

## ORIGINAL ARTICLE

# Intratissue percutaneous electolysis combined with active physical therapy for the treatment of adductor longus enthesopathy-related groin pain: a randomized trial

Carlos MORENO<sup>1\*</sup>, Gabriele MATTIUSI<sup>1</sup>, Francisco J. NÚÑEZ<sup>2</sup>, Giovanni MESSINA<sup>3</sup>, Enrico REJC<sup>4</sup>

<sup>1</sup>Medical Staff, Udinese Calcio Spa, Udine, Italy; <sup>2</sup>Department of Sports and Computing, Sport Faculty, Pablo de Olavide University of Sevilla, Sevilla, Spain; <sup>3</sup>Department of Medical and Biological Sciences, School of Motor Sciences, University of Udine, Udine, Italy; <sup>4</sup>Kentucky Spinal Cord Injury Research Center, University of Louisville, KY, USA

\*Corresponding author: Carlos Moreno, Medical Staff, Udinese Calcio Spa, Stadio Friuli, Viale A. e A. Candolini 2, 33100 Udine, Italy.  
E-mail: [Carlos.Moreno@udinesespa.it](mailto:Carlos.Moreno@udinesespa.it)

## ABSTRACT

**BACKGROUND:** *Adductor longus* enthesopathy-related groin pain (ALErGP) is the most common cause of groin pain in soccer players. The aim of this study was to evaluate the therapeutic utility of intratissue percutaneous electrolysis (EPI®) technique in combination with an active physical therapy (APT) program to treat ALErGP.

**METHODS:** Twenty-four non-professional male soccer players diagnosed with ALErGP were included in this study and randomly divided into two groups. Group A was treated with EPI® technique in combination with a standardized APT program. Group B only underwent the APT program. The Numeric Rating Scale (NRS) and the Patient Specific Functional Scale (PSFS) were used to assess the effectiveness of the two interventions. The follow-up covered a 6-month period.

**RESULTS:** Both groups significantly improved pain and functional scores after treatment and maintained this therapeutic result throughout the follow-up. The combined intervention of APT program and EPI® ensured a greater and faster reduction of pain in group A. In addition, functional recovery tended to be greater in group A than B after the treatment and throughout the follow-up by  $7.8 \pm 3.8\%$  ( $P=0.093$ ).

**CONCLUSIONS:** EPI® treatment in association with APT ensured a greater and more rapid reduction of pain and tended to promote greater functional recovery in soccer players with ALErGP compared to APT only. This positive therapeutic result lasted for at least 6 months after the end of the treatment. These findings support the combined use of EPI® and APT to treat ALErGP.

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**Key words:** Tendinopathy - Soccer - Electrolysis - Ultrasonography.

Groin pain (GP) can generally be defined as a syndrome characterized by pain in the pubic and inguinal regions,<sup>1</sup> which results in a functional deficit that can lead to severe impairment of different motor tasks, such as kicking and twisting movements while running,<sup>2</sup> and to the suspension of athletic activities.<sup>3</sup> In soccer, the incidence of this condition ranges between 10% and 18% of all time-loss injuries with relapse rates as high as 30%.<sup>3, 4</sup> In fact, the term “longstanding” GP is often

used to describe the impact of the syndrome in the long term.<sup>5</sup> The anatomy of the region is extremely complex and many different conditions provoking GP can be factors into a differential diagnosis.<sup>1, 6-8</sup> Hence, the identification of the primary cause of GP can be challenging. Despite the difficulties in diagnosis, adductor-related GP has been identified as the most common clinical pattern of GP in soccer players.<sup>9</sup> This is clinically characterized by pain that is exacerbated by the palpation of the inser-

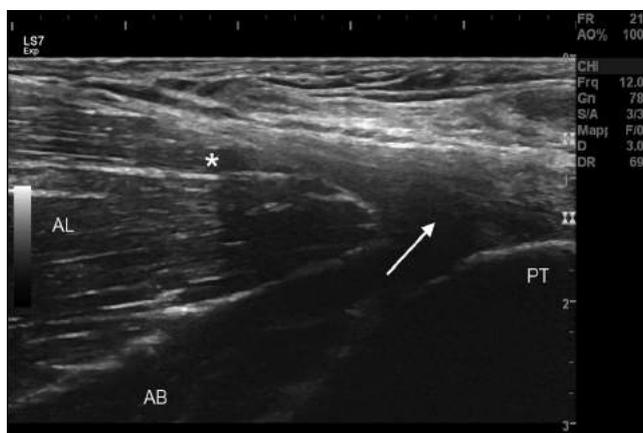


Figure 1.—Longitudinal ultrasound section of the *adductor longus* (AL). The tendon insertion on the pubic tubercle (PT) is recognized as a hypoechoic area (arrow). Additionally, the intramuscular tendon, or central aponeurosis, of the *adductor longus* (the hyper-echoic horizontal structure indicated by an asterisk), and the *adductor brevis* (AB) can also be seen.

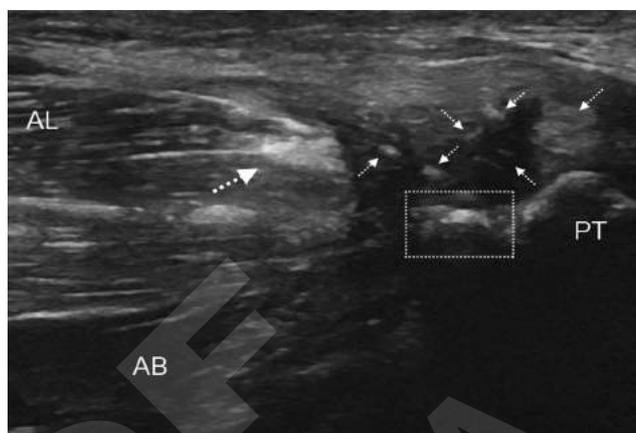


Figure 2.—Anatomic changes of the proximal tendon/enthesis of the *adductor longus* (AL) in the ultrasound examination. In the vicinity of the pubic tubercle (PT) the presence of significant calcification of the tendon can be seen (dotted box), as well as many fibrotic areas at the level of the enthesis (small arrows), which appears to be clearly deconstructed. Furthermore, it is possible to identify significant fibrotic thickening near the myotendinous unit of the muscle (thick arrow). AB: adductor brevis.

tion of the *adductor longus* (AL) on the pubic tubercle (unilaterally or bilaterally), as well as by the counter-resistance contraction of the muscle.<sup>1,9</sup> This clinical condition is often associated with AL enthesopathy, which involves also alterations of the tendon portion in close proximity to its insertion (Figure 1),<sup>10</sup> and is recognized as the most common disease in athletes with pain localized in the proximity of the pubic symphysis.<sup>6, 11</sup> Therefore, *adductor longus* enthesopathy-related GP (ALErGP) is identified as one of the main causes of GP in soccer players. Etiopathogenesis of AL enthesitis degeneration is associated with repeated functional overloading, as the fibrocartilaginous enthesis is vulnerable to prolonged biomechanical stimuli over time.<sup>12, 13</sup> Repeated functional overloading results in the progressive manifestation of histological and anatomical alterations, detectable with ultrasound and MRI.<sup>11, 14-17</sup> The fibrosis and the formation of calcifications (Figure 2) are compatible with a chronic failure of the physiological processes of adaptation and healing, resulting in ineffective microcycles of injury repair.<sup>12, 13</sup> Also, histological alterations of the enthesis contribute to the progressive loss of the biomechanical properties of the tissue and finally to the onset of symptoms and functional deficits typical of an overuse injury.<sup>1, 11, 15</sup>

Physiotherapy is usually preferred over surgical intervention to treat GP. On the other hand, surgery is con-

sidered when the rehabilitative programs are unsuccessful.<sup>18</sup> The more conservative treatments usually involve: rest (or restriction of activities); passive physiotherapy (*i.e.* massage, laser and transcutaneous electrical nerve stimulation)<sup>19</sup> to recover the joint mobility of the hip, sacroiliac joints, and lumbar spine, as well as the restoration of the visco-elastic properties of the muscles (the adductors, in particular); active physiotherapy targeted at improving the stabilizing ability of the abdominal and pelvic muscles, especially the *Transversus Abdominis*.<sup>2, 20-23</sup> It has been shown that a program of active physiotherapy is more effective than one of exclusively passive physiotherapy in the care of Adductor-related GP,<sup>19</sup> and that a multimodal program promotes even faster results than active physical therapy *per se*.<sup>24</sup> The physical therapy interventions usually last for 6 to 8 weeks.<sup>25</sup>

In addition to the abovementioned interventions, another therapeutic approach to consider is intratissue percutaneous electrolysis (EPI®), a novel technique that plays a role in the treatment of tendinopathy, enthesopathy, and fibrosis.<sup>26-28</sup> Furthermore, a recent study reported the use of this technique for the treatment of muscular lesions as well.<sup>29</sup> EPI® is an ultrasound-guided minimally invasive technique that makes it possible to degrade the diseased tissue through the electrolytic action of EPI® (electrochemical ablation), as well as to develop an extremely localized inflammatory process that can induce the heal-

TABLE I.—Enrollment phase: inclusion and exclusion criteria.

	Inclusion criteria	Exclusion criteria
General criteria	Non-professional soccer players Age 18-35 years	Previous Groin/Hip surgery
Clinical criteria	Presence of pain upon palpation of the enthesis of the <i>adductor longus</i> (unilaterally or bilaterally) Presence of pain upon contraction against resistance (Adductor Squeeze Test) of the enthesis of the <i>adductor longus</i> (unilaterally or bilaterally)	Adductor-related Groin Pain is not the primary clinical entity
Imaging criteria	The ultrasound testing revealed anatomical alterations of the proximal tendon/enthesis of the adductor longus, which was painful during clinical examination	The ultrasound and MRI showed an absence of anatomical alterations of the enthesis of the <i>adductor longus</i> , which was painful during clinical examination Presence of major pathologies revealed by the MRI
After randomization		Consumption of NSAIDs or local infiltration during treatment Absence from more than 20% of scheduled physiotherapy sessions or absence from more than one scheduled EPI® session.

ing process in the treated structure (indirect reparative action).<sup>29</sup> Other works described the therapeutic benefits of EPI® technique in the treatment of patellar tendinopathy and how this technique, in conjunction with a program of active physical therapy — eccentric exercises in particular — can promote considerable structural and functional benefits that are maintained in the long term.<sup>26, 27</sup> However, further studies are still needed to evaluate the usefulness of this technique in the treatment of other tendinopathies and enthesopathies.

The aim of this study was to evaluate the therapeutic utility of the EPI® technique in combination with an APT program to treat ALERGP, while comparing the results achieved solely from the APT program in a group of non-professional soccer players. We hypothesized that 1) the combination of EPI® and APT can promote greater and faster clinical and functional improvements than treatment relying solely on an APT program; and that 2) the functional improvements obtained in the study group will be more solidly maintained over time compared to the control group that underwent APT program alone.

## Materials and methods

### Participants and sample size

Between February and July 2014, 37 male soccer players affected by generic GP were clinically and instrumentally evaluated (see below). These athletes usually performed 2 to 4 training sessions per week, thus were considered non-professional players.<sup>24</sup> Twenty-

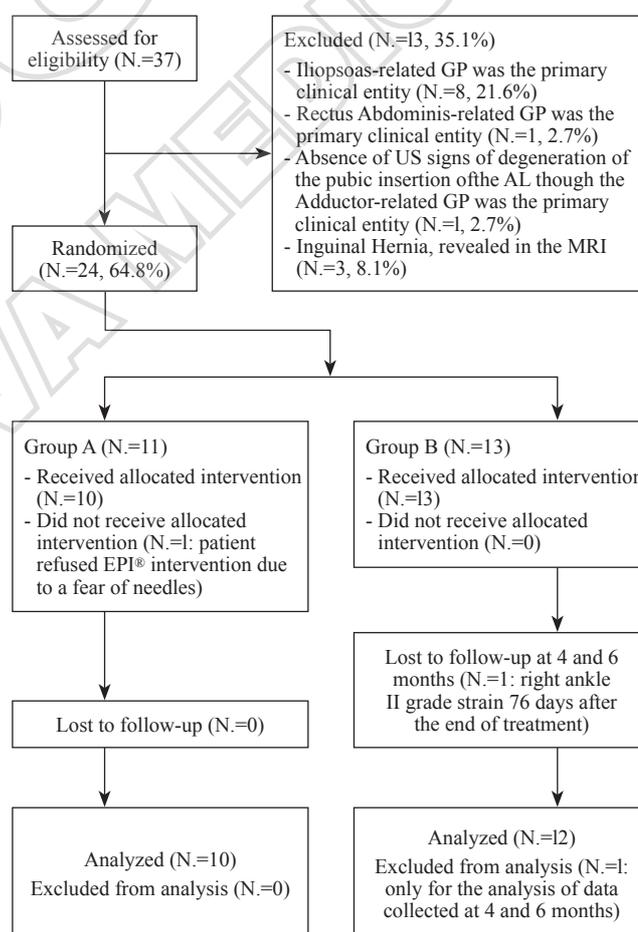


Figure 3.—Study profile.

four of these athletes (age:  $26.0 \pm 4.7$  year; stature:  $178.7 \pm 8.0$  cm; body mass:  $73.9 \pm 6.9$  kg) were diagnosed with ALErGP, satisfied the inclusion and exclusion criteria (Table I) and thus were initially enrolled in the study (Figure 3). Two subjects did not complete the study protocol; hence, data recorded from 22 players were taken into account for further analysis.

The study was ethically designed and conducted according to national and international standards. The research reported in the paper was undertaken in compliance with the Helsinki Declaration and the International Principles governing research on humans. All participants were informed of the experimental risk and gave written informed consent. In addition, the present study was designed taking into consideration the guidelines on reporting standards for clinical research on groin pain in athletes indicated by Delahunt *et al.*<sup>30</sup>

Patients initially took part in a medical interview. Their anthropometric data were collected, as well as sport-specific (level of activity, position, dominant foot) and GP-specific (laterality and duration of the symptoms) information. The final part of the interview involved the registration of Patient-Specific Functional Scale (PSFS) values. This was followed by the clinical evaluation, including recordings of the Numeric Rating Scale (NRS) values. After this evaluation, an ultrasound examination was administered. If the inclusion criteria were met, the patient was asked to undergo an MRI scan. Based on an analysis of the final report, a decision was made whether to enrol the subject. MRI scans were performed by a private clinical facility, while all other assessments and therapeutic interventions were performed within the facilities of the "Friuli" Stadium, in Udine (Italy), the sporting venue of Udinese Football Club.

#### *Clinical evaluations*

For the clinical evaluation, a standardized assessment protocol was used for athletes with GP.<sup>31</sup> This protocol was shown to be particularly valuable because it was subject to limited variation between operators. All the clinical assessments were performed by a well-trained physiotherapist who followed precisely the protocol details found in the appendix "Examination techniques for the evaluation of GP in athletes" used in the intra-observer and interobserver reliability study.<sup>31</sup> The assessor was not aware of the treatment type received by every subject.

#### *Pain assessment*

The NRS Scale,<sup>32-34</sup> which showed high test-retest reliability,<sup>32</sup> was selected among the available scales for pain assessment in adults. The patient was asked to verbally assign a value to his pain, ranging from 0 (total absence of pain) to 10 (the most intense pain imaginable). The NRS values were collected to assess the pain: upon palpation of the insertion of the AL into the pubic tubercle (NRS<sub>palp</sub>) (if pain is present bilaterally, the highest value was always recorded); upon bilateral isometric contraction against resistance (NRS<sub>contr</sub>). The values were recorded at enrolment, at the end of treatment, and at 2, 4, and 6 months after treatment (follow-up).

#### *Functional assessment*

As suggested by Hedegus *et al.*,<sup>33</sup> the PSFS was chosen to assess the functional level of subjects with GP. The patient was asked to select the activities with a reduced level of performance and to assign them with increasing values from 0 to 10, representing a complete deficit in the performance of the activity and the ability to perform the activity at the highest level of performance, respectively. To ensure uniform assessment in the sample, the authors selected 10 activities to which the patient was asked to assign a performance level, 6 non-sport specific and 4 sport specific (SS): linear running; linear sprinting; rapid braking in a sprint; twisting movements; jumping, pulling with dominant foot; jumping, pulling with the non-dominant foot; passing with the dominant foot (SS); passing with the non-dominant foot (SS); kicking with the dominant foot (SS); and kicking with the non-dominant foot (SS). The sum of the values obtained could range from 0 to 100, where 100 is the maximum level of athletic performance. The values were recorded at enrolment, at the end of treatment, and at 2, 4, and 6 months after treatment (follow-up). PSFS showed also high test-retest reliability for evaluation of the functional level for chronic syndromes such as low back pain and chronic lateral epicondylitis.<sup>35</sup>

#### *Instrumental evaluations*

Ultrasound assessment was performed by a well-trained operator (more than 10 years of experience in evaluating the lower limb muscle-skeletal system in professional and non-professional soccer players) us-

ing the GE Healthcare Logiq S7 Expert ultrasound (GE Healthcare®, Milwaukee, WI, USA) with a linear probe (6-15 MHz). Ultrasound assessment was performed only before the intervention; it was aimed at evaluating any eventual anatomical alterations of the proximal tendon and enthesis of the *adductor longus*, which was painful during clinical examination, in order to define the inclusion/exclusion criteria (Table I). The assessor was neither aware of the clinical evaluation results nor the type of treatment that the subject would have received.

Ultrasound evaluation was followed by an MRI of the pubic region which was necessary to confirm the diagnosis and to rule out any other condition: subjects with significant comorbidities (such as inguinal hernia, muscle injuries, femoroacetabular impingement, visceral diseases, etc.) were excluded from the study.

#### *Treatment protocols*

Two randomized groups were created: the study group, or group A, and the control group, or group B. In group A, the EPI® technique was used along with a standardized APT program, whereas group B only underwent the APT program. To randomize the groups, the following tool was used: “Create a blocked randomization list” (Sealed Envelope Ltd. 2014), available online from: <https://www.sealedenvelope.com/simple-randomiser/v1/lists>. The block size was set at 10 subjects (1:1 allocation). The tool also generated a unique randomization code. After the assessments, each subject included in the study was given their personal code assigning them to one of the two groups. The code was enclosed in sealed envelopes (numbered to identify the block).

#### *Eco-guided EPI® intervention*

The patient was placed in a supine position, with the limb in slight abduction and external rotation of the hip in order to better expose the enthesis of the AL to be treated. The entire pubic and inguinal region was previously disinfected with isopropyl alcohol. The treatment was performed by a well-trained operator (more than 10 years of experience in applying this technique for ALERGP in professional and non-professional soccer players) using a specifically developed medically

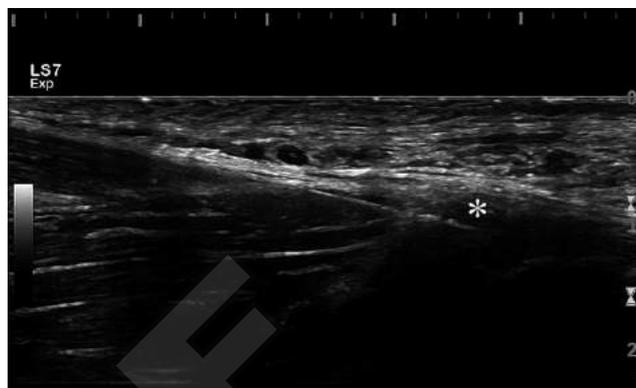


Figure 4.—Ultrasound-guided intratissue percutaneous electrolysis. The operator inserts the needle (asterisk) into the treatment area.

certified (Directive 93/42/EEC) device (EPI Advanced Medicine®, Barcelona, Spain). The chemical process of electrolysis is induced by the modulated galvanic current generated by the device. The current is transferred to the tissue to be treated using an appropriate needle (0.33x50 mm); its insertion is ultrasound-guided in order to reach precisely the targeted area. In the present study, the GE Healthcare Logiq S7 Expert® ultrasound with a linear probe (6-15 MHz) was used to guide the insertion of the needle (Figure 4). Group A subjects received EPI® intervention during Phase 1 of the APT program. EPI® intervention protocol was similar to that reported by Abat *et al.*<sup>26, 27</sup> for the treatment of patellar tendinopathy. In particular, two treatment sessions were held each week during Phase 1 of the APT program (EPI® intervention was completed 15 minutes prior to the start of the physical therapy session). The pre-set program “Adductors Tendinopathy” was used, with the device set at 3mA (current intensity). Each session consisted of 3 applications (3 right + 3 left if the ALERGP was present bilaterally), with a duration of 5 seconds each. Each session had a maximum duration of 10 minutes.

EPI® intervention was overall well tolerated by the subjects. Some of them experienced minor discomfort during needle insertion. In addition, the electrolytic treatment caused moderate to moderately strong pain in some of the participants; however, the short duration of every stimulus, 5 seconds, resulted in a tolerable pain. Indeed, none of the subjects asked to pause or stop the treatment, being these options available after every single 5-second stimulus. Furthermore, no adverse events

TABLE II.—*The standardized Active Physical Therapy program: description of the exercises and method of administration.*

Phase 1	1) Bilateral isometric contraction of the AL: patient in supine position. Isometric adduction against a fit ball (Ø=30cm) positioned between the knees.	10 s of holding (+20 s pause) for 8 repetitions
	2) Bilateral isometric contraction of the AL: patient in supine position, hips flexed at 45°. Isometric adduction against a fit ball (Ø=30 cm) positioned between the knees.	10 s of holding (+20 s pause) for 8 repetitions
	3) Unilateral eccentric contraction of the AL: patient in supine position, hip in neutral position. The physiotherapist slowly abducts the hip up to 45° and the patient is asked to slow down the muscle elongation.	5 s of contraction (+5 s pause) for 8 repetitions for 4 sets (2 for each leg)
	4) Bilateral eccentric contraction of the AL: patient in supine position, hips flexed at 45° and fully adducted. The physiotherapist slowly abducts both hips up to 30°, while the patient is asked to slow down the muscle elongation.	5 s of contraction (+10 s pause) for 8 repetitions for 2 sets
Phase 2	1) Spinning bike (warm up).	10 min
	2) Bilateral eccentric contraction of the AL: patient in supine position, hips flexed at 45° and fully adducted. The physiotherapist slowly abducts both hips up to 30°, while the patient is asked to slow down the muscle elongation (warm up).	5 s of contraction (+10 s pause) for 8 repetitions for 4 sets
	3) Isoinertial eccentric training for AL: patient in supine position. Overload: 2 Kg (Concentric + Eccentric phases duration: ~3 s).	6 repetitions for 4 sets (2 for each leg)
	4) Isoinertial eccentric training for AL: patient in upright position. Overload: 4 Kg (Concentric + Eccentric phases duration: ~3 s).	6 repetitions for 4 sets (2 for each leg)
Phase 3	1) Spinning bike (warm up)	10 min
	2) Bilateral eccentric contraction of the AL: patient in supine position, hips flexed at 45° and fully adducted. The physiotherapist slowly abducts both hips up to 30°, while the patient is asked to slow down the muscle elongation (warm up).	5s of contraction (+10s pause) for 8 repetitions for 4 sets
	3) Isoinertial eccentric training for AL: patient in supine position. Overload: 3 kg (concentric + eccentric phases duration: ~3 s).	6 repetitions for 4 sets (2 for each leg).
	4) Isoinertial eccentric training for AL: patient in supine position. Overload: 4 kg (concentric + eccentric phases duration: ~6 s).	4 repetitions for 4 sets (2 for each leg).
	5) Isoinertial eccentric training for AL: patient in upright position. Overload: 4 kg (concentric + eccentric phases duration: ~3 s).	6 repetitions for 4 sets (2 for each leg).
	6) Isoinertial eccentric training for AL: patient in upright position. Overload: 6 kg (concentric + eccentric phases duration: ~6 s).	4 repetitions for 4 sets (2 for each leg).

AL: adductor longus.

such as fainting or nausea occurred during the treatment. Some patients reported minor pain in the treated location up to 12 hours after the end of EPI® intervention.

### *The standardized active physical therapy program*

For all participants, the program began within 10 days of enrolment and was performed under the constant supervision of a physical therapist, who did not know which subjects were also treated with Eco-Guided EPI® intervention. Table II specifically shows the therapeutic proposals of each of the 3 phases comprising the treatment. The APT protocol was defined taking into consideration: 1) previous studies that investigated the effects of active physiotherapy (*i.e.* isometric and eccentric muscle contractions performed against manual resistance) on GP;<sup>19, 24</sup>; 2) previous studies aimed at examining the combined effects of EPI® technique and

isoinertial eccentric exercises on the treatment of patellar tendinopathy;<sup>27</sup> 3) previous studies that examined the effects of isoinertial eccentric exercises on muscle function in healthy athletes;<sup>36, 37</sup> 4) pilot studies carried out by our research group. The duration of each phase depended on the functional and symptomatic improvement shown by each individual. In particular, the achievement of specific NRSpalp, NRscontr and PSFS threshold values (see below) resulted in the phase completion. However, each subject was required to perform at least 1 week of training for each phase.

### PHASE 1

The aim of this phase was to reduce the ALERGP symptoms. Subjects were required to completely suspend all sport-related activities and perform three rehabilitative sessions per week, which included isometric

lower limb adductions and AL eccentric contractions performed against manual resistance (Table II). The duration of each session was about 30 minutes. At the beginning of each session, NRSpalp and NRscontr tests were replicated. When the values of both tests were  $\leq 3/10$ , subjects advanced to Phase 2.

## PHASE 2

The objective was non-sport specific functional recovery. As in the previous phase, 3 sessions per week (30 minutes/session) were performed by the subjects. Phase 2 involved the use of a machine (Element Sport™, Sevilla, Spain; Figure 5) for performing isoinertial eccentric exercises. This isoinertial machine was equipped with a 7 kg flywheel (moment inertia:  $0.09 \text{ kg/m}^2$ ) and additional overloads (between 3 and 6 kg) that were appropriately set by the operator (Table II), and was very similar to those described in other studies that used isoinertial exercise as an intervention.<sup>27, 36, 37</sup> In particular, an important feature of this machine is that the concentric-eccentric phase transition is extremely fast (*i.e.* the isometric phase is negligible). During the concentric contraction phase, the kinetic energy is transmitted to the spinning cone (flywheel) through the extraction of the nylon cord wrapped around it. When the cord is completely extended, the stored energy causes the cone to continue its rotation through inertia, in turn rewinding of the cord. At this point the subject is required to perform an eccentric contraction (proportional to the effort exerted during the concentric phase) in order to break and stop the rotation of the cone, thereby completing the repetition. During APT phase 2 (as well as phase 3), the two initial exercises were proposed as controlled warm-up activity (Table II). The initial 3 repetitions of each of the subsequent exercises were performed by the subjects at a lower intensity because they were aimed at familiarizing with the isoinertial equipment. It is worth noting that eccentric exercise was reported to be effective as an “active stretching” intervention for tendon tissue.<sup>38</sup> In addition, isoinertial eccentric exercise was shown to be effective for increasing muscle mass and improving muscle function.<sup>36, 37</sup> At the beginning of each session, the PSFS was assessed for the non-sport specific activities. When the score of this test was  $\geq 8$ , subjects advanced to phase 3.

During phase 2, subjects were also allowed to perform

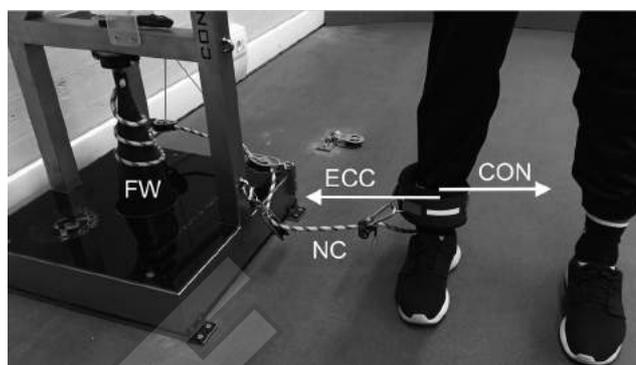


Figure 5.—Isoinertial machine. The nylon cord (NC) is wrapped around the flywheel (FW) and secured at the athlete's ankle. A concentric contraction (CON) of the adductor muscles results in the initiation of FW rotation while unwinding the NC. Once the pushing CON phase has been completed, the NC rewinds because of the kinetic energy of the FW and pulls the lower limb toward the machine. Hence, the athlete is required to perform an eccentric contraction (proportional to the effort exerted during the concentric phase) in order to break and stop the rotation of the FW, thereby completing the repetition. After bringing the FW to a stop, a subsequent CON muscle contraction is instantly initiated.

up to two unsupervised training sessions per week, performing linear running, sprinting, twisting movements and jumping; during these sessions, the use of the ball was not allowed. The duration of the first unsupervised training sessions was 10 minutes; if no adverse events occurred, the subject was allowed to increase the duration of the subsequent session by 10 minutes. Duration increments were allowed in order to reach a maximum session length of 40 minutes. In addition, subjects were required to limit the exercise intensity during the unsupervised training sessions. In particular, the perceived exertion should have been lesser than 3/10 (moderate exertion) referring to the Borg CR-10 Scale, which is commonly used for rating the perceived exertion in male soccer players.<sup>39</sup>

## PHASE 3

The goal was to restore a level of physical performance sufficient for participating consistently in subsequent full training sessions as well as soccer matches. The endeavors started in phase 2 were continued, while increasing the sessions load. Each session lasted up to 40 minutes, and was performed twice a week. In order to achieve the goal of this phase and complete the APT program, preliminary observations carried out by our team suggested that the player was required to obtain

TABLE III.—*Baseline characteristics of the participants.*

	Group A	Group B	P value
Age (years) (mean±SD)	26.9±4.5	25.2±4.9	0.384
Stature (cm) (mean±SD)	176.3±7.9	180.7±7.8	0.164
Body mass (kg) (mean±SD)	74.5±8.3	73.4±5.7	0.816
Position			
Goalkeeper	1	1	
Defender	2	5	
Midfielder	3	4	
Striker	5	3	
Dominant foot			
Right	7	11	
Left	4	2	
Athletic activity/week			
<6 hours	1	2	
>6, <10 hours	7	7	
>10 hours	3	4	
Activity status			
Normal	5	6	
Restricted	3	3	
Suspended	3	4	
Duration of the symptoms			
0-4 weeks	5	6	
4-10 weeks	4	3	
10-26 weeks	2	3	
>26 weeks	0	1	
Groin pain			
First case	0	3	
Recurrent	11	10	
ALERGP laterality			
Right	7	7	
Left	1	2	
Bilateral	3	4	

ALERGP: *adductor longus* enthesopathy-related groin pain.

at least 80 points on the PSFS, assigning each of the sport specific and non-sport specific activities a score of  $\geq 8$ . We did not set a “complete recovery” threshold (100/100) because this would have exponentially delayed the restart of individual soccer activities, conceivably impairing the compliance to the study protocol and increasing dropout.

During phase 3, subjects were allowed to perform two unsupervised soccer-specific training sessions per week, the maximal duration of which was set as 60 minutes. Similar to phase 2, the maximal duration of the first unsupervised training sessions was 20 minutes; if no adverse events occurred, subjects were allowed to increase the duration of the subsequent session by 20 minutes. Also, the perceived exertion of each session was required to be equal or lesser than 5/10 (hard exertion) referring to the Borg CR-10 Scale.<sup>39</sup> During these

soccer-specific training sessions, subjects were allowed to perform passing and kicking as well as running, sprinting, twisting movements and jumping.

#### FOLLOW-UP

From the end of APT program to the end of the follow-up period (6 months), subjects were allowed to perform up to 3 soccer-specific training sessions (duration: 60 minutes) and one official game every week.

#### Statistical analysis

Data are reported as means±standard deviation (SD). The distribution of quantitative variables was tested for normality using the Kolmogorov-Smirnov Test with the Lilliefors correction to apply a parametric or non-parametric test for group comparison. Since the assumption of normality distribution for the investigated variables was not met, the differences between independent samples were analyzed using the non-parametric Mann-Whitney *U* test, and the differences between related samples were analyzed using the non-parametric Friedman Test and Kendall Coefficient of concordance. Alpha level for all of these analyses was set at  $P < 0.05$  (two-tail test). Data were analyzed using SPSS 13.0 (SPSS Inc., Chicago, IL, USA).

## Results

#### Characteristics of the participants

Group A and B presented similar characteristics at baseline. Age, stature and body mass were not significantly different between the two groups (Table III). Also, when the medical interview occurred, soccer-related activities were already restricted or suspended for 6 players (group A) and 7 players (group B). In addition, GP was recurrent in all group A subjects and in 10 out of 13 players enrolled in group B.

#### Pain and functional assessments

Both Groups significantly improved pain and functional scores after treatment ( $P < 0.001$ , Table IV). Furthermore, NRS<sub>palp</sub>, NRS<sub>contr</sub>, and PSFS values recorded after treatment were similar to those recorded throughout the follow-up in both groups ( $P > 0.05$ ).

TABLE IV.—Numeric Rating Scale (NRS) and Patient Specific Functional Scale (PSFS) values registered at the end of treatment and during the follow-up (2, 4, and 6 months).

		Pre	End	2 months	4 months	6 months	Time	Group	Time x group
NRS <sub>palp</sub>	Group A	7.5±1.9 #	1.6±1.1	0.7±0.8 **	1.0±0.9 **	1.1±0.9	<0.001	0.010	0.457
	Group B	8.1±1.9 #	2.5±1.5	2.4±1.3	2.3±0.9	2.0±1.5			
NRS <sub>contr</sub>	Group A	8.5±1.4 #	1.3±0.9 *	1.3±1.1 *	0.7±0.7 *	0.5±0.7 *	<0.001	0.011	0.013
	Group B	8.0±1.6 #	2.2±1.7	2.8±1.6	2.2±1.4	1.6±1.3			
PSFS	Group A	55.5±22.2 #	91.6±3.8	93.7±3.6	93.8±4.2	95.4±4.1	<0.001	0.093	0.200
	Group B	56.7±20.6 #	87.5±5.6	81.5±10.8	86.3±7.5	89.9±6.8			

NRS<sub>palp</sub>: Numeric Rating Scale: pain upon palpation of the insertion of the adductor longus. Scale: 0-10; lower score indicates better outcome.  
 NRS<sub>contr</sub>: Numeric Rating Scale: pain upon bilateral isometric adductor longus contraction against resistance. Scale: 0-10; lower score indicates better outcome.  
 PSFS: Patient Specific Functional Scale: 0-100; higher score indicates better outcome.  
 # Time effects. Values recorded at Pre were significantly different (P<0.01) than those recorded at the other time points; \*Significant differences between the two groups; \*P<0.05; \*\*P<0.01.

TABLE V.—Active physical therapy program duration.

	Group A	Group B	P value
Phase 1 (days)	11.9±4.7	20.7±9.3	0.048
Phase 2 (days)	14.8±4.8	16.0±4.2	0.948
Phase 3 (days)	11.0±3.8	12.7±3.3	0.512
Total duration (days)	37.9±8.5	48.8±9.4	0.098

When comparing the two groups, baseline values of NRS<sub>palp</sub> and NRS<sub>contr</sub> were also similar between group A and B (P=0.442 and P=0.505, respectively; Table IV). However, at the end of the APT program, NRS<sub>contr</sub> was significantly lower in group A (0.9 points, P=0.047). Lower NRS<sub>contr</sub> values in group A were also recorded at the three follow-up time points (P<0.05). Furthermore, time x group interaction was also significant for this parameter (P=0.013, Table IV). NRS<sub>palp</sub> showed a trend similar to NRS<sub>contr</sub>, with values that tended to be lower in group A than group B at the end of treatment and follow-up (Table IV); however, statistical significance was achieved only at the 2- and 4-month follow-up (P=0.003 and P=0.005, respectively).

On the other hand, no significant difference for PSFS between the two groups was found (P=0.093, Table IV). However, while the PSFS baseline value was very similar between group A and B (55.5±22.2 and 56.7±20.6, respectively), it tended to be greater in group A after treatment and throughout the follow-up by 7.8±3.8%.

It is also worth noting that the duration of Phase 1 was on average 8.8 days shorter in group A (P=0.048). The same trend, without statistical significance, was also shown by Phase 2, 3 and total duration (Table V).

## Discussion

This study investigated the therapeutic utility of the EPI® technique in combination with a standardized APT program to treat ALERGP in non-professional soccer players. The assessment of pain- and functional-related outcomes in the experimental group (A), who underwent the APT program in combination with EPI® treatment, and in the control group (B), who underwent the APT program only, revealed that: 1) both groups significantly improved pain and functional scores after treatment and maintained this therapeutic result throughout the 6 months after treatment; 2) the combined intervention of APT program and EPI® ensured a greater and faster reduction of pain compared to the APT programme alone; 3) functional recovery was not significantly different between the two groups, although it tended to be greater in group A after the treatment and throughout the follow-up.

### *APT program with and without EPI® effectively reduced pain and improved functional recovery*

High quality studies on non-surgical treatment of long-standing adductor-related GP are rather scanty.<sup>40</sup> For example, Hölmich *et al.*<sup>19</sup> showed that 79% of the patients with adductor-related GP that were treated with exercise therapy (static and dynamic exercises aimed to improve strength and coordination of the pelvic muscles) resumed their usual physical activity without symptoms. On the other hand, in the study conducted by Weir *et al.*,<sup>24</sup> the success rate of an active physiotherapy programme aimed at the strengthening of adduc-

tor and core muscles, associated to a return-to-running programme, decreased to 50%. The present study supports the view that an active physiotherapy programme that promotes significant eccentric muscle contraction of the AL via isoinertial eccentric training is conceivably a valuable intervention for long-lasting pain reduction and functional improvement. Indeed, both group A and B significantly improved pain and functional scores after the treatment. Generally, the time course of these improvements throughout the ATP program was related to the initial GP symptoms of each individual: the more severe the symptoms, the longer the duration phases. Also, pain and functional scores were similar at the end of the ATP program and throughout the subsequent 6-month follow-up.

The positive effects of active physiotherapy on adductor-related GP can be related to the connective tissue remodeling that occurs physiologically as a result of the mechanical stimulation exerted by the exercise.<sup>38, 41</sup> In particular, Apostolakos *et al.*<sup>12</sup> emphasized that biological factors are important for the proper modulation and regulation of collagen production, while mechanical stimuli are crucial for the proper collagen fibers orientation; thus, both factors are essential for the proper healing of the degenerated enthesis. For this reason, eccentric exercise represents one of the most considered therapeutic solutions in the treatment of collagen-rich tissues pathologies,<sup>38, 41-43</sup> and isoinertial eccentric training one of the effective methods to perform eccentric exercise.<sup>27, 36, 37</sup>

*The integration of EPI® and APT interventions promoted greater and faster pain reduction compared to APT intervention alone*

The pain-related clinical testing proposed in the present study showed substantial differences between group A and group B after the treatment and during the 6-month follow up. In particular, the scores of the active test form proposed in the present study (NRScontr) were significantly lower in group A than group B at the end of the treatment and for the entire duration of the follow-up. The “time x group” interaction was also significant for this parameter. In addition, NRSpalp values tended also to be lower in Group A after the treatment, and significantly lower at the 2-month and 4-month follow up. Interestingly, Mosler *et al.*<sup>44</sup> supported the view

that NRScontr is better than NRSpalp for evaluating and quantifying GP in athletes.

The relevant effect of EPI® treatment integration with the APT intervention on GP was also underlined by the fact that the duration of phase I of the APT programme, which was focused on pain reduction, was significantly shorter (-8.8 days) in group A than in group B. These results support the view that the combination of EPI® and APT interventions was more effective than APT intervention alone for reducing AL enthesopathy-related symptoms. It is plausible that EPI® electrolytic action promoted the removal of excessive deposits of connective tissue (fibrosis), so decreasing the tendon tissue tension<sup>28</sup> and consequently reducing GP. It is worth noting that EPI® intervention initially induces a local and controlled inflammatory process that subsequently promotes the histological enthesis healing process,<sup>28</sup> the duration of which is reported to be longer than 14 days.<sup>12</sup> Hence, a proper protocol of active exercises should be proposed as a parallel intervention to the EPI® treatment in order to ensure that the new production of collagen (resulting from the inflammatory process) develops adequately from a biomechanical point of view.<sup>40</sup> With this respect, the association of EPI® intervention and isoinertial eccentric exercises has already produced encouraging results in the treatment of patellar tendinopathy, and in particular for the tendon tissue repair.<sup>26, 27</sup>

*Effects of EPI® intervention on functional recovery*

In the present study, functional recovery was evaluated by PSFS, which consisted of 10 motor tasks (see Methods) that did not require a selective, sustained and maximal AL muscle contraction. For example, maximal effort soccer kick requires a substantial level of AL activation during a limited part of the kicking swing phase (30% to 45%);<sup>45</sup> furthermore, AL activation is primarily aimed at controlling the hip extension rather than contributing substantially to hip flexion and to completing this complex motor task.<sup>45</sup> In addition, Delmore *et al.*<sup>46</sup> underlined that AL activation intensity recorded by EMG during twisting movements was about half of that observed during Adductor Squeeze Test. In the present study, the experimental group that underwent EPI® intervention and APT programme tended to achieve greater functional recovery after treatment and throughout the follow up (+7.8±3.8%) compared to the control

group that underwent APT programme only. However, this difference was not statistically significant. The fact that PSFS lacks in motor tasks that specifically and substantially involve AL activation is conceivably one of the main causes of this finding. The total duration of the treatment was also not significantly different between the two groups, although it tended to be shorter (-10.9 days) in group A. These data suggest that further studies are required to better assess the effectiveness of EPI® treatment on functional recovery in soccer players suffering from ALerGP. It is also worth noting that an intrinsic limit of the non-surgical treatments is that they reduce only to some extent the anatomical alterations of the enthesis. Therefore, while the functional recovery and symptoms reduction can be achieved by these non-surgical treatments, the connective tissue alteration often persists,<sup>15</sup> even in asymptomatic patients.<sup>17</sup> As a consequence, these residual anatomical alterations of the enthesis might result more likely in a premorbid condition. From this perspective, further studies should investigate whether the substantial reduction of the enthesis anatomical alteration brought about by EPI® intervention may eliminate or reduce such premorbid condition.

#### Limitations of the study

One of the limitations of this study is the lack of a graduation in the severity of the ultrasound imaging of the proximal tendon of the AL: we differentiated between “tendons with anatomical changes” and “healthy tendons”. However, we hypothesize that a worse ultrasound image could potentially be associated with a lower expectation of therapeutic success, regardless of the intervention. In addition: 1) the EPI® intervention protocol lacks validation (the technique has recently been developed); 2) research participants were not blinded with respect to the treatment received; thus, placebo effect could have played a role in the subjective scoring, especially in the earlier stage of the study protocol. On the other hand, it is less likely that any eventual EPI®-related placebo effect could have lasted throughout the follow-up; 3) the copresence of GP secondary clinical patterns (*i.e.* iliopsoas-related GP, *rectus abdominis*-related GP) or comorbidity (snapping *iliopsoas*, hip arthrosis, ilioinguinal nerve entrapment) could have potentially played the role of confounding variables.

Finally, 5) the subjects of this study resumed independent soccer-related activities without supervision after the end of the treatment. So, different factors such as amount and characteristics of the physical activity performed by each individual could also have influenced the follow-up results.

#### Conclusions

EPI® treatment in association with active physiotherapy ensured a greater and more rapid reduction of pain and tended to promote greater functional recovery in soccer players with ALerGP compared to active physiotherapy only. This positive therapeutic result lasted for at least 6 months after the end of the treatment. This finding, together with the fact that EPI® treatment is minimally invasive and was overall well tolerated by the patients, support the combined use of EPI® and active physiotherapy in soccer players with GP syndrome. Further studies on the effects of EPI® treatment on functional recovery in ALerGP and on clinical conditions similar to ALerGP (*i.e.* *rectus abdominis* enthesopathy and tendinopathy, *gracilis* enthesopathy, degenerative pubic symphysis, *iliopsoas* syndrome, *rectus femoris* apophysitis) are needed to gain more insight into the effectiveness of EPI® treatment on GP syndromes.

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