

EXTRACORPOREAL SHOCKWAVE THERAPY (ESWT) IN OSSEOUS NON-UNIONS – A GERMAN COHORT STUDY

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ABSTRACT

BACKGROUND — Shockwave therapy is less or more established as an alternative treatment to surgical interventions for impaired osseous healings like delayed or non-unions after fractures or arthrodeses. This cohort study looked for own results and best practice of focused shockwaves in adequate cases.

MATERIALS & METHODS — Between 2001 and 2010 381 unselected bone fractures or stiffed joints with persistent impaired healing as delayed or non-unions were included in this pilot study. Details about outcomes were received by questionnaires, X-ray-evaluations and transmitted informations from doctors or these patients. Only hard facts concerning bony consolidation in the gaps have been of interest to assess bony healing.

RESULTS — Overall 239/381 cases (63%) showed sufficient bony consolidation after ESWT. Cases of impaired fracture-healing showed better (66%) success rates than those of impaired arthrodesis-healing (47%). Healing-rates in impaired unions ranged from 93% after scaphoid-fractures to only 23% after talocalcaneonavicular arthrodeses.

CONCLUSION — So long as inconsistent pseudarthrosis-definitions and non-comparable results of post-surgical outcomes in cases of impaired osseous healing exist the ESWT is an alternative to surgery in selected indication-subgroups because of their satisfying success rates in selected groups of impaired bone healing.

DISCUSSION — As the ESWT demands to exist as a serious alternative to surgery in cases of impaired bone healings all doctors who use this option must be certificated and have to use comparable shockwave devices in the interest of improvement of successful therapy protocols for different bone healing-complications.

KEYWORDS

extracorporeal shockwave therapy, ESWT, fracture, arthrodesis, impaired bone healing, delayed union, non-union, pseudarthrosis, bone healing, bony consolidation Abstract

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BACKGROUND

Non-unions in orthopaedic surgery is a challenging problem. Golden standard for delayed or non-unions is surgery. Their results are different and dependent from definitions of pseudarthrosis, which are also inconsistent. Since more than fifteen years the use of shockwaves as an alternative or support to surgery is performed, also in Germany. Encouraging results with the ESWT in the treatment of non-unions



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are reported from some shockwave-centers. Main condition for ESWT in the treatment of disturbed bone healings is full fracture-or joint-stability. Concerning ESWT-techniques it is necessary to apply focused acoustic shock-waves. After ESWT the follow up has to be similar to common surgical rules (load, range of motion, immobilization ...) In Hanover / Germany we treated 453 unselected consecutive cases of impaired bone and joint healings by extracorporeal shockwaves. First we defined all delayed unions as elder than three and younger than six and all non-unions as elder than six months after accident resp. surgery in knowledge that this definition is not the common sense. Indications for ESWT were different: concerning delayed unions the purpose to avoid a non-union and in those cases the purpose to avoid implant-failure resp. repeated surgical-interventions. Our main purpose was to prove, if ESWT may be as successful as surgery. Next purpose was to evaluate the own therapy-protocols for different anatomical localisations and indications to determine the best practice for shockwave treatment.

METHODS & MATERIALS

In a cohort design a total number of at last 381 different bone fractures (n=326) and stiffed joints (n=55) with persistent impaired healing after three months (139 delayed fracture and 29 delayed arthrodesis-unions) or after six months (187 fracture-non- and 26 arthrodesis-non-unions) were included in this pilot study after exclusion of 72 cases (62 cases without sufficient follow up and 10 cases as drop outs). All treatments were performed in a ten-year-period (2001 – 2010) by the author of this study. The evaluation was retrospective: most results were obtained in 2011.

eswt study 2011 – methods & materials (1)

	all pat.	follow up	drop out	studygroup
delayed fracture-union	160	142	3	139
non-fracture-union	233	192	5	187
nr.	393	334	8	326
delayed arthrodesis-union	32	30	1	29
nonarthrodesis-union	28	27	1	26
nr.	60	57	2	55
total nr.	453	391	10	381

107 cases belonged to women and 284 to men (drop outs included) — some patients had several localisations. 232/381 cases were complications after formerly occupational accidents. The mean interval between last surgery resp. immobilisation after fracture or osteotomy and begin of ESWT was 4.1 (range 3–5) months in the delayed union-and 10.9 (range 6–47*) months in the non-union-group resp. 3,9 (3–5) and 11,8 (6–43) in these groups after arthrodesis. Distinct patterns of prior treatment in both groups were evident as conservative treated (n=55) or surgical treated (n=327); of course, all arthrodesis-cases had surgery. Main criterias for shockwave therapy were full gap-or joint-stability due to osteosynthesis resp. immobilization and patient’s compliance for distinct follow ups after ESWT.

eswt study 2011 – methods & materials (2)

	study-group	pat. with surgery before	months since surgery / trauma	occupationalaccidents
delayed fracture-union	139	116	4.1 (3-5)	94
non-fracture-union	187	156	10.9 (6-47*)	101
nr.	326	272		195
delayed arthrodesis-union	29	29	3.9 (3-5)	20
nonarthrodesis-union	26	26	11.8 (6-43)	17
nr.	55	55		37
total nr.	381	327		232

For fractures a total number of 2.4 ESWT-sessions (range 1–6) of middle-to high energetic focused shockwaves (mean 6984) and for arthrodeses a total number of 2.4 ESWT-sessions (range 1–3) of middle-to high energetic focused shockwaves (mean 6740) were applied with two different shockwave devices:

Modulith SLK with an optoelectronic navigation tool (n=268) or Duolith SD1 without this computer-assisted navigation (n=89) or both (n=24) – all devices from STORZMEDICAL™ / Switzerland.

eswt study 2011 – methods & materials (3)

	studygroup	device: STORZ Modulith SLK	device: STORZ Duolith SD1	both devices	shockwave sessions	nr. of shockwaves
delayed fracture-union	139				2.4	6614
non-fracture-union	187				2.4	7260
nr.	326					6984
delayed arthrodesis-union	29				2.3	6621
nonarthrodesis-union	26				2.5	6874
nr.	55					6740
total nr.	381	268	89	24		
%		70.3	23.4	6.3		

According to the subdivision in delayed or non-unions each treatment in delayed union-cases was started later than three and each in non-union-cases later than six months following last surgical resp. non-invasive way to stabilize the gap or joint. In all cases it was a specialist for orthopaedic surgery who diagnosed the kind of healing-disturbance and stayed involved in follow up after ESWT. In all cases these physicians who were responsible for follow up as well as the patients received written medical reports and therapy protocols. We had a continues overview of some cases since beginning of our ESWT activities (databank) to get sufficient informations to improve the own running ESWT-practice. In May 2011 we started one single follow up-procedure: by questionnaires (IBH-and IAH-scores, see below), X-ray-evaluations, patient’s or doctor’s informations. We were only interested in hard facts like total or sufficient bony / joint consolidation after five months at the latest; weaker criterias like “improvements”, “better range of motion”, “lower pain level” or “obviously consolidated gap” were considered as unhealed cases.

Level of evidence: III (Cohort Study)

RESULTS

Basicly in 239/381 cases (63%) a sufficient bony consolidation was achieved: 52% in females and 65% in males. Our 326 cases of impaired fracture-healing showed better results (65%) than our 55 cases of impaired arthrodesis-healing (47%). We have seen no serious adverse effects nor ESWT-related complica-

* in 181 of 187 documented treatment-protocols

eswt-study 2011 – IBH (Impaired Bone Healing Score)				
	completely true	mostly true	partly true	not true
My former fracture was evaluated by a radiologist, surgeon as healed.	4	2	0	0
Further surgery for bony healing were to be no longer considered necessary.	3	1	0	0
I was -based on the old bone injury -a largely full load capability certified.	2	1	0	0
My concern -based on the old bone injury -by now is well and significantly better.	2	1	0	0
I am now -based on the old bone injury -again good mobility and strength.	2	1	0	0
If I am unable to work yet, this is due to failure to perform those bone healing back on account of which I had received the shock wave therapy.	0	0	1	2
Based on the old injury, everything is as before.	0	0	0	1
In reference to my original bone healing disorder, I feel healed.	2	1	0	0
Score (completely stable: = >8 largely stable: >6)				bätje©

eswt-study 2011 -IAH (Impaired Arthrodesis Healing Score)				
	completely true	mostly true	partly true	not true
My former joint was evaluated by a radiologist, surgeon as healed.	4	2	0	0
Other operations for joint stiffness were to be no longer considered necessary.	3	1	0	0
I have been proven to substantially full loading capacity.	2	1	0	0
My concern -based on the OP -by now is well and significantly better.	2	1	0	0
I am now -of course with the exception of the former joint -again good strength.	2	1	0	0
If I am unable to work yet, this is due to failure to perform those joint stiffness back on account of which I had received the shock wave therapy.	0	0	1	2
Based on the joint problem after arthrodesis everything is as before	0	0	0	1
In reference to my original joint disorder, I feel healed.	2	1	0	0
Score (completely stable: = >8 largely stable: >6)				bätje©

cases of all fracture-non-unions. Following arthrodesis delayed unions showed full stability in only 12/29 (41%) cases compared with 14/26 (54%) cases of all non-unions.

eswt study 2011 -results (1)					
	study-group	healed (all pat.)	%	healed (women)	healed (men)
delayed fracture-union	139	99	71.2	20	79
non-fracture-union	187	114	60.1	26	89
nr.	326	213	65.3	46	168
delayed arthrodesis-union	29	12	41.4	1	11
nonarthrodesis-union	26	14	53.8	9	5
nr.	55	26	47.3	10	16
total nr.	381	239	62.7	56/107	184/284
%				52.3	64.8

All surgical treated fractures (after 1st, 2nd or 3rd procedure) were considered as healed in 52% (171/326). Tibia-fracture-complications were most frequent and showed bony consolidation in 53/90 cases (59%) Related to other anatomical subgroups within all impaired fracture-unions (n=326) we achieved different results from a 93%-healing rate in scaphoids to only 54% in femurs.

eswt study 2011 -results (2)									
	studygroup	tibia: healed	femur: healed	metatarsalia: healed	foot bones: healed	clavicle (healed)	upperarm (healed)	naviculare (hand): healed	radius (healed)
delayed fracture-union	139	17/33	15/24	10/11	14/15	2/4	7/10	4/5	11/16
non-fracture-union	187	36/57	26/51	13/15	15/17	3/4	4/8	10/10	4/5
nr.	326	53/90	41/75	23/26	29/32	5/8	11/18	14/15	15/21
%		58.9	53.8	88.5	90.6	62.5	61.7	93.3	71.4

Talocrural arthrodesis in different stages of impaired osseous healing were most frequent and showed bony consolidation in 8/16 cases (50%). Related to other anatomical subgroups within all impaired arthrodesis-unions (n=55) we also achieved different results from a 79%-healing rate in tarsometatarsal arthrodeses to only 23% after stiffness of talocalcaneonavicular joints.

tions. Following fractures delayed unions were healed in 99/139 (71%) cases compared with 114/187 (60%)

eswt study 2011 -results (3)

	studygroup	talocrural joint: healed	talocalcaneonav. joint: healed	tarsus (metatarsal) joint: healed	(Carpo) metacarpal joint:healed
delayed arthrodesis-union	29	3/7	3/9	0/3	4/6
nonarthrodesis-union	26	5/9	0/4	11/11	0/0
nr.	55	8/16	3/13	11/14	4/6
%		50.0	23.1	78.6	66.7

ESWT-specific results:

When the hospital-device STORZ Modulith SLK (almost used for long bones) was used, 62% (166/268) were considered as healed compared with 71% (63/89) of those cases, were the doctor's office-device STORZ Duolith SD1 (almost for smaller bones and joints in hands and feet) was used; if both devices were used for treatment (almost in cases of metatarsal-fractures or ankle-arthrodesis) 67% (16/24) showed bony consolidation.

eswt study 2011 -results (4)

	studygroup	healed with STORZ Modulith SLK	healed with STORZ Duolith SD1	healed with both devices
total nr.	381	166/268	63/89	16/24
%		61.9	70.8	66.7

Fracture-delayed unions, -non-unions and arthrodesis-delayed unions showed highest percentages of bone-healing after three (and more) sessions (32%) compared with 28% after two and 12% after one single ESWT-session. In our smaller group of arthrodesis-non-unions two ESWT-sessions were more successful (31%) than three (19%) or only one (4%) treatment.

eswt study 2011 -results (5)

	studygroup	ESWT-sessions (mean nr.)	healed after 1 session	healed after 2 sessions	healed after > =3 sessions
delayed fracture-union	139	2.4	16	39	44
non-fracture-union	187	2.4	17	41	56
nr.	326		33	80	100
delayed arthrodesis-union	29	2.3	2	4	6
nonarthrodesis-union	26	2.5	1	8	5
nr.	55		3	12	11
total nr.	381		36/23 9	92/23 9	111/23 9

Independent of the stage of impaired healing after fractures or arthrodeses those treatments with less shockwaves were more successful than those with more shockwaves.

eswt study 2011 -results (6)

	studygroup	nr.ofshockwaves (mean)	healed with mean nr. of shockwaves	unhealed with mean nr. of shockwaves
delayed fracture-union	139	6613	6260	7488
non-fracture-union	187	7260	6889	7838
nr.	326			
delayed arthrodesis-union	29	6620	5804	7198
nonarthrodesis-union	26	6873	5404	8588
nr.	55			
total nr.	381			

More benefit for arthrodesis-non-unions could be watched in cases with shorter intervals between surgery and begin of shockwave therapy (mean 7,6 months in healed vs. mean 17 months in unhealed joints. In cases after fractures this difference couldn't confirmed.

eswt study 2011 -results (7)

	studygroup	months since surgery / trauma	healed after mean months since surgery	unhealed after mean months since surgery
delayed fracture-union	139	4.1 (3-5)	4	4
non-fracture-union	187	10.9 (6-47)	11	10
nr.	326			
delayed arthrodesis-union	29	3.9 (3-5)	4	4
nonarthrodesis-union	26	11.8 (6-43)	7.6	17
nr.	55			
total nr.	381			

CONCLUSION

Is ESWT as successful as the classic technique, the surgical intervention in cases of delayed or non-unions after fractures or arthrodeses? And what is the best practice? Unique datas about success rates after

surgery in earlier or later stages of impaired bone healing concerning different bone- or joint-localisations are not existing as we think to know. According to the most optimistic comments in literature (97% healing rate) the ESWT isn't a serious alternative. According to our personal overview with the fact that many cases will have repeated surgery without a positive outcome we recommend the ESWT as one other hopeful option. With our ESWT-experience -second purpose -we are optimistic to offer good alternatives in selected cases because of the high acceptance in patients, the unserious adverse effects of the procedure and the low risks (no complication seen in all treatments). Secondly, our study showed us where we could distinguish between better and poorer prognosis for good results: better in smaller bones and joints, in foot- and hand-bones, in delayed fracture-unions and arthrodesis-non-unions, in patients with shorter intervals after fracture or arthrodesis (and obviously in non-smokers – not evaluated here). And, important, our recommendation for orthopaedic surgeons to initiate the ESWT in the delayed-union-stage after fractures and not to wait for the non-union-stage.

DISCUSSION

The treatment of impaired bony healing after surgical or conservative treated bone fractures or in problem-cases of arthrodeses with focused and high-energetic (energy flux density $> 0,30 \text{ mJ/mm}^2$) shockwaves is quite good established since 1999. The purpose is to offer a good alternative to the usual procedure of consecutive surgical interventions in cases of pseudarthroses and re-pseudarthroses which is the golden standard in industrial nations. Shockwave-centers in Austria, Colombia, Italy and Taiwan published encouraging results of ESWT in those indications with success-rates of approximately 80%. Since the knowledge about comparable success-rates after classic surgery is poor, it seems that this percentage of healed cases is encouraging and should be copied by others. The scientific shockwave –societies like the ISMST and the DIGEST enables their members the sharing of experiences and study-results since more than ten years and improves the comparability of the use of different shockwave-devices. Here some standards are important: possibility to apply high-energetic and focused shockwaves which are able to send this focus to the targeted bone localisations in depths up to 15 cm underneath the skin surface, if possible (or necessary) with computer-assisted target-navigation-tools. All high-energetic ESWT-sessions have to be performed by specialized, surgical-skilled medical doctors with certification and good skills for this treatment. Some patients need special advices

for defined post-treatment-periods like temporary immobilisation. Smaller bones or joints need two to three, bigger ones up to five months for complete healing – like after surgery. Our overall success rate is poorer than those results received in centers in Austria or Italy. Comparisons of therapy protocols and cohorts are necessary to evaluate the own results. But some subgroups of patients certainly realized a very good benefit of our ESWT. So we recommend that ESWT is a good alternative but not yet the next golden standard for the treatment of every non-union but for some selected cases of course. Our spectrum of treated fracture- or arthrodesis-complications is too large in comparison to the quantity of treated cases to get sufficient prior datas about ideal inclusion criterias and ideal therapy protocols.

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