Ultrasound and osteogenesis: effective in 20 minutes









Effective in just 20 minutes a day.

FAST therapy is a non-invasive low-intensity pulsed ultrasound medical device (LIPUS: 1.5 MHz, 30mW / cm²).

FAST therapy promotes and accelerates bone healing in just 20 minutes a day.

FAST therapy works quickly and safely.











Treatment protocol

CLINICAL INDICATIONS	MIN/DAY	THERAPY DURATION DAYS
fresh fractures	.I.	45-60
delayed unions		45-90
non-unions	— 20 min	45-90

Clinical evidence

Courtesy of dr Alexander Kirienko (Milan, Italy)

NON-UNION

MALE, 57 YEARS OLD

Post-traumatic pseudarthrosis of the forearm undergoing treatment with two fixation plates.

- 1. Treatment with Ilizarov for 6 months and beginning of FAST therapy for 60 days.
- 2. Result 3 months after removal of the fixator.
- 3. Clinical recovery with restoration of forearm length and wrist function.







Safety

To ensure safety and efficacy, FAST therapy parameters are preset by IGEA and cannot be changed, even accidentally (CEI EN 60601-1-11 Standard).



Efficacy

Osteogenetic efficacy is guaranteed by the ability to maintain the physical characteristics of the signal at the fracture site for the entire duration of the therapy.



Compliance

FAST therapy calendar allows the patient to easily follow the doctor's recommendations on treatment time and duration.



Courtesy of dr Carlo Luca Romanò (Milan, Italy)

INFECTED NON-UNION

MALE, 45 YEARS

Traumatic infected non-union (staphylococcus aureus): exposed diaphyseal fracture of tibia and fibula (Gustilo I) treated with intramedullary nail.

No sign of bone callus progression.

- 1. Start of FAST therapy 7 months after the trauma.
- 2. 4 months after beginning of FAST therapy bone callus progression is seen.
- 3. 18 months from the trauma: removal of the nail and complete bone healing.









How to use it



Place the bracelet on the fracture site.



Apply the gel on the ultrasound transducer.



Insert the transducer into the bracelet.



Close the protection.

References

- 1. Corradi C, Cozzolino A. Effect of ultrasonics on the development of osseous callus in fractures. Arch Ortop. 1953;66:77-98.
- 2. Ryaby JT, Mathew J, Duarte-Alves P. Low intensity pulsed ultrasound affects adenylate cyclase activity and TGF-β synthesis in osteoblastic cells. Trans Orthop Res Soc. 1992;7:590.
- 3. Heckman JD, Ryaby JP, McCabe J, Frey JJ, Kilcoyne RF. Acceleration of tibial fracture healing by non-invasive, low-intensity pulsed ultrasound. J Bone Joint Surg Am. 1994 Jan;76(1):26-34.
- Kristiansen TK, Ryaby JP, McCabe J, Frey JJ, Roe LR. Accelerated healing of distal radial fractures with the use of specific, low-intensity ultrasound. A multicenter, prospective, randomized, double-blind, placebo-controlled study. J Bone Joint Surg Am. 1997 Jul;79(7):961-73.
- 5. Mayr E, Wagner S, Ecker M, Rüter A. Treatment of nonunions by means of low-intensity ultrasound. Unfallchirurg. 1997;268:958-62.
- 6. Mayr E, Rudzki MM, Rudzki M, Borchardt B, Häusser H, Rüter A. [Does low intensity, pulsed ultrasound speed healing of scaphoid fractures?]. Handchir Mikrochir Plast Chir. 2000 Mar;32(2):115-22.
- Nolte PA, et al. Low-intensity pulsed ultrasound in the treatment of nonunions. J Trauma Injury Infect Crit Care. 2001;51(4):693-702.
- Rubin C, Bolander M, Ryaby JP, Hadjiargyrou M. The use of low-intensity ultrasound to accelerate the healing of fractures. J Bone Joint Surg Am. 2001 Feb;83-A(2):259-70. Review.
- Leung KS, Lee WS, Tsui HF, Liu PP, Cheung WH. Complex tibial fracture outcomes following treatment with low-intensity pulsed ultrasound. Ultrasound Med Biol. 2004 Mar;30(3):389-95.
- 10. Ricardo M. The effect of ultrasound on the healing of muscle-pediculated bone graft in scaphoid non-union. Int Orthop. 2006;30(2):123e127.
- Jingushi S, Mizuno K, Matsushita T, Itoman M. Low-intensity pulsed ultrasound treatment for postoperative delayed union or nonunion of long bone fractures. J Orthop Sci. 2007;12(1):35-41.
- 12. Trezza P, Meani E. Trattamento di una frattura della diafisi femorale con bendaggio funzionale e ultrasuoni pulsati a bassa intensità: illustrazione

- di un particolare caso clinico. Quaderni di infezioni osteoarticolari. Supplemento a: Giornale del Medico 20-Ottobre 2007. Elsevier Masson Srl. Milano.
- 13. Fassina L, Saino E, Sbarra MS, Visai L, Cusella De Angelis MG, Mazzini G, Benazzo F, Magenes G. Ultrasonic and electromagnetic enhancement of a culture of human SAOS-2 osteoblasts seeded onto a titanium plasmaspray surface. Tissue Eng Part C Methods. 2009 Jun;15(2):233-42.
- 14. Romanò CL, Romanò D, Logoluso N. Low-intensity pulsed ultrasound for the treatment of bone delayed union or nonunion: a review. Ultrasound Med Biol. 2009;35(4):529-36.
- Massari L, Caruso G, Sollazzo V, Setti S. Pulsed electromagnetic fields and low intensity pulsed ultrasound in bone tissue. Clin Cases Miner Bone Metab. 2009 May;6(2):149-54.
- 16. Schofer M, Block JE, Aigner J, Schmelz A. Improved healing response in delayed unions of the tibia with low-intensity pulsed ultrasound: results of a randomized sham-controlled trial. BMC Musculoskel Disord. 2010;11(1):229.
- Fassina L, Saino E, De Angelis MG, Magenes G, Benazzo F, Visai L. Low-power ultrasounds as a tool to culture human osteoblasts inside cancellous hydroxyapatite. Bioinorg Chem Appl. 2010:456240
- 18. Fassina L, Visai L, Magenes G, Schelfhout J, Bloise N, Riva F, Omes C, Avanzini MA, Cusella De Angelis MG, Benazzo F, Dierick M, Van Hoorebeke L, Dubruel P, Van Vlierberghe S. Ultrasound stimulus to enhance the bone regeneration capability of gelatin cryogels. Conf Proc IEEE Eng Med Biol Soc. 2013;2013:846-9.
- Carlson EJ, Save AV, Slade JF III, Dodds SD. Low-intensity pulsed ultrasound treatment for scaphoid fracture nonunions in adolescents. J Wrist Surg. 2015;4(2):115e12o.
- 20.Nolte P, Anderson R, Strauss E, Wang Z, Hu L, Xu Z, Grant Steen R. Heal rate of metatarsal fractures: A propensity-matching study of patients treated with low-intensity pulsed ultrasound (LIPUS) vs. surgical and other treatments. Injury. 2016 Nov;47(11):2584-2590.

The device complies with the Medical Device Directive 93/42 / EEC and subsequent amendments and it is marked CE 0051.

It complies with the CEI EN 60601-1 standard for the safety and essential performance of medical devices.

It complies with the CEI EN 60601-1-11 standard for the safety of medical devices for home use.