Final Report on the

Application Study of

CRYOLIGHT Pain Therapy

Project carried out by:

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1. Introduction

1.1 Fasciitis plantaris vs. heel spur - definitions

In the German-speaking area, the term fasciitis plantaris is used in the same way as the Anglo-American term "plantar fasciitis". However, from a pathological anatomical point of view, fasciitis plantaris is equivalent to the Anglo-American "heel pain syndrome", while "plantar fasciitis" refers to corresponding symptoms further removed under the second metatarsal base and the second os cuneiforme. Incorrectly however, the term heel spur, which merely expresses a radiographic change in the plantar heel bone in a different way, is generally used.

In 60 - 70% of symptomatic cases (Chigwanda 1997, Ouba & Ireland 1986), radiographic evidence can be found of a plantar heel spur, to which no pathological significance is accorded per se. According to Rubin & Witton (1963), around 10% of radiographically identified heel spurs are symptomatic. However, a plantar heel spur can only be radiographically documented in 8% of pain-free control feet (Onuba & Ireland 1986). Riepert et al. (1995) found a prevalence of plantar heel spur totalling 11.2% for a mid-European population. The prevalence of the spur then increases significantly with increasing age. The fact that a combined occurrence of plantar and dorsal heel spur is found in 4.8% of cases (Riepert et al. 1995) points to a systematic, enthesopathic constellation. The term fasciitis plantaris is therefore used in the following text.

1.2 General

Fasciitis plantaris is one of the most frequent degenerative tendon injuries for runners. Quaschnick (1996) states that 10% of running-induced disorders are caused by a fasciitis plantaris. Fasciitis plantaris is a degenerative disease of the origin of the aponeurosis plantaris on the tuber calcanei. The symptoms occur depending on the stress at the plantar, mediodorsal inner edge of the foot. The typical soreness of the dorsomedial planta pedis is activated by physical stress (Lohrer, 2002). An appropriate account of the medical history and clinical and/or imaging diagnosis is initially followed by conservative therapy with stress modification, physiotherapy, injections and shockwave therapy. As operative therapy has a success rate of only 50-60% (Mann, 1978), it is to be used as a last resort as the last treatment option, and should be used only after unsuccessful conservative therapy and chronic progression (>6 months) and high psychological strain.

1.3 The Institute for Sports Medicine (Sportmedizinisches Institut) Frankfurt am Main

Sportsmen and women of all performance classes from elite athletes to recreational sporting enthusiasts and even non-sportsmen are cared for and treated preventively and curatively and conservatively and operatively in the Orthopaedic Department of the Frankfurt am Main Institute for Sports Medicine. With 22%, insertion tendinopathies constitute the most frequent diagnosis group in the range of the Orthopaedic Department of the Frankfurt am Main Institute for Sports Medicine. 3.7% of our patients suffer with a fasciitis plantaris. At the same time, it is striking that the rate of those who require operative intervention in the course of treatment compared with other tendon injuries of the foot is pleasingly low at 1.0%. This means that this condition basically responds well to conservative therapy.

Up to now, conservative therapy (Lohrer, 2002) has been carried out by means of:

- Orthopaedic insoles
- Physiotherapy/Physical exercise
- Extracorporeal shockwave therapy
- Injections
- X-ray stimulation therapy

Numerous studies have been carried out in the past at the Frankfurt am Main Institute for Sports Medicine on the treatment of fasciitis plantaris with extracorporeal shockwaves (Haupt et al. 2007; Lohrer et al. 2002; Schöll et al. 2001, Lohrer et al. 2009).

1.4 Cryolight® therapy

The treatment of fasciitis plantaris with Cryolight® therapy constitutes a reflex therapeutic approach. By the application of medical CO_2, a thermal reaction takes place in the area treated, as a result of which an anti-inflammatory, pain-relieving and lymph-vessel-stimulating effect is achieved.

2. Problem statement

The treatment of fasciitis plantaris with Cryolight® therapy (ELMAKO GmbH & Co. KG, Iffezheim) constitutes an innovative pain-relieving and anti-inflammatory concept, but up to now there has been no evidence of a reduction in pain induced by the therapy.
The focus of the planned application study is therefore to analyse the effectiveness of CRYOLIGHT pain therapy within the framework of an application study.

2.1 Hypotheses and working points of view:

1. The impairment of the patient caused by a fasciitis plantaris can be affected in a relevant manner by CRYOLIGHT® therapy.

2. No undesirable side-effects are caused by CRYOLIGHT® therapy.

3. Material and methods

3.1 Test personnel

After checking the criteria for inclusion and exclusion, a total of 20 patients with a diagnosis of fasciitis plantaris were recruited for the application study in the Frankfurt am Main Institute for Sports Medicine. At the point of inclusion in the study, all patients had previously undergone therapy using at least one method of treatment (Table 1).

Patients	Previous therapies
Patient 1	Insoles, X-ray stimulation therapy, massage
Patient 2	ESWT, insoles
Patient 3	ESWT, insoles
Patient 4	Insoles, ESWT, laser therapy
Patient 5	Insoles
Patient 6	Insoles, physiotherapy, NSAR
Patient 7	Insoles, ESWT
Patient 8	Insoles
Patient 9	Insoles, physiotherapy
Patient 10	Insoles, ESWT
Patient 11	Insoles
Patient 12	Insoles, NSAR, physiotherapy
Patient 13	ESWT
Patient 14	Insoles, ESWT, NSAR
Patient 15	Insoles, cortisone injection
Patient 16	Insoles
Patient 17	Insoles
Patient 18	Insoles, physiotherapy
Patient 19	Injections
Patient 20	Physiotherapy

Table 1: Prior treatments for the 20 study patients

Inclusion criteria:

- Typical local pressure pain
- VAS pressure pain > 5
- Symptoms of discomfort > 3 months
- Age >18 years
- Willingness to dispense with other therapy measures for the duration of the bandage testing (six weeks)

Exclusion criteria:

- Proven systemic illnesses
- Neuropathies
- Peripheral arterial circulatory disorders
- Venous insufficiency
- Operatively pre-treated fasciitis plantaris

3.2 Investigation procedure

A four-week period was planned for the treatment of fasciitis plantaris with CRYOLIGHT® therapy. Once the study had been approved/sanctioned by the client (ELMAKO GmbH & Co. KG), the patients were recruited and the inclusion and exclusion criteria checked. On completion of the preliminary examination, the clinical and subjective parameters (see 3.2) were documented as initial values and the following therapy scheme with the CRYOLIGHT®-SYSTEM applied:

1st week → 3x a week

2nd week → 3x a week

3rd week → 2x a week

4th week → 1x a week

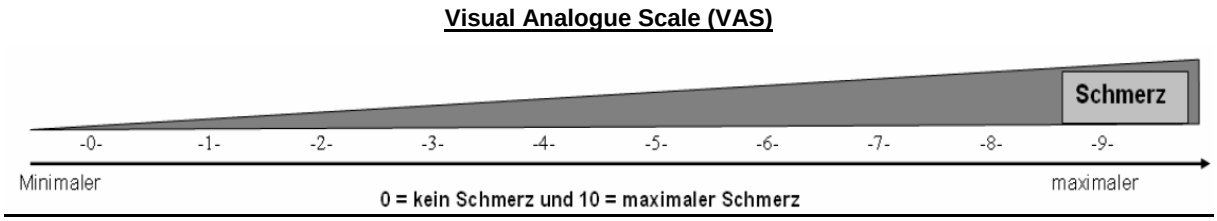
3.3 Investigation parameters/evaluation instruments

3.3.1 Subjective level

Various standardised questionnaires were used in parallel as part of the preliminary examination and in subsequent examinations.

a) Foot and Ankle Outcome Score (FAOS): this examination sheet, which is completed by the patient himself, has already been validated with regard to fasciitis plantaris (Roos et al. 2001). It includes and differentiates five different sub-groups (pain, other symptoms, function in everyday activities, sport and leisure, quality of life).

b) Visual Analogue Scale (VAS): this is a scale for measuring sensitivity to pain (Scott-Huskisson 1974). Here, the patient marks his subjectively perceived present state on a specified 10-cm-long line between the limits "optimum, no discomfort whatsoever" and "maximum imaginable pain" (Figure 1).



Pain
Minimum
Maximum
0 = no pain and 10 = maximum pain

Figure 1: Visual Analogue Scale. The scale ranges from 0 = no pain to 10 = maximum pain.

3.3.2 Clinical level:

The clinical examination of the foot was carried out with reference to swelling, pressure pain and mobility.

a) The soreness during the course of the treatment was assessed with a "dolormeter" combined with the Visual Analogue Scale (see 3.4.1). To do this, a pressure of 50 N was applied to the point of maximum pain.
b) The pain threshold, as that pressure which the patient just perceives as painful, was also determined with the "dolormeter".

The "dolormeter" has already been used in the past in comparable studies for evaluating the effect of extracorporeal shockwave therapy (Schöll et al., 2001; Figure 2).

Figure 2: Dolormeter for the application of a defined pressure of 0-50 N. Pressure is applied over a circular area of 1 cm.

3.4 Investigation procedure

A six-week course was planned for the investigation. Once the study had been approved/sanctioned by the client (ELMAKO GmbH & Co. KG), the patients were recruited. On completion of the preliminary examination (T0), the patients were treated with Cryolight® therapy for four weeks in accordance with the treatment scheme (Chapter 3.2) and subsequently invited to the first follow-up examination (T1). At this time, the therapy was discontinued. The second follow-up examination (T2) was carried out after six weeks (two weeks after the first follow-up-examination) using the same evaluation instruments.

3.5 Evaluation

The subjective and clinical evaluation (see 3.4) of the results of the treatment was carried out by means of a descriptive analysis (mean values and standard deviations) in the longitudinal section and an additional interference statistic. A single-factor variance analysis with repeated measurement (significance level $\alpha = 0.05$) and, for further verification of the significance, a Turkey post - hoc test were carried out for this purpose.

3.6 Results

25 patients presented themselves at the start of the study at the Sportmedizinischen Institut Frankfurt am Main e.V. for the preliminary examination. A total of 20 patients were recruited for the application study on evaluation of the inclusion and exclusion criteria. All 20 patients participated in the two follow-up examinations (T1 and T2) (follow-up examination quota = 100%). The patient group was made up of nine women and 11 men of ages 49±10 years. The duration of fasciitis plantaris symptoms before starting the Cryolight® therapy was 8±6 months. The right-hand side was affected 12 times and the left hand side eight times (Table 2). At the time of all examinations, the top and bottom ankle joints of the affected feet of the patients were equally mobile on both sides, had no swelling and had an isolated, reproducibly triggerable pressure pain on the medioplantar side of the heel bone (= fascia plantaris origin).

Table 2:
Anthropometric parameters for the patients at the start of the investigation. Values given are mean values and standard deviation (SD).

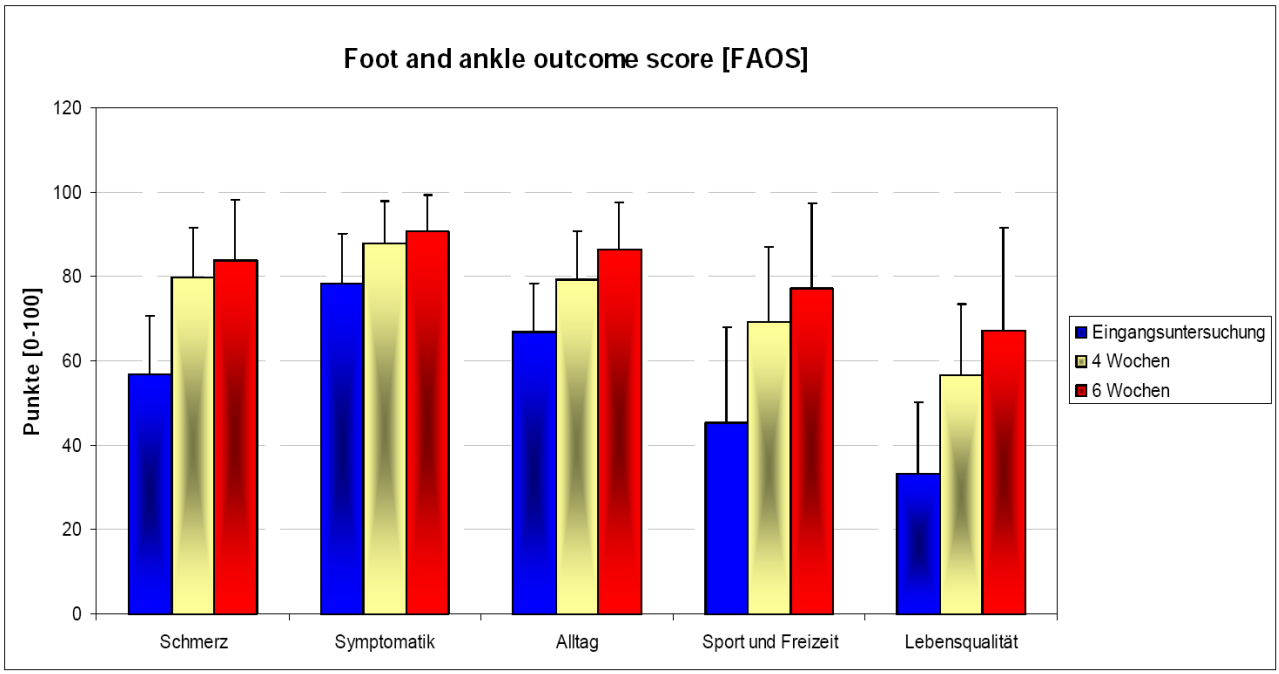
n	Age [years]	Height [m]	Weight [kg]	BMI [kg/m²]	Injured side [left/right]
20	49±10	1.73±0.1	77±12	26±5	12x right; 8x left

3.6.1 Foot and Ankle Outcome Score

The pain subscale of the Foot and Ankle Outcome Score (Roos et al., 2001) at the start of the investigation (T0) was 56.9±13.6 points and by the first follow-up examination (T1) had improved to 79.9±11.6 points (p= 0.000). At the second follow-up examination (T2), the average subscale values had increased further to 83.9±14.2 points (p= 0.000). On the other hand, there was no significant difference between the T1 and T2 follow-up examinations (p= 0.637).
At the time of the examination T0, the symptoms were measured at 78.3±11.8 points and by T1 had increased to 87.9±10.1 points (p= 0.018) and by T2 to 90.8±8.7 points (p= 0.002). No significant change was established between the T1 and T2 follow-up examinations (p = 0.676).
The ability to carry out everyday activities was evaluated at the preliminary examination as 66.9±11.6 points, at T1 as 79.3±11.4 points (p= 0.006) and at T2 as 86.3±11.2 points (p= 0.000). The difference between the T1 and T2 examinations was not significant (p= 0.161).

At T0, sport and recreation activities were evaluated as 45.3±22.7 points, at T1 as 69.1±18.0 points and at T2 as 77.1±20.2 points. The difference between T0 and T1 and from T0 to T2 was in both cases significant (p= 0.003 and 0.000). On the other hand, the values between T1 and T2 did not differ significantly (p= 0.471).

At the preliminary examination, the quality of life was quantified as 33.4±16.8 points and at T1 as 56.6±17.0 points (p= 0.002). At T2, the mean number of points was 67.2±24.4 (p= 0.000). No further statistically relevant improvement was established between T1 and T2 (p= 0.250; Figure 3).



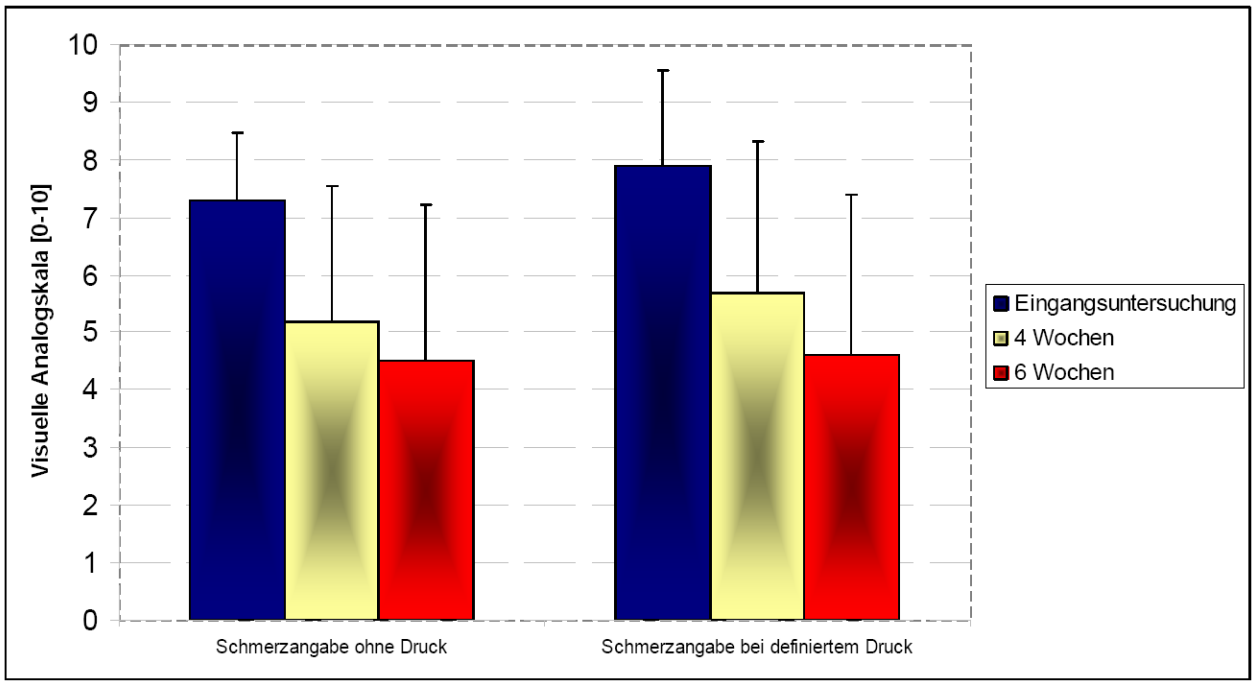
Points [0-100]
Pain
Symptoms
Daily routine
Sport and leisure
Quality of life
Preliminary examination
4 weeks
5 weeks

Figure 3: Subjectively perceived changes due to Cryolight® therapy for fasciitis plantaris. Mean values and standard deviations over the study period are shown.

3.6.2 Visual Analogue Scale

At the start of the investigation, the patients indicated an average pain intensity of 7.3±1.2 points on the VAS scale. By T1, the pain intensity had reduced significantly to 5.2±2.3 points (p= 0.012) and by T2 to 4.5±2.7 points (p= 0.001). No statistically significant change was established between T1 and T2 (p= 0.662).

At T0, the examination with an applied pressure of 50 N gave a subjectively perceived sensation of pain of 7.9±1.7 points on the VAS scale, which by T1 had reduced to 5.7±2.6 points (p= 0.021) and by T2 further to 4.6±2.8. A significant reduction in the sensation of pain at a defined pressure was observed when comparing T0 with T2 (p= 0.000), whereas this was not seen when comparing T1 and T2 (p= 0.360; Figure 4).

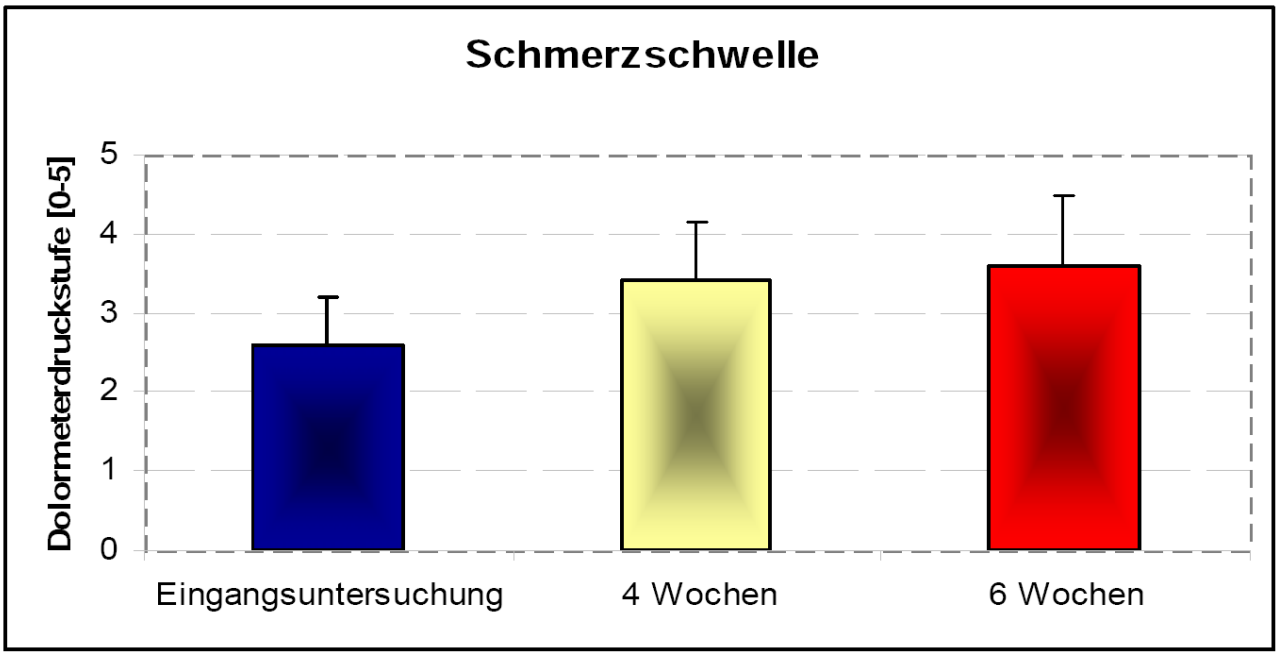


Visual Analogue Scale [0-10]
Pain indication without pressure
Pain indication at a defined pressure
Preliminary examination
4 weeks
6 weeks

Figure 4: Subjectively perceived changes due to Cryolight® therapy for fasciitis plantaris. Mean values and standard deviations over the study period are shown.

3.6.3 Investigation of the pain threshold

The pain threshold improved very significantly from 2.1±0.6 points at the start of the study to 3.4±0.7 points at T1 (p= 0.000). A further improvement to 3.6±0.9 points was observed by T2. When comparing T0 with T2, the pain threshold was statistically significantly increased (p= 0.001), whereas this could not be seen when comparing T1 and T2 (p= 0.676; Figure 5).



Pain threshold
Dolormeter pressure step [0-5]
Preliminary examination
4 weeks
6 weeks

Figure 5: Results of the Dolormeter measurements. Mean values and standard deviations for the preliminary examination, follow-up examination 1 and follow-up examination 2 are shown.

3.6.4 Side-effects

No side-effects were documented for any of the participants in the study within the study period.

4. Discussion

In most cases, fasciitis plantaris can be successfully treated by conservative means. Because of the frequent chronification of the symptoms and the associated long period of suffering, it still presents a challenge for the doctor treating the condition. Patience and cooperation on the part of the doctor and the patient are decisive factors in the effective treatment of fasciitis plantaris. The objective of treatment is always the relief of pain caused by inflammation, whereas asymptomatic spur requires no therapy.

As with practically all other degenerative tendon injuries, the methods for treating fasciitis plantaris are not all trusted under the criteria of Evidence Based Medicine that are required today. Most publicised approaches to treatment are based on the experience of the respective authors. It is said that the results of treatment are very good or good in about 70% of cases. Patient overweight, soreness on both sides, systematic associated illnesses and a chronification of the symptoms evidently have a negative effect on the results of treatment (Lohrer 2001). The basic treatment strategy initially includes a reduction of the triggering stress, a bio-mechanically oriented insole

supply and physiotherapeutic treatments. Particularly with sportsmen and women, local cortisone infiltration increases the risk of a relevant tendon injury (partial rupture or rupture).
In this application study, the short-term results of treatment with Cryolight® therapy in the case of fasciitis plantaris have initially been prospectively checked based on a relevant number of patients (n=20). The results show a relevant reduction in pain in 80% of the treated patients within the study period of 6 weeks. After four weeks, all the parameters measured as part of the investigation already showed a significant improvement, which did not deteriorate even after discontinuing Cryolight® therapy. The success of the treatment is therefore comparable with that which has previously been presented in the appropriate literature for other conservative and operative methods of treatment of Fasciitis plantaris.
The strengths of this study lie in its prospective approach and the fact that it was possible to observe all patients right up to the last follow-up examination (no "dropout"). However, the clinical significance of the results is limited due to the absence of a control group. The results shown should be checked and confirmed with a higher level of evidence in further randomised and controlled investigations.

5. Conclusions

The results of this study show that, as a result of Cryolight® therapy, a positive effect on fasciitis plantaris can be achieved after just a four-week period of treatment. In particular, this also applies to patients who have already been treated using various conservative methods. Further studies are necessary to further confirm the results shown.

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