

ORIGINAL ARTICLE

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Extracorporeal shock-wave therapy for chronic lateral tennis elbow – prediction of outcome by imaging

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Abstract Today the clinical use of extracorporeal shock-wave application (ESWA) for the treatment of lateral tennis elbow is hampered by the lack of results from randomized controlled trials and of predictive parameters of clinical outcome. The present prospective study aimed to provide the latter by means of magnetic resonance imaging (MRI). Twenty-three female and 19 male patients with unilateral chronic tennis elbow of the dominant site were clinically examined before and after repetitive low-energy ESWA. MRI was performed before ESWA to evaluate signal intensity changes or contrast enhancement of the common extensor tendon and the lateral epicondyle. After ESWA (mean follow-up period 18.6 months for all patients), clinical evaluation showed a significantly better mean clinical performance after ESWA than before treatment. Interestingly, male patients showed a significantly better mean clinical performance after ESWA than female patients, and male and female patients differed significantly in the signal intensity of the common extension tendon cross-section and tendon thickening on MRI. For female patients, MRI scans could be applied for predicting a positive clinical outcome of ESWA. This study reports the first indication of predictability of positive clinical outcome of the treatment of chronic lateral tennis elbow by ESWA using imaging prior to treatment. This may serve as an important step towards overcoming the thera-

peutic nihilism with respect to the non-operative management of this condition recently in the literature.

Keywords Lateral tennis elbow · Extracorporeal shock-wave application · Magnetic resonance imaging

Introduction

Lateral tennis elbow is characterized by pain at the insertion site of the common extensor muscles at the lateral humeral epicondyle (see [2, 3] for review). The pathogenesis of lateral tennis elbow is unknown. Mechanical and/or metabolic overload of the extensor muscles leading to mucoid degeneration of the extensor origin and subsequent failure of the tendon are discussed [2, 3]. Numerous conservative modalities have been described for the treatment of lateral tennis elbow. Most are lacking in sound scientific rationale [3]. There is evidence in favour of beneficial effects of extracorporeal shock wave application (ESWA) [5, 9, 10]. However, the clinical use of ESWA for the treatment of lateral tennis elbow is hampered by the lack of results from randomized controlled trials (see [2] for details) and of predictive parameters of the clinical outcome. The present study aimed to provide the latter by means of magnetic resonance imaging (MRI). This is based on the known ability of MRI to demonstrate various changes of the common extensor tendon in patients with lateral tennis elbow [12]. Patients with chronic lateral tennis elbow (henceforth abbreviated as CLTE) were subjected to MRI before ESWA, and the clinical outcome was evaluated by comparing data of clinical examinations before ESWA and after a mean follow-up period of approximately 19 months.

Patients and methods

During a 4-year-period (1996–1999) 23 female and 19 male patients with unilateral CLTE of the dominant side were investigated. The age of the female patients was 52.0 ± 8.9 years (mean \pm SD, range 37–67 years) and of the male patients 51.6 ± 10.9 years

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(range 36–71 years). LTE was diagnosed by the following clinical signs: local tenderness over the origin of the extensor musculotendinous structures at the radial epicondyle, especially the tendinous origins of extensor carpi radialis brevis and extensor digitorum communis; pain in the lateral epicondyle during resisted wrist dorsiflexion [13] and during resisted extension of the third finger [8]; and pain of the lateral epicondyle while lifting a chair with one hand in a position of forearm pronation and wrist palmar flexion [4] (see also [3]). The inclusion criteria were chronic course of LTE of more than 6 months' duration and unsuccessful use of conservative therapies such as injections of local anaesthetics and corticoids, ultrasound treatment, bracing or antiphlogistic medication over a 6-month period. In line with [3], the exclusion criteria were radial tunnel syndrome, radiologically proven degenerative changes of the radiohumeral joint, elbow instability, local bursitis, rheumatoid arthritis, gout, pain and dysfunction of the ipsilateral shoulder joint, neurological abnormalities, previous trauma, surgery or previous ESWA to the affected lateral elbow, pregnancy, immature skeleton and prolonged blood coagulation. Exclusion criteria with respect to MRI and ESWA were cardiac pacemakers, metal implants (e.g. prosthesis) and injections into the investigated elbow within 12 weeks before ESWA. Inclusion and exclusion criteria were evaluated by anamnesis and clinical and radiological examination. The latter involved anteroposterior (AP) and lateral radiography of the elbow.

MRI before ESWA

According to accessibility, patients were assigned to be investigated by MRI either with a 1.0-T high-field system (Magnetom Impact, Siemens, Germany; 6 women and 6 men) or with a low-field system (Magnetom Open, Siemens or Artoscan, Esaote, Italy; 17 women and 13 men) [12]. For all patients a T1-weighted spin-echo sequence (T1) and a T2-weighted turbo spin-echo sequence (T2) were acquired of the treated elbow in sagittal and coronal slice orientations. Furthermore, except for 5 patients who refused contrast medium application, a contrast-enhanced, T1-weighted, spin-echo sequence (T1-CM) was acquired of the treated elbow in sagittal and coronal slice orientations after intravenous contrast medium injection (0.1 mmol/kg gadolinium diethylene triamine penta-acetic acid, Gd-DTPA; Magnevist, Schering, Berlin, Germany).

MRI investigations were evaluated by two radiologists and one orthopaedic surgeon, all experienced in musculoskeletal imaging. The MRI scans were evaluated for the presence or absence of signal intensity changes or contrast enhancement of the common extensor tendon. Signal intensity changes and contrast enhancement of the common extensor tendon were classified as shown in Table 1 [12].

Table 1 Criteria for magnetic resonance imaging (MRI) classification of signal intensity changes and contrast enhancement of the common extensor tendon according to [12]

Grade	Criteria
0	Dark common extensor tendon, no signal intensity changes, no contrast enhancement
1	Focal area of increased signal intensity (i.e. contrast enhancement) without thickening of common extensor tendon
2	Area of increased signal intensity (i.e. contrast enhancement) involving less than 50% of common extensor tendon cross-section with tendon thickening
3	Area of increased signal intensity (i.e. contrast enhancement) involving more than 50% of common extensor tendon cross-section with tendon thickening

ESWA

Treatments were performed using electromagnetic shock-wave devices. According to availability, ESWA was carried out by using a Minilith SL1 device (Storz Medical, Kreuzlingen, Switzerland) during the 1st year, a Compact S device (Dornier MedTech, Wessling, Germany) during the 2nd year and an Epos Ultra device (Dornier) from the 3rd year on. All devices had comparable low-dose energy levels as measured by laser hydrophones [6]. For all treatments, the radial epicondyle was detected with ultrasound (7.5-MHz sector scan) for focussing the shock-wave device to the insertion zone of the common extensor tendons. The shock-wave source was secured to the radial epicondyle by means of a water-filled cushion. Castor oil was used as the coupling medium [7]. All treatments were performed on an outpatient basis with an energy flux density of $0.15 (\pm 0.03)$ mJ/mm². Three or five single sessions were carried out at weekly intervals. ESWA was discontinued after three sessions if a patient was subjectively painfree. Otherwise, two additional sessions were carried out. All sessions of one patient were carried out using the same shock-wave device. Each session comprised the application of 2,000 pulses with a frequency of 2 Hz. No local or regional anaesthesia was given during the application. Before and after each session patients were examined for the presence of short-term procedural complications and side-effects such as skin injury with or without consecutive bleeding, superficial or deep haematoma, and clinical signs of nerve lesions. During the time period of ESWA and the subsequent follow-up, patients were directed to use the treated arm as normally as possible but to avoid painful stress. No other directions, treatments or drugs were recommended.

Clinical examination before and after ESWA

The extent of overall pain of the radial epicondyle was scored with the Visual Analogue Scale [1] (VAS) ranging from 0 (i.e. no pain) to 100 (i.e. maximum pain) before ESWA and after a follow-up period of 18.6 ± 11.4 (range 5–46) months for female patients and of 18.6 ± 8.6 (range 6–36) months for male patients. Furthermore, ESWA performance was evaluated by using the Roles and Maudsley (RM) score after the follow-up period [8]. RM is an established score for categorizing ESWA performance [11] and comprises four categories: grade 1, excellent (i.e. no pain, full movement, full activity); grade 2, good (i.e. occasional discomfort, full movement, full activity); grade 3, acceptable (i.e. some discomfort after prolonged activities); grade 4, poor (i.e. pain limiting activity). Grades 1 and 2 were interpreted as a satisfactory clinical outcome, whereas grades 3 and 4 were interpreted as an unsatisfactory clinical outcome.

Statistical analysis

Statistical analysis was carried out by using the Mann-Whitney U-test (U-test), Wilcoxon matched pairs test (W-test), Spearman's rank correlation (S-correlation), chi-square test (C-test) and Fisher's exact test (F-test). Details are given below. For all tests $P < 0.05$ was considered statistically significant. All calculations were carried out by means of GraphPad Prism version 3.00 for Windows (GraphPad Software, San Diego, Calif., USA).

Results

Clinical investigations

There was no significant difference in mean age between female and male patients (U-test, $P = 0.950$).

Figure 1A shows the frequency distributions of VAS scores before and after ESWA as a function of the pa-

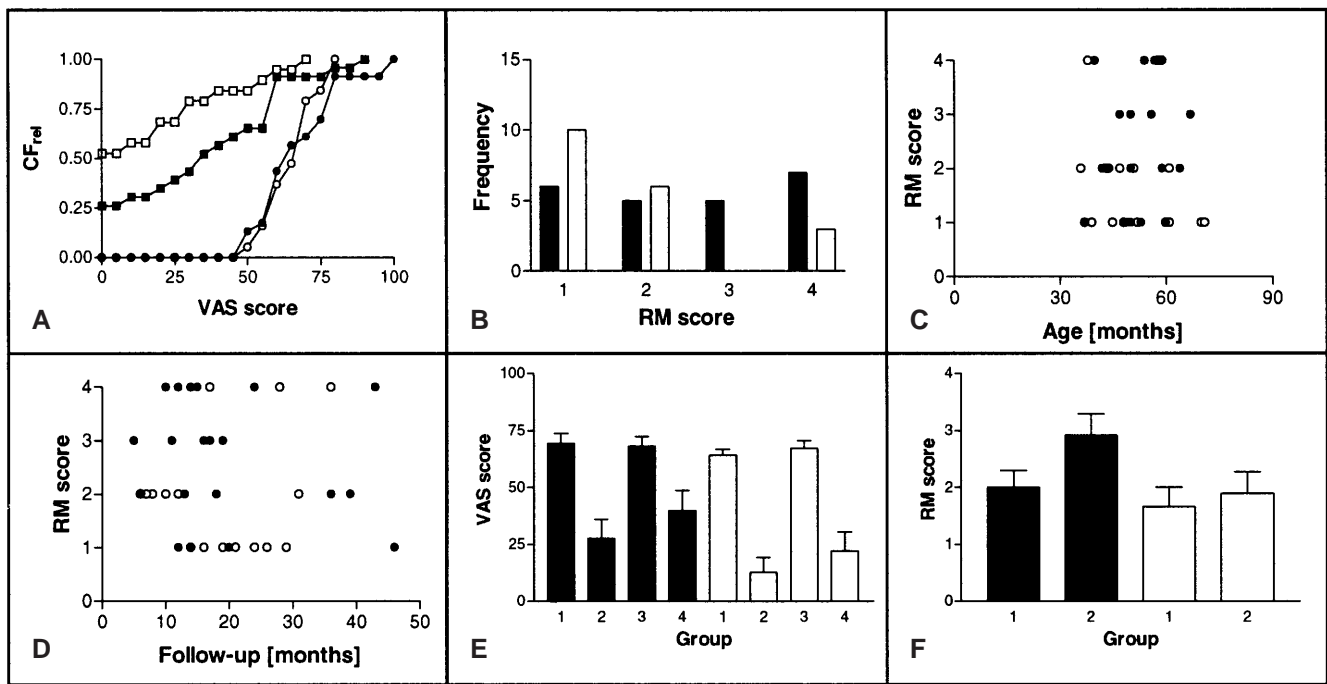


Fig. 1A–F Results of clinical investigations. **A** Cumulative frequencies in relative values (CF_{rel}) of VAS scores before and after extracorporeal shock-wave application (ESWA) as a function of the patients' gender: *solid circles* women before ESWA, *open circles* men before ESWA; *solid squares* women after ESWA, *open squares* men after ESWA. **B** Frequency distributions of Roles and Maudsley (RM) scores as a function of the patients' gender: *solid bars* women, *open bars* men. **C** RM scores as a function of the patients' age: *solid circles* women, *open circles* men. **D** RM scores as a function of the follow-up period: *solid circles* women, *open circles* men. **E** Mean and SD of visual analogue scores (VAS) as a function of the investigated group: *solid bars* women, *open bars* men, 1 and 2 patients receiving ESWA three times either before (1) or after (2) ESWA, 3 and 4 patients receiving ESWA five times either before (3) or after (4) ESWA. **F** Mean and SD of RM scores as a function of the investigated group: *solid bars* women, *open bars* men, 1 patients receiving ESWA three times, 2 patients receiving ESWA five times

tients' gender. Mean VAS scores before ESWA were 68.9 or 66.0 (female or male patients) and 34.1 or 17.6 (female or male patients) after ESWA, respectively. There was no significant difference of VAS scores between female and male patients before ESWA (U-test, $P = 0.686$). However, we found one after ESWA (U-test, $P = 0.040$). Moreover, both female and male patients showed a significant difference when comparing VAS scores before and after ESWA (W-test, $P < 0.001$).

Figure 1B displays the frequency distributions of RM scores as a function of the patients' gender. There was a significant difference of RM scores between female and male patients (U-test, $P = 0.046$).

Figure 1C shows RM scores as a function of the patients' age. Neither for female nor for male patients was a relationship found between RM score and patients' age (S-correlation, women $P = 0.452$, men $P = 0.287$).

Figure 1D displays RM scores as a function of the follow-up period. Neither for female nor for male patients

was a relationship found between RM score and the follow-up period (S-correlation, women $P = 0.500$, men $P = 0.822$). Furthermore, there was no significant difference of mean follow-up period between female and male patients (U-test, $P = 0.613$).

Figure 1E shows VAS scores before and after ESWA as a function of the number of ESWA sessions. Eleven female and 9 male patients received ESWA three times, while 12 female and 10 male patients received ESWA five times. Neither for female nor for male patients was there a significant difference of VAS scores between those who received ESWA three times and those who received ESWA five times either before or after ESWA (U-test: women, before ESWA, $P = 0.711$; after ESWA, $P = 0.294$; men, before ESWA, $P = 0.447$; after ESWA, $P = 0.549$). By contrast, for both female and male patients receiving ESWA either three or five times, a significant difference was found when comparing VAS scores before and after ESWA (W-test: women, three times ESWA, $P = 0.002$; five times ESWA, $P = 0.012$; men, three times ESWA, $P = 0.004$; five times ESWA, $P = 0.004$).

Figure 1F displays RM scores as a function of the number of ESWA sessions. Neither for female nor for male patients was there a significant difference of RM scores between those who received ESWA three times and those who received ESWA five times (U-test: women, $P = 0.101$; men, $P = 0.780$). None of the investigated patients showed any side-effect of ESWA.

MRI investigations

In Figure 2 some representative MRI scans are shown in coronal slice orientation. Figure 2A and B represent a T1 sequence (low-field system) and a T2 sequence (low-field

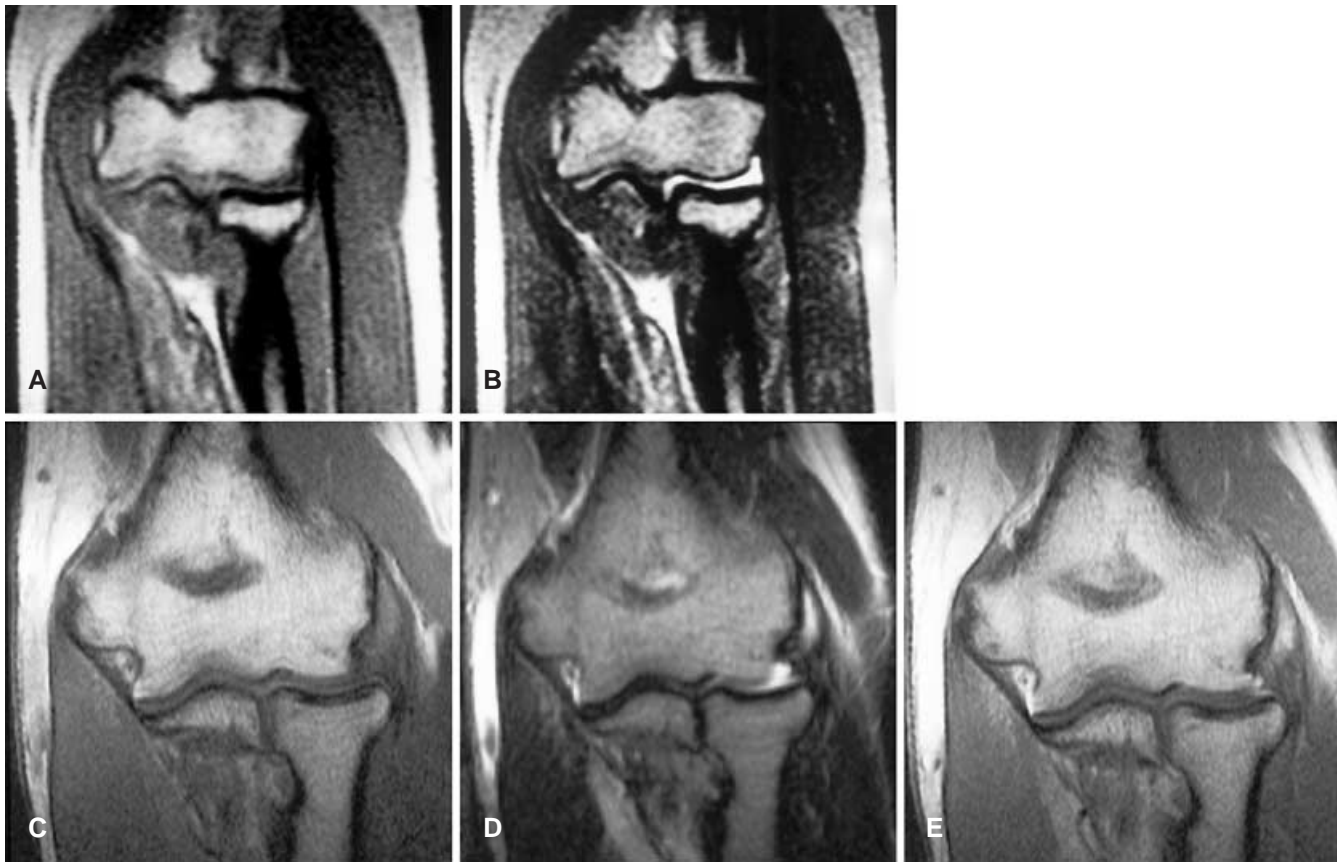


Fig. 2 A–E Representative magnetic resonance imaging (MRI) scans in coronal slice orientation. **A** T1 sequence (low-field system) classified as grade 0. **B** T2 sequence (low-field system) classified as grade 0. **C** T1 sequence (low-field system) classified as grade 3. **D** T2 sequence (low-field system) classified as grade 3. **E** T1-CM sequence (low-field system) classified as grade 3

system) classified as grade 0. Figure 2C and D represent a T1 sequence (low-field system) and a T2 sequence (low-field system) classified as grade 3. Figure 2E represents a T1-CM sequence (low-field system) classified as grade 3.

Figure 3A shows MRI classifications of female patients as a function of the MRI device used and the sequence acquired; Figure 3B displays the corresponding results for male patients. Neither female nor male patients showed any significant differences of MRI classifications between those investigated with the high-field system and those investigated with the low-field systems (women: T1 C-test, $\chi^2 = 1.332$, $P = 0.722$; T2 C-test, $\chi^2 = 1.699$, $P = 0.637$; T1-CM C-test, $\chi^2 = 4.593$, $P = 0.204$; men: T1 (considering only grades 2 and 3) F-test, $P = 1.000$; T2 (considering only grades 1 to 3) C-test, $\chi^2 = 2.149$, $P = 0.322$; T1-CM C-test, $\chi^2 = 3.353$, $P = 0.340$).

Figure 3C shows MRI classifications of female and male patients as a function of the acquired sequence. For T1 and T2 (but not for T1-CM), a significant difference was found between female and male patients (T1 C-test, $\chi^2 = 10.99$, $P = 0.012$; T2 C-test, $\chi^2 = 21.36$, $P < 0.001$; T1-CM C-test, $\chi^2 = 2.230$, $P = 0.526$).

Table 2 displays MRI classifications of female and male patients as a function of the number of ESWA sessions as well as a function of RM scores. For female and male patients, no significant difference was found for T1 nor for T2 or T1-CM between patients who received ESWA three times and patients who received ESWA five times (data in lines 1, 2, 5 and 6 of Table 2; F-test: women, T1 $P = 1.000$, T2 $P = 0.155$, T1-CM $P = 0.617$; men, T2 $P = 0.582$, T1-CM $P = 1.000$; no statistical analysis possible for T1). Furthermore, for female patients and T2 and T1-CM (but not for T1), a significant difference was found between patients with RM score 1 or 2 and patients with RM score 3 or 4 (data in lines 3 and 4 of Table 2; F-test: T1 $P = 0.680$, T2 $P = 0.037$, T1-CM $P = 0.033$). By contrast, for male patients no significant difference was found for T1, T2 or T1-CM between patients with RM score 1 or 2 and patients with RM score 3 or 4 (data in lines 7 and 8 of Table 2; F-test: T2 $P = 0.422$, T1-CM $P = 1.000$; no statistical analysis possible for T1).

In Table 3 female patients were categorized with respect to MRI classifications and RM scores. According to the aforementioned significant difference of T2 and T1-CM classifications between patients with RM score 1 or 2 and patients with RM score 3 or 4, the following predictive values could be calculated. Using T2, the diagnosis 'area of increased signal intensity with tendon thickening of common extensor tendon' (i.e. grade 2 or 3) had a positive predictive value of 0.61 (i.e. 11 patients with MRI grade 2 or 3 of the 18 patients with satisfactory clinical

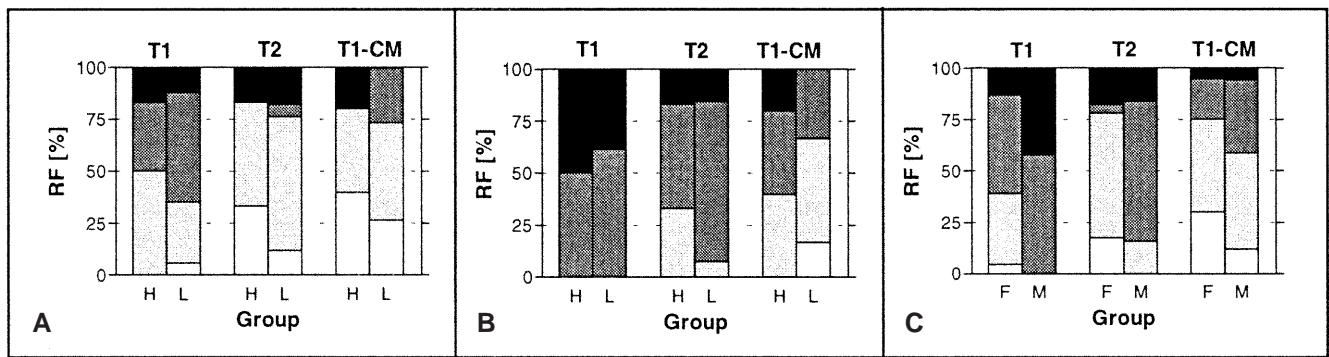


Fig. 3A–C Results of MRI investigations. **A** Relative frequencies (*RF*) of MRI classifications (grades 0 to 3, see Table 1 for details) of female patients as a function of the MRI device used and the acquired sequence. **B** *RF* of MRI classifications of male patients as a function of the MRI device used and the acquired sequence. **C** *RF* of MRI classifications as a function of the patients' gender and the acquired sequence. *T1* T1-weighted spin-echo sequence, *T2* T2-weighted turbo spin-echo sequence, *T1-CM* contrast enhanced, T1-weighted, spin-echo sequence, *H* high-field system, *L* low-field system, *F* female patients, *M* male patients, white bars grade 0, light grey bars grade 1, dark grey bars grade 2, black bars grade 3

outcome), a sensitivity of 1.00 (i.e. 11 patients with satisfactory clinical outcome of the 11 patients with MRI grade 2 or 3) and a specificity of 0.42 (i.e. 5 patients with unsatisfactory clinical outcome of ESWA of the 12 patients with MRI grade 0 or 1). Using T1-CM, the diagnosis 'area of increased signal intensity with tendon thickening of common extensor tendon' had a positive predictive value of 0.67, a sensitivity of 1.00 and a specificity of 0.5.

Discussion

The principal findings of the present study are: (1) after a mean follow-up period of approximately 19 months, 52% of female patients and 84% of male patients with CLTE showed better clinical performance after ESWA than before treatment (i.e. RM score 1 or 2); (2) on average, male patients showed better clinical performance after ESWA than female patients; (3) male and female patients differed in signal intensity of common extension tendon cross-section and tendon thickening in T1 and T2 MRI scans of CLTE; (4) for female patients, T2 and T1-CM MRI scans could be used for predicting a satisfactory clinical outcome of ESWA.

With respect to the clinical outcome the results of the present study are in line with previous reports of CLTE treatment by ESWA with shorter follow-up periods but with comparable shock-wave energy flux density, number

Table 2 MRI classifications of female and male patients as a function of the number of ESWA sessions as well as a function of RM scores. In lines 1, 2, 5 and 6, data are given considering the number of ESWA sessions but not RM scores. In lines 3, 4, 7 and

8, data are given considering RM scores but not the number of ESWA sessions. *T1* T1-weighted spin-echo sequence; *T2* T2-weighted turbo spin-echo sequence; *T1-CM* contrast-enhanced, T1-weighted spin-echo sequence

Variable	Line	1	2	3	4	5	6	7	8
	RM scores	1 to 4		1 or 2	3 or 4	1 to 4		1 or 2	3 or 4
	No. of sessions	3	5	3 or 5		3	5	3 or 5	
	Classification	No. of female patients				No. of male patients			
T1	0 or 1	4	5	4	5	0	0	0	0
	2 or 3	7	7	8	6	9	10	16	3
T2	0 or 1	7	11	7	11	2	1	2	1
	2 or 3	4	1	5	0	7	9	14	2
T1-CM	0 or 1	6	9	5	10	5	5	8	2
	2 or 3	3	2	5	0	4	3	6	1

Table 3 Categorization of female patients with respect to MRI classifications and RM scores

	Grade of T2			Grade of T1-CM		
	0 or 1	2 or 3	Total	0 or 1	2 or 3	Total
RM score 1 or 2	7	11	18	5	10	15
RM score 3 or 4	5	0	5	5	0	5
Total	12	11	23	10	10	20

of pulses and shock-wave frequency [5, 10]. The mean follow-up period of approximately 19 months of the present study was one of the longest follow-up periods ever done for studying the clinical outcome of conservative treatment of CLTE [2, 3]. On the one hand, the results presented here must be interpreted with care, since we did not carry out a randomized controlled trial [2]. In particular, we did not investigate any control groups. It is therefore generally possible that improvement of clinical performance after ESWA was not exclusively due to ESWA but to spontaneous cure as the spontaneous course of CLTE is unknown [2]. On the other hand, we found that the diagnosis 'area of increased signal intensity with tendon thickening of common extensor tendon' on T2 and T1-CM MRI scans was predictive of a satisfactory clinical outcome of ESWA in female patients. It is therefore unlikely that improvement of clinical performance after ESWA was mainly due to spontaneous cure. Rather, we found evidence in favour of a relationship between CLTE morphology on MRI scans and clinical outcome of ESWA. To the best of our knowledge, this is the first indication of predictability of a positive clinical outcome of any conservative treatment of CLTE by imaging prior to treatment. The reason for the difference between female and male patients in signal intensity of the common extension tendon cross-section and tendon thickening on T1 and T2 MRI scans of CLTE is unknown so far.

Interestingly, both female and male patients classified as grade 2 or 3 on T2 MRI scans showed a better clinical outcome on average than patients classified as grade 0 or 1. Grade 2 or 3 on T2 MRI scans of the common extensor tendon is supposed to reflect fluid collection or fibrovascular proliferation within a degenerating tendon [12]. Thus, one might speculate that such tendons are vital and have a healing potential which may be activated by ESWA. By contrast, grade 0 or 1 is either interpreted as healthy tendons or supposed to reflect cicatricial tendon degeneration [12] with low or no regenerative potential. Taken together, these findings may point to a new perspective for understanding the working mechanism of ESWA in soft tissue. Corresponding in vivo animal model studies are already in progress.

To summarize, our study reports the first indication of predictability of a positive clinical outcome of CLTE treatment by ESWA using imaging prior to treatment. This may serve as an important step towards overcoming the therapeutic nihilism with respect to the conservative management of this condition recently seen in the litera-

ture [3]. Many questions remain to be answered, such as why male patients show a better clinical performance after ESWA than female patients or why there are differences between female and male patients on MRI scans of CLTE. Nonetheless, in our view the results presented here encourage us to answer these questions by randomized controlled trials combining MRI scans and treatment of CLTE by ESWA. It is to expect that these trials will also verify the predictive value, sensitivity and specificity of MRI scan evaluation prior to treatment of CLTE by ESWA as found in the present study.

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