

Shockwave Surgery and Autologous Growth Factors Combined Therapy for Non Unions and Pseudoarthrosis

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Bone healing in non unions and pseudoarthrosis has been a challenge for the orthopaedic surgeon since the beginning of times. Improved surgical techniques, better biomaterials and hardware, as well as the use of appropriate grafting and tissue banking has made the revision process for a non united fracture less often and more predictable. However, surgical procedures in non unions and pseudoarthrosis always involve large operations that significantly increase pre and postoperative risk factors, and also represent a longer and more difficult recovery period and rehabilitation process. Many non invasive techniques have been implemented to enhance the process of bone healing in difficult circumstances. Extracorporeal shockwave stimulation of bone has proved that enhancement of the production of endogenous growth factors, free radicals and NO is possible, and results in bone healing in unfriendly soil. These effects have been studied in both molecular biology and clinical scenarios and ESWT is currently one of the most important tools in the orthopaedic arsenal of the 21st century. By means of stimulating bone with focalized high energy ultrasound in the form of repetitive shockwaves, today we are able to enhance the healing process by causing neo-vascularization, periosteal stimulation and cell differentiation that result on bone callus in areas that would otherwise need surgical intervention and grafting. This procedure is non invasive, and has proven to be able to replace surgical procedures in stable non unions with no serious associated complications reported in more than 15 years of worldwide application. However, shockwave application in bone requires usually high energy generators that cause pain during the procedure, and in many occasions it must be done under general anaesthesia in an operating room. The cost of these devices is high for many countries, and difficult to introduce in the therapeutic arsenal of many hospitals. Being a non invasive procedure, rehabilitation protocols are shorter and recovery time reduced, but healing time, as seen in X-Rays, CT Scans or MRI's, is probably similar to large surgical interventions. In order to find a system that would reach the same minimally invasive goals as ESWT, using less expensive devices, we have tried Radial Shockwaves in combination with the injection of Platelet Autologous Growth Factors (AGF's). Both Orthopaedic and Maxillo Facial Surgeons have used AGF's for many years to reach the same goals as Shockwave Surgery. AGF's can be easily obtained from the alpha granules of platelets from the own patient's blood. It can be prepared in the form of a gel obtained from the Puffy Coat portion of centrifuged blood, which can be mixed to auto or allografts during a surgical procedure. We have developed a protocol to apply Radial Shockwaves with energies of 0.3mJ/mm², in order to stimulate vascularization and periosteal reaction in the area. We have used them only in non unions lying in bones not deeper than 1.5 inches, like tibia, ulna, distal femur and humerus. We give 4000 radial Shockwaves in the surrounding area, and under fluoroscopy we apply 10 cc of AGF's in different points of the fracture soft callus. In selected cases, where there is a defect larger than 2 cm², we mix the AGF's with lyophilised 300 micron bone allografts that act as an osteoconductor. All this procedure is done in a surgical room with no anesthesia and under aseptic surgical conditions. We have done 12 patients to date with stable postoperative non unions, in which the surgical procedure would have been a large incision that would involve hardware removal and replacement, bone drilling and grafting. Some of our patients also had thin skin after free grafts or vascular grafts from their original interventions that would indicate extra care for surgical approaches or higher energy ESWT. We have treated 5 tibias, 3 humerus, 2 distal femurs and 2 ulnas. All of them have healed promptly, with dramatic x-ray changes after 6 weeks. We have no complications related to the procedure and all patients and referring doctors are highly satisfied with the results. We believe that the use of radial shockwaves is not enough to create adequate bone healing by themselves, both because of the lower energy and the loss of flux density as it goes deeper into the tissues. The use of single AGF's is also a

good addition to surgical procedures where the trauma caused by the surgery itself will cause revascularization and cell migration to the area where the growth factors would cause some effect. However, used percutaneously alone, the AGF's would act only as a seed in a dry soil, not being able to help in the process of bone healing. We have very impressive results so far, and this has been an interesting finding that must be reported to the scientific community, as we have not found any previous report of any form of ESWT & AGF combined therapy. Of course we need to go further in the research of which one is the primary therapeutic element, so we are currently working on an experimental model in dogs, analysing in four groups the effects of single ESWT treatment, single AGF treatment, ESWT & AGF combined, and a control group. We will present in June 2005 in the ISMST meeting in Vienna our clinical results as a case- series study, and the preliminary results of our experimental study in animals. This new approach to non unions could make the treatment even easier than high energy ESWT or other surgical alternatives.