeneration of soft tissues and of bone tissue.

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The results with respect to wound healing revealed that the efficacy of the treatment was strictly dependent on the dose used and that at a low energy dosage it was possible to obtain a concrete stimulation of tissue healing (at the same time, to high dosages corresponded longer recovery times). Furthermore, as concerns the effect of the shock wave on bone tissue, using as outcomes radiological, histological and biochemical analyses, the authors were able to confirm the actual osteogenic potential of this therapy.

In 1988, the two Bulgarian researchers Valchanou and Michaílou 9, supplied the first clinical results of the treatment, through shock waves, of the delays of bone consolidation and of pseudoarthrosis: it could be found that the therapy was a success in the 85% of cases, although unfortunately there was no mention of the patient’s medical history, any concomitant treatments and there was no follow-up. The authors advanced the hypothesis that shockwave treatment broke the sclerotic bone and produced microcracks, which increased the supply of blood and nutrients to the area, stimulating its healing. In addition, the presence of small bone fragments partially attached to the periosteum could be a further element of osteogenetic stimulation.

The results of Bürger 10–11 and Witzsch studies (et al 12) on the effect of biostimulation on the bone reported a lower success rate (compared to the study of Valchanou and Michaílou) but it was possible to observe a complete bone consolidation in 35% of cases and the formation of bone callus in 21%, on a sample of 37 patients.

Another author, Haist 13, took pains to differentiate the results obtained according to whether the type of pseudoarthrosis found in the patient was hypertrophic or atrophic. While all patients with hypertrophic pseudoarthrosis showed complete healing of the fracture, only 3 out of 13 of those found with atrophic pseudoarthrosis achieved this result.

Schleberger and Senge 14 supported the treatment of this complication by shock waves, also indicating that pseudoarthrosis would have had a better outcome if stabilized in post-treatment with a suitable orthosis (to avoid cutting, rotational and curvature forces), but that it was anyway absolutely necessary to ensure an adequate axial pressure on the treated area.

The first treatments with extracorporeal shockwaves on calcific shoulder tendinopathy began in the 90s: the proven efficacy that ensued allowed to extend the non-invasive treatment also to plantar fasciitis and epicondylitis 15.

In a 1995 consensus meeting, the German Lithotripsy Society officially recommended the use of shockwave for different therapeutic indications: pseudoarthrosis, bone consolidation...
delays, enthesopathies (tennis elbow, painful shoulder, calcaneal spine), algia to the soft tissues proximal to the bone components and tendinopathies with extraosseous calcifications.

Concerning pseudoarthrosis, it is still recognized as a first choice non-invasive treatment 16 (in particular for the hypertrophic type).

Starting from the same year (1995), this means started to be used in the treatment of calcific deposits: several studies have shown its great effectiveness in reducing pain and in the lysis of calcifications, in particular using a high energy dose and through local anaesthesia of the area to be treated 17 18 19.

Moreover, a comparative study between the effects of treatment with shock wave and those with arthroscopy 20 shows that the two methods are absolutely superimposable, with the added value of ESWT (Extracorporeal Shock Wave Therapy) being a non-invasive method and with a very low percentage of complications / side effects (follow-up controls of the Daecke et al study).

From further studies 21 carried out at the beginning of the 2000s it was decided to expand the use of the shock wave to the therapy of patellar tendinitis ("jumper’s knee"), osteochondritis dissecans and avascular necrosis of the femoral head, with very satisfactory results.

Moreover, for about a decade, ESWT has been used with great effectiveness also in the treatment of hypertonus in spastic syndromes 22 23 and it is also reported a regenerative effect on the nervous tissue and on the spinal structures 24, with reorganization of the cellular memory (pathological) and with an effective action on neurological pain control.

More recently, extracorporeal shockwaves have also been used in aesthetic medicine in the treatment of cellulite and localized adiposity, with excellent results 25.

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Mechanism of action

The biological effects of shock waves are strictly dependent on different characteristics: the type of generator used (electrohydraulic, electromagnetic, piezoelectric and pneumatic), the specific characteristics of the acoustic signal, the density of mechanical energy produced by the wave, the physical characteristics of the substrates that the wave must cross and the percentage of water contained within them. Another distinction must be made: if the effects obtained are of direct type (when the wave comes into contact with the tissue and locally there is an expansion followed by a contraction, they are due to changes in intra and extracellular pressure) or indirect (caused by cavitation or the collapse of air bubbles produced by the direct or “initial” effect of the shock wave).

Among the physical characteristics it is very important to consider the acoustic impedance, closely related to each tissue density: the shock wave can be absorbed in different quantities, and then reflected, diffused or refracted.

For example, muscle and adipose tissues have a very low acoustic impedance and this allows the acoustic wave to be almost completely absorbed, and propagated, with a minimum reflection index.

As far as energy density is concerned, the effect of disintegration of the shock wave occurs thanks to specific devices for lithotripsy which allow high and focused energy dosages, so as to hit the calculus, shatter it (pulverize it) and allow its expulsion. In this case, the body area to be treated must be carefully identified to avoid damage to the neighbouring tissues. However, in the case of low (and average) energy dosages therapy (ESWT), although the mechanisms that allow the shock wave to activate some biological reactions are not completely known yet, it is proven that the specific characteristics of some mechanosensitive cells allow the identification, transmission and conversion of the exogenous stimulus into a biological tissue effect (biostimulation, neoangiogenesis, analgesic effect, anti-inflammatory, reabsorption of calcareous deposits in the calcifications).

Specifically, after perceiving and processing the mechanical information deriving from the extracellular environment and due to the propagation of the shock wave in the tissue, these cells convert these biomechanical forces into biochemical responses, which in turn will influence some fundamental functions of the cell (such as migration, proliferation, differentiation and apoptosis) and of its life cycle.

In particular, functional modifications of the cellular organelles (cytoplasmic) have been observed and involve a stimulation of the nuclear functions and an increase of the production of proteins, nitric acid and of specific angiogenic growth factors (eNOS and VEGF) which in turn determine correct revascularization (neoangiogenesis) and an

10.1016/j.ijssu.2015.11.030;
27 NdR: It is of fundamental importance to know the physical properties of the tissues to be treated to guide the operator on a correct therapeutic rationale.
adequate intake of nutrients (to allow tissue repair). In addition to stem cells and mesenchymal stromal ones, other cells are also directly involved in tissue regeneration, in particular through this mechanism of "mechanotransduction", determined by shock waves: tenocytes, osteocytes and their precursors, endothelial cells and fibroblasts.

The tenocytes in particular are recognized as cells sensitive to mechanical stress and it is believed that the shock wave acts directly on them by stimulating their mitogenic response (i.e. in cell proliferation and duplication). Specifically, after processing the mechanical stimulus, we see: a reduced expression of several metalloproteinases and interleukins (MMPs and ILs), an adequate regulation of cellular vitality and proliferation, the expression of several typical tendon markers and anti-inflammatory cytokines. Furthermore, ESWT is a stimulus for the proliferation and synthesis of collagen, increases the expression of lubricin and allows the increase (in vitro) of the functional activities of the tenocytes produced as a result of tendon damage (proliferation and migration) that contribute to determine a correct morphofunctional regeneration of the structure.

Bone tissue is probably the biological substrate in which the effects of the shock wave are more clearly outlined. The osteocytes in fact possess a high mechanical sensitivity as well as their precursors (osteoblasts).

In vitro experiments show that the shock wave acts not only directly on bone and periosteal tissue, but is also able to regulate the continuous "communication" (and programming) between osteoblasts and osteoclasts and bone vasculature.

In detail, the effects observed at bone level include: a direct stimulation of osteoblasts and periosteum cells, an osteogenic differentiation of mesenchymal cells and an accelerated migration of osteoblasts. Moreover (as it happens for the tendinocytes) the expression of angiogenic growth factors (eNOS and VEGF) starts, the synthesis of nitric oxide at the endothelial level and the proliferation of nuclear antigens which, besides the opening of new vessels, they result in an increase in blood supply that provides the district with nutrients essential for tissue regeneration.

This stimulation is not limited only to the bone cells but also extends to the periostium: the consequent inhibition of the prosteoclastogenic factors modulates the osteoclastic activity of bone remodelling.

The same effects of activation of angiogenic factors, structural remodelling and biostimulation are also found for the other mechanosensitive cells present in the treatment area and stressed by the shock wave.

Shockwave dual power

Shockwave is the Winform device that revolutionizes the classic concept of therapeutic shockwave. The field of action of the ESWT devices described in the previous chapter is thus greatly amplified, thanks to the synergic interaction of the shock wave with diathermy and transdermal vehiculation.

[For specific details about the two technologies, see our dossiers “diathermy” and “transdermal vehiculation”: physical principle and interactions].

Diathermy allows the modification of the extracellular matrix with an increase in the percentage of water in the area (nb the greater contribution of water to the treated structure allows a high absorption of the shock wave with a minimum percentage of refraction or dispersion of the same wave), an increase of mitochondrial activity and of the sodium-potassium pump. There is an initial effect of neoangiogenesis which is emphasized following stimulation of the shock wave. A greater flow of blood supply allows the intake of nutrients to the area being treated and a more rapid disposal of inflammatory catabolites.

This process, through the vehiculation of specific active ingredients (in particular oxygen-ozone) has an extensive anti-inflammatory, analgesic and anti-oedema effect.

A true biostimulation is thus obtained, which leads to the regeneration of the tissue and a restoration of the structure, which will allow a more timely functional recovery.
Biological effects of ShockWave

- neoangiogenesis;

- restoration of supply and nourishment of the ischemic areas;

- acceleration of the flogistic and lesional and perilesional healing effects (anti-inflammatory effect);

- analgesic effect;

- biostimulation: tissue regeneration (consolidation delays, pseudoarthrosis, tendon and muscle lesions ...), rapid reabsorption of calcareous deposits (calcifications);

- nourishing and trophic effect on the biological structures involved in the treatment;

- anti-oedema and draining effect;

- quick return to functional activity;
Therapeutic instructions

- adhesive capsulitis ("Frozen Shoulder")
- calcifications
- enthesis
- epitrocleitis
- carpal tunnel
- chronic-degenerative arthropathies
- bone consolidation delays
- tarsal tunnel
- calcaneal spur
- Morton's Neuroma
- plantar fasciitis
- pseudoarthrosis
- chondropathies
- osteitis pubis
- muscular spasticity
- epicondylitis
- chondropathies

Biological effects
The first painless Acoustic Wave.

ShockWave Dual Power is the innovative device for focused shock wave therapies in multimodal mode SHOCKDUAL® and SHOCKFOCUS®.

The patented SHOCKDUAL® mode, based on the principle of therapeutic synergy, allows the therapy to be delivered following an optimal biological process. The return of water, obtained by means of diathermic biostimulation, allows the shock waves to implode and propagate more easily than with any other shockwave technology available on the market. The therapeutic process is completed by the possibility to vehiculate, at the same time, active principles in water-soluble form.

ShockWave Dual Power is the only shockwave device that is totally painless for the patient.

ShockWave Dual Power is able to detect tissue modifications and absorptions, providing the operator with the certainty of repeatable therapeutic results.

ShockWave Dual Power has a library of preset programs that allow the operator to easily and intuitively choose the treatment to be applied.
Programs
Treatments can be set by choosing the appropriate protocol from the library of programs, divided by pathology. It is also possible to create custom programs and save them in the device memory.

SIVSEA and SCE
ShockWave Dual Power uses and displays two fundamental parameters to manage and understand the effects induced to the tissue. The domain of SIVSEA and SCE are part of the industrial patents that ShockWave Dual Power owns.

Handpieces
ShockWave Dual Power has patented SHOCKDUAL® handpieces with synergic emission of Sound Wave, Tecar and Transdermal vehiculation with heads to treat small, medium and large surfaces as well as the SHOCKFOCUS® handpiece for selective and super-focused treatment.

Guaranteed safety
ShockWave Dual Power has safety systems that actively intervene if excess energy is given to the patient, thereby eliminating any errors. Safety is guaranteed by a "watch dog" system that constantly checks that the software is working correctly.
Preset programs

Library of preset programs divided by pathology to perform experimental treatments effectively tested on athletes of the highest level (Italian Volleyball Federation, Benetton rugby, etc.) and on thousands of patients in the Medical Centres of Study and Research Winform. The easiest way to access the great Winform experience in the field of physical therapy.

Software

Maximum customisation.
The most demanding therapist can create and save new therapeutic protocols, personalising them according to the needs of each individual patient. Possibility to modify the frequency, the number of strokes, the intensity level of each single therapeutic element of the synergic system for shockwaves dual power.
SHOCKFOCUS® handpiece is specific for the application of focused shockwaves. The particular shape of the contact surface allows to provide selective and precise treatments, while maintaining the pressure of the beam constant and reaching anatomical areas that are difficult to treat with classic handpieces. Ergonomic handle and soft touch surfaces. Shell with high resistance to falls.

The patented handpiece SHOCKDUAL® is a concentrate of technology and design. Treatment head with "Multimodal shockwave" technology, the new revolutionary system for shockwaves with synergic action by Winform Medical engineering for a deep and painless effect. Integrated system for detecting and transmitting skin impedance data and measuring the energy absorbed by the patient (Joule Control System). Bright feedback of successful contact and correct execution of the treatment. Ergonomic handle and soft touch surfaces. Shell with high resistance to falls.
### Technical specifications

<table>
<thead>
<tr>
<th>Power:</th>
<th>200 Watts absorbed</th>
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</thead>
<tbody>
<tr>
<td>Max power:</td>
<td>9 Watt/cm² per stroke</td>
</tr>
<tr>
<td>Display:</td>
<td>TFT 10.2”</td>
</tr>
<tr>
<td>Medical device vers.:</td>
<td>Class IIb classified according to 93/42/EC</td>
</tr>
</tbody>
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### Compatible handpieces

- **MANSKWP**
  *Bipolar handpiece for large areas with AISI 316 stainless steel electrodes for combined shockwave and vehiculation treatments.*

- **MANSKW**
  *Bipolar handpiece for medium areas with AISI 316 stainless steel electrodes for combined shockwave and vehiculation treatments.*

- **MANSKWF**
  *Focus handpiece with AISI 316 stainless steel electrode for focused treatment in small areas.*

### Assessment kit  KITVAL02

- **TERCAM**
  *Digital thermal camera for thermographic detection of the tissues.*
SHOCKWAVE LAPTOP

Power: 200 Watts absorbed
Max power: 9 Watt/cm² per stroke
Display: TFT 10.2"
Medical device vers.: Class IIb classified according to 93/42/EC

Compatible handpieces

MANSKWPT
Bipolar handpiece for large areas with AISI 316 stainless steel electrodes for combined shockwave and vehiculation treatments.

MANSKWT
Bipolar handpiece for medium areas with AISI 316 stainless steel electrodes for combined shockwave and vehiculation treatments.

MANSKWFT
Focus handpiece with AISI 316 stainless steel electrode for focused treatment in small areas.

Assessment kit KITVAL02

TERCAM
Digital thermal camera for thermographic detection of the tissues.

Optional accessories

STAWF01
Stand with wheels that makes it easier to move the device inside the centre.

CASEWFENDO3
Trolley for off-site transport of the device.

Technical specifications

- 200 Watts absorbed
- 9 Watt/cm² per stroke
- TFT 10.2"
- Class IIb classified according to 93/42/EC
YOUR VALUE
OUR PASSION
YOUR SUCCESS
University La Sapienza of Rome,
IFO Hospitaler Physiotherapeutic Institutes-Rome,
Local Health Care Unit of:
Milan, Venice, Palermo, Florence,
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