

Radial extracorporeal shock-wave therapy in rotator cuff calcific tendinosis

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Summary

The objective of the study is to evaluate the effectiveness of Radial Extracorporeal Shock-wave Therapy (RESWT) compared with High Power LASER Therapy (HPLT) for the treatment of patients with Rotator Cuff Calcific Tendinosis (RCCT). RCCT is widely diffused, it is painful and invalidating. It is an important public health problem with social and economic implications. The most common therapeutic approach is a physiotherapeutic one. Both HPLT and RESWT give positive results. There is a debate on which is to be preferred. Therefore there is need to obtain scientific evidence to support either case.

An observational study was carried out in the period between October 2008 and September 2009 in our outpatient clinic with 62 patients, divided into 3 groups: group A 36 patients treated only with RESWT, group B 26 patients treated only with HPLT and group C 16 patients with only short term improvement with HPLT retreated with RESWT. Patients were evaluated with Constant-Murley scale before and after treatment (immediately, 1 month and 3 months) for mean constant score, pain and range of movement. Data were examined statistically with SPSS. Criteria for inclusion and exclusion were defined.

Patients treated with HPLT have shown good clinical results but have returned to original syndrome 1 month after treatment. RESWT has given improvement after treatment extended in time (3 months) in terms of pain and recover of functionality with a limited number of applications.

The evidence collected indicates that RESWT is the method of choice.

KEY WORDS: Radial Shockwaves, Shoulder Calcific Tendinosis.

Introduction

The rehabilitation aspect of shoulder calcific tendinopathy (SCT) is of considerable interest because of difficulties in preventive and therapeutic measures and also because of its high incidence in the general population (1). The etiology and pathogenesis of calcific tendinopathy is subject to controversy. In any case calcifications occur when, following local trophic disorders or general metabolic alterations, calcium salts precipitate in the tendinous tissue without production of a tissue morphologically and structurally comparable to the bone tissue (1).

The most common therapeutic approach to SCT foresees a pharmacological and physical therapy treatment (2-4). Keeping in mind the frequent collateral effects and the failures of systemic pharmacotherapy, physical therapy treatment represents an important therapeutic option (5).

The Radial Extracorporeal Shock-wave Therapy (RESWT) is the last innovative method for the treatment of calcific tendinopathy (6-8). This treatment is an important break-through in rehabilitation medicine because of the limited energy used, the simplicity of use (it is not necessary to sedate the patient and/or to monitor with radiographic or ecographic devices) but particularly for the excellent therapeutic results. As regards physical therapy instruments there are studies, although not definitely conclusive, that have demonstrated the effectiveness of high power LASER therapy (HPLT) a new method of application of LASER with higher penetration capacity in tissues compared with traditional Low Level LASER Therapy (LLLT) (9).

The purpose of the present study is to evaluate the therapeutic effectiveness of RESWT compared with HPLT in patients with rotator cuff calcific tendinosis (RCCT). Calcific tendinopathy occurs frequently in the shoulder with incidence between 2.7% and 7.5%, particularly in female with average age between 40 and 50 (10). Calcific tendinosis, sometimes called chronic tendinitis, tendinosis, chronic tendinopathy or chronic tendon injury, is damage to a tendon at a cellular level. It is thought to be caused by micro tears in the connective tissue in and around the tendon, leading to an increase in tendon repair cells. This may lead to reduced tensile strength, thus increasing the chance of tendon rupture (11).

The aetiology of calcific tendinosis is still under debate (1). It seems that tissue hypoxia and localized mechanical compressions intervene as casual factors. The site of most common origin is the supraspinatus tendon localized 0,5 to 1,5 cm from the insertion on the greater tubercle. The calcification is composed of calcium phosphate salts such as hydroxyapatite and calcium pyrophosphate. Basically 2 different mechanisms have been proposed leading to the formation of calcium deposits (11). In the first the degeneration of tendinous fibers precedes the formation of calcifications (12,13). This theory has been accepted for a long time by various authors (14,15). The main cause of degeneration of tendinous fibers is supposed to be aging. According to Brewer (16), in aging in the tendon a reduction of vascularization occurs associated with collagen modifications which constitutes the framework of the tendon (17,18). The authors supporting the second mechanism, on the other hand believe that calcifications are formed in vital tendinous tissue through an active cell mediated process (19,20).

From the clinical point of view patients with calcified tendinopathy

may be without symptoms or with a chronic pain and functional limitation (21, 22). Pain is related to the start of a chronic inflammatory process in tissues near mineral deposits following the accumulation produced by calcification which determines continual mechanical irritations during movements (23, 24). According to Uthoff³ the patient is without symptoms or presents chronic signs during the phase of formation of calcified deposits whereas he presents acute signs during the absorption phase. Pain is typically localized at the shoulder tip with a possible irradiation towards the deltoid distal insertion. Frequently the pain syndrome reappears during the night interfering with sleep. Pain is stimulated by palpation at the level of the greater tubercle of the humerus by active movements, passive and counter resistance in abduction, intra-extra rotation, and in movements of abduction and rotation together. The functional limitation is more evident in abduction and rotation associated movements. Instrumental diagnosis is relatively simple and is based traditionally on radiographic and ecographic examination of the shoulder.

Great importance is given to conservative therapy, particularly to the application of physical means in various forms of kinesiotherapy exercises to avoid rigidity of the shoulder. Purpose of the therapy is to reduce pain, diminish calcium deposits thus improving joint functionality.

RESWT (26, 27) is generated through a special pistol-like hand-piece, the barrel of which is closed at the extremity by a metallic stopper against which a steel bullet is thrown through a 4 to 5 bar pressure compressed air. From collision a shock wave is produced which through the metallic stopper expands radially through the skin and in the first underlying tissue layer. Therefore radial short waves are generally used in very superficial pathologies. Furthermore radial instruments require a greater number of shockwaves and of sessions. The shape of the radio shock waves resembles that of shock waves but without a negative phase and with a softer pulse spike.

Materials and Methods

Between October 2008 and September 2009 patients with shoulder pain referring to the outpatient clinic of the "Agenzia di Recupero e Riabilitazione, CTO, AOU Careggi" (Rehabilitation Department of the Trauma Center, University Hospital of Careggi, Florence) have been enrolled if diagnosed with Rotator Cuff Calcific Tendinosis (RCCT).

Criteria of inclusion in this study were: failure of conservative therapies, presence of pain lasting for at least 4 months, a radiographic or ecographic picture of calcification of rotator cuffs and the adult age of the patient. Excluded from the study were patients with signs of rupture of rotator cuff with previous shoulder surgery, presence of poliarticular inflammatory pathologies, neurological alterations, tumors in the field of application, infections, coagulopathies or anticoagulant therapy, thrombosis, polyneuropathies in case of diabetes, cortisone therapy up to 6 weeks before the first session, pregnancy and pacemaker carriers. The evaluation of the presence of inclusion criteria and the absence of exclusion criteria was carried out during the clinical examination by medical personnel specialized in Physical and Rehabilitation Medicine.

The machine used for the treatment with RESWT was the MASTER PLUS MP2000 of STORZ MEDICAL. The treatment protocol utilized was a weekly session for a total of 6 weeks. For every session 2000 impulses at 3 bar (0.12mJ/mm²) at the frequency of 10 Hertz were administered.

No patient received local anesthesia before treatment. The following side effects were noted during treatment: swelling, redness, petechia and small haematomata. These side effects usually disappeared 3 or 4 days after the session.

During the treatment the patient was in a sitting position on the

examination table. Having localized the painful point some gel is placed on it. Then the ERST is applied through a hand-piece which is maneuvered on the painful point in a circular way. 15 mm Shockmaster Applicator was utilized where the effective depth of penetration is 0 – 40 mm.

The HPLT protocol consisted of 5 sessions: 3 sessions a week on alternate days. The apparatus used is a high power Neodymium Yag (Nd:Yag). Treatment takes place with the patient sitting on the bed. The program utilized is the antalgic one. The initial phase of the treatment is carried out at rapid scanning; the intermediate phase is carried out with the method of erogation by points, identifying the antalgic points; the final phase is carried out at slow scanning. The modulation of each session is of almost 20 minutes.

Our patients have been evaluated with the Constant-Murley scale (CMs). All the patients have been evaluated before the treatment (T0), immediately after the last session (T1), then after 1 month from the last session (T2) and then the last evaluation (T3) three months after the last session. Data have been examined statistically with SPSS.

Results

Out of 62 patients selected 36 have been treated only with RESWT (group A) and 26 patients have been treated with HPLT (group B). From this group 16 patients who had not shown improvement with HPLT have been retreated with RESWT (group C). Demographic data are shown in Table 1.

In group A, treated with RESWT, 14 were males and 22 females. Average age was 58 with a minimum of 35 and a maximum of 81 years. In group B, treated with HPLT 9 were males and 17 females. The average age was 54 with a minimum of 34 and a maximum of 74 years. On the other hand in group C, after HPLT retreated with RESWT, 5 were males and 11 females. The average age was 53 years with a minimum of 34 and a maximum of 74 years. All the patients had pain since 4 to 6 months at the time of treatment.

In group A the mean Constant score for all patients before treatment (T0) was 65 points (extremes 8 – 90). The score at the end of the treatment (T1) after 6 sessions was 83 points (extremes 53 – 100). After a month from the end of treatment (T2) the score was 88 points (extremes 45 – 100). And after 3 months after the end of the treatment (T3) it had gone up to 91 points (extremes 56 – 100).

Pain (possible range 0 – 15) moved from a mean score of 5 points (extremes 0 – 10) in T0 to 10 points (extremes 0 – 15) in T1. The value in T2 was 10 points (extremes 5 – 15) and in T3 10 points (extremes 0 – 15) 3 months after the end of the treatment.

Range of motion (ROM) (possible range 0 – 40°) made it possible to underline the following variations. In T0 it was 28 points (extremes 6 to 40) then in T1 at the end of the treatment it was 34 points (extremes 18 – 40). After a month from the end of treatment in T2 it was 36 points (extremes 16 – 40). Finally there was a further increment in T3 at 37 points (extremes 28-40). Data are shown in Table 2 and Graph 1.

In group B the mean constant score for all patients before treatment (T0) was 69 points (extremes 23 – 88). The score at the end of the treatment (T1) after 5 sessions was 79 points (extremes 4 – 95). After a month from the end of treatment (T2) the score was 81 points (extremes 20 – 95). Pain moved from a mean score of 4 points (extremes 0 – 10) in T0 to 8 points (extremes 0 – 10) in T1. The value in T2 was 8 points (extremes 0 – 10). ROM made it possible to underline the following variations. In T0 it was 30 points (extremes 8 to 40) then in T1 at the end of the treatment it was 33 points (extremes 0 – 40). After a month from the end of treatment in T2 it was 33 points (extremes 10 – 40). Data are shown in Table 3 and Graph 2. Graph 3 compares percentage pain sco-

Table 1 - Demographic data.

	Number	M/F	Shoulder R / L	Mean	Stdev	Age Min	Max
HPLT up to T2	26	5/11	7/9	54	10	34	74
HPLT up to T3	10	4/6	9/1	56	9	44	70
Only RESWT	36	14/22	23/13	59	15	35	81
RESWT after HILT	16	5/11	7/9	53	11	34	74
Total patients treated	62	23/39	39/23	57	13	34	81

*Stdev: Standard Deviation, Min: minimum value, Max: maximum value

Table 2 - Constant score, pain and ROM of Group A (36 patients) treated with RESWT at T0, T1, T2, and T3.

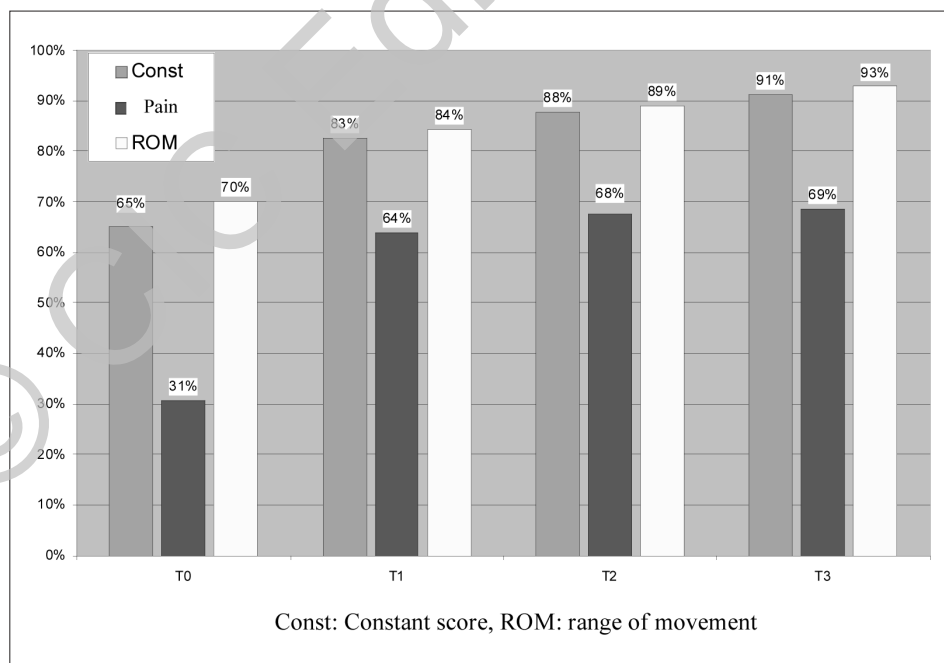
	Constant Score			
	T0	T1	T2	T3
Mean	65	83	88	91
Stdev	18	13	10	8
Min	8	53	45	56
Max	90	100	100	100
	Pain			
	T0	T1	T2	T3
Mean	5	10	10	10
Stdev	3	3	3	3
Min	0	0	5	0
Max	10	15	15	15
	ROM			
	T0	T1	T2	T3
Mean	28	34	36	37
Stdev	8	7	5	3
Min	6	18	16	28
Max	40	40	40	40

Stdev: Standard Deviation, Min: minimum value, Max: maximum value, ROM: Range of Movement

res between the 2 groups (26 patients with HPLT and 36 patients with RESWT) of treated patients from T0 to T2. Data are shown in Table 3 and Graph 2.

In group C the mean constant score for all patients before treatment (T0) was 72 points (extremes 20 – 91). The score at the end of the treatment (T1) after 6 sessions was 83 points (extremes 34 – 100). After a month from the end of treatment (T2) the score was 89 points (extremes 44 – 100). And after 3 months after the end of the treatment (T3) it had gone up to 92 points (extremes 42 – 100). Pain moved from a mean score of 6 points (extremes 0 – 10) in T0 to 9 points (extremes 0 – 15) in T1. The value in T2 was 10 points (extremes 5 – 15) and in T3 11 points (extremes 5 – 15) 3 months after the end of the treatment. ROM showed respectively in T0 was 31 points (extremes 10 to 38), in T1 at the end of the treatment 35 points (extremes 14 – 40), after a month from the end of treatment in T2 it was 37 points (extremes 20 – 40) and finally there was a further increment in T3 at 38 points (extremes 20-40). Data are shown in Table 4 and in Graph 3. In Graph 4 is shown the percentage of Constant score, pain and ROM of Group C (10 patients) treated with HPLT at T0, T1 and T2 and after with RESWT at T0, T1, T2, and T3.

From the radiological and ecographic view point it has been possible to observe the disappearance of calcification in 16 shoulders (31%) and the decrease of calcification in 10 shoulders (19%). Calcification was always visible even after RESWT in 26 shoulders (50%).



Graph 1 - Percentage of Constant score, pain and ROM of Group A (36 patients) treated with RESWT at T0, T1, T2, and T3.

Table 3 - Constant score, pain and ROM of Group B (26 patients) treated with RESWT at T0, T1 and T2.

Constant Score			
	T0	T1	T2
Mean	69	79	81
Stdev	17	19	17
Min	23	4	20
Max	88	95	95

Pain			
	T0	T1	T2
Mean	4	8	8
Stdev	3	3	3
Min	0	0	0
Max	10	10	10

ROM			
	T0	T1	T2
Mean	30	33	33
Stdev	7	9	7
Min	8	0	10
Max	40	40	40

Stdev: Standard Deviation, Min: minimum value, Max: maximum value, ROM: Range of Movement

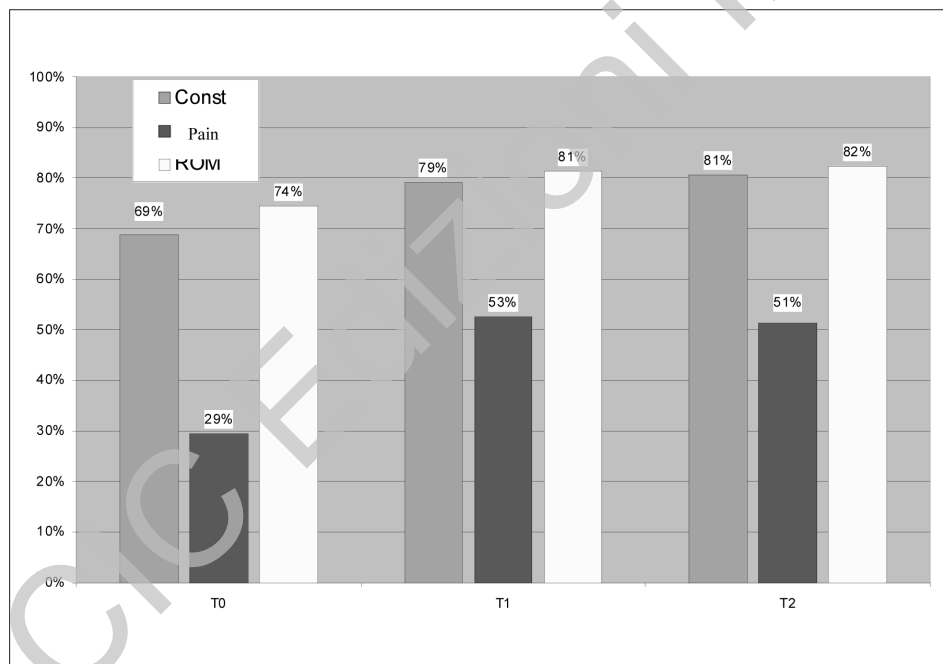
Table 4 - Constant score, pain and ROM of Group C (10 patients) treated with RESWT at T0, T1, T2, and T3 (after treatment with HPLT).

Constant				
	T0	T1	T2	T3
Mean	72	83	89	92
Stdev	21	19	16	14
Min	20	34	44	42
Max	91	100	100	100

Pain				
	T0	T1	T2	T3
Mean	6	9	10	11
Stdev	3	3	3	3
Min	0	0	5	5
Max	10	15	15	15

ROM				
	T0	T1	T2	T3
Mean	31	35	37	38
Stdev	8	7	6	5
Min	10	14	20	20
Max	38	40	40	40

Stdev: Standard Deviation, Min: minimum value, Max: maximum value, ROM: Range of Movement



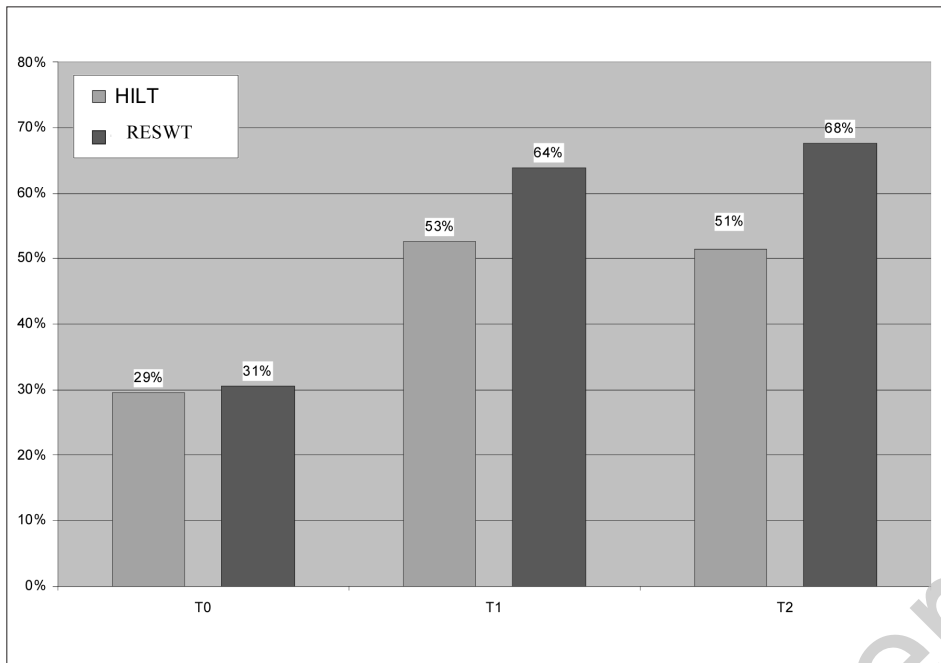
Graph 2 - Percentage of Constant score, pain and ROM of Group B (26 patients) treated with HPLT at T0, T1 and T2

Conclusions

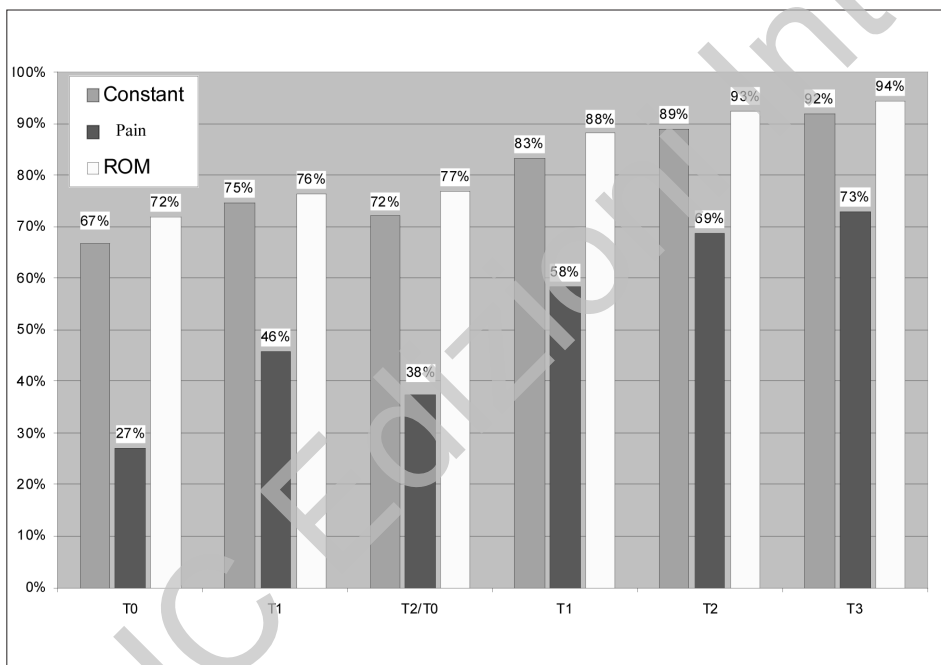
From the analysis of the results it is evident that patients treated with HPLT have shown good clinical results after the treatment but had receded to the initial clinical symptoms 1 month after the end of the treatment. For this reason 16 patients who had shown no improvement with HPLT were retreated with RESWT but this did not interfere with the conclusions drawn. Ethical reasons that brought to treat again are fully justified. In fact the outpatient clinic to which patients report has the main function to restore their

health as much as possible according to the patient's expectations.

Patients treated with RESWT have shown an improvement at the end of the treatment as well as 3 months after the end therefore with a better result extended in time. The results suggest that the use of RESWT in the treatment of RCCT offers remarkable advantages compared with HPLT. It is important to underline that such a method obtains satisfactory results from a clinical point of view and a quick return of joint functionality with a limited number of applications.



Graph 3 - Percentage of pain after treatment with HPLT and RESWT at T0, T1 and T2 (HPLT 26 Patients, RESWT 36 patients)



Graph 4 - Percentage of Constant score, pain and ROM of Group C (10 patients) treated with HPLT at T0, T1 and T2 and after with RESWT at T0, T1, T2, and T3.

In spite of the availability of user friendly instruments not excessively costly, RESWT are not widely used in such a pathology. Probably this is due to the limited number of studies on this subject, but it is hoped that other workers will be able to confirm the data we have obtained. However the significance of this study is an initial attempt to collect relevant evidence as soon as possible. It is recognized that the number of patients involved in the study is rather limited. Therefore it is recommended that further studies be carried out as regards the number of patients in order to obtain greater statistical significance. Another area of study is that of cost benefit. The demonstration that such a diffused pathology may be treated successfully with reduction in costs and time will give the method additional interest for wider application.

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