EFFICIENCY of the SHORTYSTRAP in the TREATMENT of GROIN PAIN

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Introduction:

Groin pain is common, mainly in males [1-5], in many sports, in particular in team sports, notably football. According to studies, groin pain affects 5 to 18 % of athletes, all sports combined [8, 9], and 58 % of footballers have a history of groin pain [10]. It is all the more lengthy and difficult to treat that it is diagnosed late [1, 6–8]. We also know that this pathology has a high level of recurrence [5, 11]. This can lead to the stopping of the physical activity for several months and a requirement for lengthy physiotherapy, or even surgery in some cases.

The device named "Shortystrap" is an elastic compression device made of a tight pair of shorts, similar to those worn by cyclists, on which are sewn two elastic straps that tightly hug the lower limbs and induce an adductor effect of the lower limbs (Figure 1). It was designed with the goal of avoiding the stopping of sporting activities by reducing or even annihilating the pain. It is manufactured and distributed by the PHILAU SPORT company.

The first testimonies from Shortystrap wearers reveal a sharp decrease in groin-related pain during the practice of the sport while enabling the physical activity to be continued. However, no studies have yet been published to evaluate this external device.

The main objective of this study was to evaluate the efficacy of the Shortystrap device in athletes presenting with a groin pain in terms of maintaining a sporting activity.

The secondary objective was to evaluate the progression of pain as a function of time when using the Shortystrap device.

Materials and method:

Study population:

It is a prospective, monocentre, Phase 2, non controlled, non randomised, open-label study on a single group of patients.

The included population were males aged between 18 and 50 years who regularly practise a team sport (≥ 3 hours per week) involving a large portion of running (football, rugby, etc.), and who present with groin pain which appeared at least 4 weeks prior while practising their sport and who are consulting about it for the first time.

The following were excluded: professional athletes, athletes having received medical treatment in the form of anti-inflammatories and rest, cyclists, athletes presenting with another pahthology requiring NSAIs, patients allergic to neoprene, patients presenting with a contraindication to MRIs (claustrophobia, any metallic devices, pace-maker, etc.), patients in whom the MRI led to a differential groin pain diagnosis (stress fracture, coxopathy, etc.), patients simultaneously participating in other biomedical research and patients under legal protection.

Patient follow-up:

Patients were recruited at the end of a consultation with a sports physician. If the patient met the inclusion criteria, he was then directed to the sports medicine unit of the Rennes CHU university hospital for consultation with the three physicians participating in the study for the inclusion visit. During this inclusion visit (D0), the study was explained, the inclusion and non-inclusion criteria were checked and the informed consent was collected. A clinical examination was conducted to confirm the groin pain. The Shortystrap was tried on, the adductor effect was tested, and pain was evaluated during the last physical activity session.

An MRI of the pubic region was systematically performed to rule out any differential diagnoses.

The Shortystrap was used at each sports session. Starting at the first session, the adductor effect and the evaluation of pain during activity were rercorded using a questionnaire filled in at home by the patient (DRS0).
Two follow-up visits were scheduled 15 days (DRS15) and 30 days (DRS30) after resuming the sport with the device. A clinical examination was conducted, the Shortystrap's adductor effect was verified and the pain was evaluated.
A last pain evaluation was performed via phone consultation or via email 60 days after resuming the sport with the device (DRS60).
The adverse events were collected at each stage of the follow-up.

During this protocol, non-steroidal anti-inflammatories, infiltrations and physiotherapy sessions were not allowed. Only step 1 and step 2 analgesic treatments were allowed.

Measuring instruments:

Pain was evaluated using two separate scores. The Ferretti scale is a hetero-evaluation pain scale which the physician uses to evaluate the patient's pain from 0 to 5 (0: No pain; 1: Pain only felt after intense exercise, with no impact on physical and sporting activities; 2: Pain during warm-up, disappears then re-appears after exercise, limits activities; 3: Pain increases when sport is practised; 4: Pain limits the level of practice; 5 : Permanent pain, sport is stopped).
The Visual Analog Scale (VAS) is a self-evaluation pain scale which the patient can use to evaluate their own pain from 0 to 10 (0: No pain; 10: Worst imaginable pain).

Statistical analyses:

According to the exact method described by A'hern [12], 50 patients are to be included in order to be able to determine if the minimum required efficacy is plausible based on what is observed in clinical practice. The theoretical success threshold being 34, the device will be considered efficacious if the observed number of successes is greater or equal to 34.
Success was defined as a patient with a Ferretti score of less than 3 at D15.
The main endpoint was the evaluation of sporting practice-related pain at DRS15 using the Ferretti scale.
The secondary endpoint was the evaluation of the evolution of pain between D0 and DRS60 using the VAS.
The evolution of the Ferretti score between the 3 visits (D0, DRS15 and DRS30) was analysed using a generalised linear model (GEE: Generalized Estimating Equations), taking this score as an ordinal qualitative variable.
The evolution of the VAS score between the 5 timepoints (D0, DRS0, DRS15, DRS30 and DRS60) was analysed using an analysis of variance on repeated measurements, taking this score as a quantitative variable.
The VAS scores were also compared to 2 by 2 as a function of collection time using Fisher tests.

Based on VAS scores at D0, 3 classes were created corresponding to the tertiles: VAS <6 (n1=15), 6<=VAS<8 (n2=16) and VAS>=8 (n3=16). It was in this way possible to adjust the model based on the VAS class at D0. These classes also helped to visualise on a graph the evolution of the VAS scores for these 3 groups of patients (Figure 3).
The data were entered using Epidata softwares and the statistical analyses were conducted with the SAS software (version 9.3)

Results:

The inclusion period extended from 12/04/2013 to 26/08/2015. A total of 49 patients were included in the study. In 1 patient, a differential diagnosis of groin pain was made further to the MRI and 1 patient was lost to follow-up prior to the DRS15 visit. The analysis therefore covered 47 patients.

Concerning the group's characteristics, the mean age was 29 years (minimum: 18.3; maximum: 50.1; standard deviation: 6.7). The groin pain had been progressing for an average of 10.2 weeks (minimum: 4; maximum: 70.2; standard deviation: 14.1). The most represented sports were football (n=43 patients or 91.5 %), rugby (n=1 or 2.1 %), handball (n=1 or 2.1 %), roller hockey (n=1 or 2.1 %) and running (n=1 or 2.1 %). The noteworthy medical histories reported featured 3 knee ligamentoplasties and 1 bilateral inguinal hernia repair by plate.

At D0, 11 of the 47 patients had a Ferretti score strictly lower than 3 (Table 1).

At DRS15, 41 had a Ferretti score strictly lower than 3 (Table 2). The theoretical success threshold for this study which was set to 34 patients has therefore been reached.
As for progress, the Ferretti score was lower at DRS15 than at D0 in 40 of the 47 patients (87%), and lower or stable stable in 44 of the 47 patients (96%). For 2 patients (4%), the Ferretti score was higher (Table 3). At DRS30, the Ferretti score was lower than at DRS15 in 14 of the 47 patients (30%), and lower or stable in 39 of the 47 patients (83%). For 8 patients (17%), the Ferretti score was higher (Table 4).
The multivariate analysis of the Ferretti score found a significant difference between the Ferretti scores evaluated at the 3 timepoints ($p<0.0001$). The figures 2 and 3 represent respectively the evolution of the VAS score as a function of time and the progression of the VAS score as a function of the VAS class at D0.The multivariate analysis of the progression of the VAS score found a significant difference between the VAS scores at the 5 timepoints ($p<0.0001$), as well as between the 3 VAS D0-score classes ($p=0.0005$).
There are also significant differences between D0 and DRS0 ($p<0.0001$), between DRS0 and DRS15 ($p<0.0001$), and between DRS30 and DRS60 ($p=0.0017$), while no significant differences were found between DRS15 and DRS30 ($p=0.4601$).

Ten of the 47 patients experienced an increase of the Ferretti score at DRS15 and/or DRS30 (2 between D0 and DRS15, and 8 between DRS15 and DRS30). Among these 10 patients, none saw their VAS score worsen between D0 and DRS15, but 9 saw their VAS score worsen between DRS15 and DRS30. No significant link could be identified between the increased Ferretti scores and the clinical examination data.

Regarding adverse events, 2 intrinsic muscle lesions of the adductors, 2 ankle sprains and 1 intrinsic muscle lesions of the hamstrings were reported. No serious adverse event was reported.

Discussion:

This study provides new arguments in favour of a new therapeutic option in the treatment of groin pain. The main objective was to evaluate the efficacy of the Shortystrap device using the Ferretti scale in athletes presenting with a groin pain in terms of maintaining a sporting activity. This work provided objective data on its efficacy at D15. Additionally, an improvement or stabilisation was noted in more than 80 % of patients beyond D15.

Concerning the secondary endpoint which was to evaluate the progression of pain as a function of time, a tendency towards improvement was also reported, with significant gains at the time of implementing the Shortystrap and after 15 days of physical activity, regardless of the initial VAS value.

It was also reported that of the patients who saw a their Ferretti score worsen, none experienced a worsening of their VAS score between D0 and DRS15, however 9 saw it worsen thereafter. It is interesting to note that there is one – larger – group that responds and one group that does not respond. Where the Shortystrap has a beneficial action, it is observed within the first 15 days of wearing the device, meaning it can be fairly quick to decide whether there is value or not in the use of the Shortystrap as part of the overall care of the patient.

Literature data typically subdivide groin pain into 3 diagnosis groups, namely the symphyseal pathology group, the adductor pathology group and the abdominal wall pathology group [13, 14]. These 3 forms can be entangled. In our study, the data reported from the clinical examination at inclusion could not distinguish between the different forms of groin pain. This may be one of the explanations as to why some patients, not many, did not experience any improvement when wearing the Shortystrap. Indeed, it is easy to imagine that one pathology group may not respond to the effects of the device. Other studies on the efficacy of the Shortystrap according to pathological form is needed to better direct its indication.

Another limit of this study is that it was not possible to perform it against a control group. Unfortunately, this could not be implemented as a result of the Opinion returned by the Committee on the protection of individuals.

This study was the first to evaluate the efficacy of the Shortystrap in the treatment of groin pain. These results are encouraging and incite further evaluation of the Shortystrap, notably against a control group.

The literature review by King in 2015 [15], highlighted fairly long absences from the fields, ranging from 7.2 to 23.1 weeks, depending on the pathological form and the treatment type, i.e physiotherapy vs surgery. Based on these delays, there may value in offering the Shortystrap which seems to offer fairly rapid efficacy, as our study shows, and prevents from having to stop the sporting activity. Its place within therapeutic care however remains to be defined.

The two elastic straps on the Shortystrap create an adductor effect on the lower limbs. However no studies on the biomechanical analysis of the effect of wearing the Shortystrap, or on how running is modified, have yet been published. This would also be of interest in order to better understand the mechanisms of action.

Conclusion:

This study provides new arguments in favour of a new therapeutic option in the treatment of groin pain, in particular by avoiding the stopping of the sport. These results are encouraging and incite further evaluation of the Shortystrap, in order to define its indication and its place within therapeutic care. Conducting an evaluation of the biomechanical effect of wearing the Shortystrap would also be of interest to better understand its mechanisms of action.

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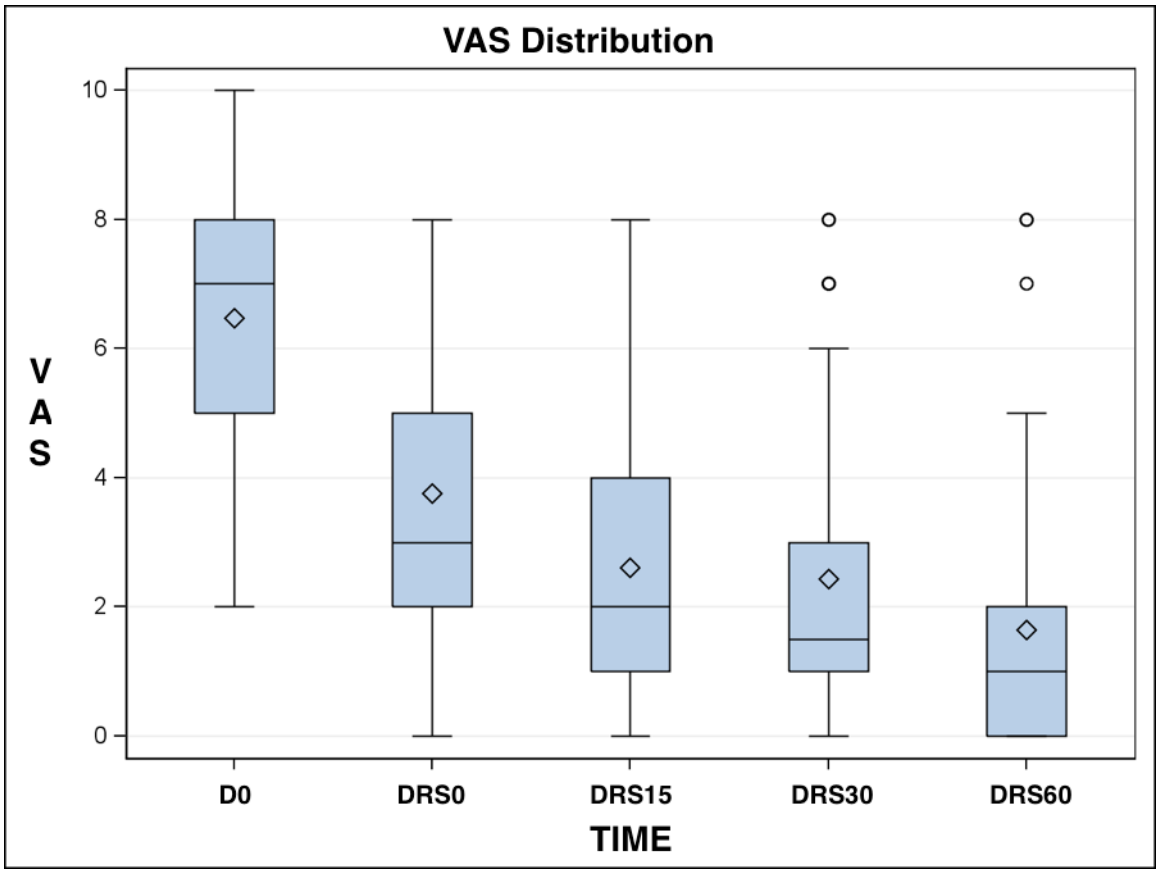
Abstract :

The main objective of this study was to evaluate the efficacy in maintaining a sporting activity in athletes with groin pain of an elastic compression device called Shortystrap, which made of a tight pair of shorts, similar to those worn by cyclists, on which are sewn two elastic straps that tightly hug the lower limbs and induce an adductor effect of the lower limbs.
It is a prospective, monocentre, non controlled, non randomised, open-label study on a single group of men aged between 18 and 50 years who regularly practise a team sport involving a large portion of running, and who present with a groin pain which appeared at least 4 weeks prior while practising their sport.
The Shortystrap was used at each sports session after the inclusion. The maintaining a sporting activity by the Ferretti scale and the evaluation of the pain were collected for 60 days.
The primary outcome was the evaluation of sporting practice-related pain at 15 days of use of the shortystrap by the Ferretti scale. At that time, 41 patients had a Ferretti score strictly lower than 3. The theoretical success threshold according to the exact method described by A'hern which was set to 34 patients has therefore been reached.
Concerning the evolution of pain as a function of time, a tendency towards improvement was also reported, with a significant gains at the time of implementing the shortystrap and after 15 days of physical activity.
This study provides new arguments in favour of a new therapeutic option in the treatment of groin pain.

Figure 1: The medical device under study: “Shortystrap"

Figure 2 : Evolution of the VAS score as a function of time (box-and-whisker plot)



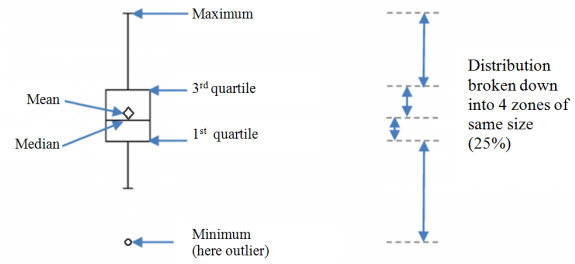


Figure 3 : Progression of the VAS score as a function of the VAS class at D0

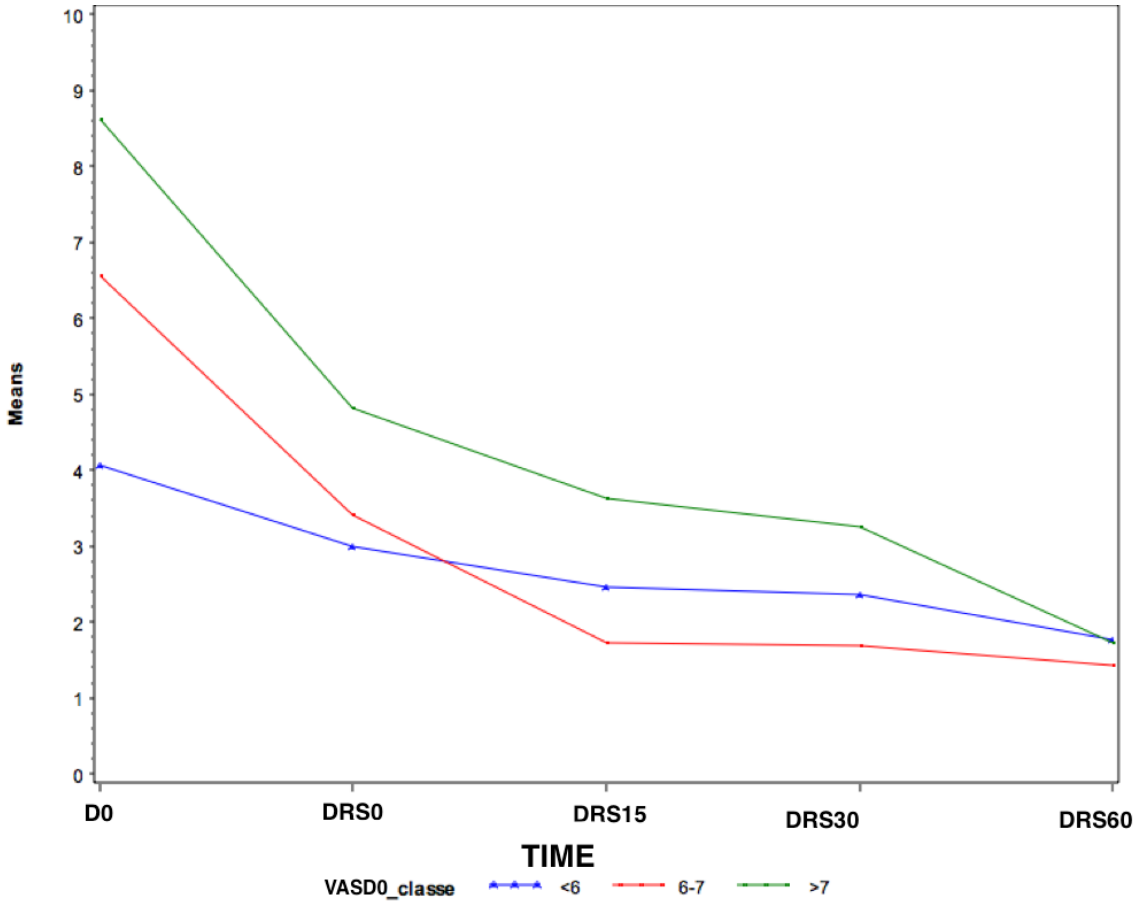


Table 1: Evaluation of the Ferretti score at D0

Evaluation of the Ferretti score at D0				
D0	**Frequency**	**Percentage**	**Cumulative frequency**	**Cumulative percentage**
0	0	0	0	0
1	3	6.52	3	6.52
2	8	17.39	11	23.91
3	15	32.61	26	56.52
4	15	32.61	41	89.13
5	5	10.87	46	100.00

Table 2 : Evaluation of the Ferretti score at DRS15

Evaluation of the Ferretti score at DRS15				
DRS15	**Frequency**	**Percentage**	**Cumulative frequency**	**Cumulative percentage**
0	8	17.02	8	17.02
1	23	48.94	31	65.96
2	10	21.28	41	42
3	2	4.26	43	91.49
4	4	8.51	47	100.00
5	0	0	47	100.00

Table 3 : Difference in Ferretti scores between DRS15 and D0

Difference in Ferretti scores between D0 and DRS15				
DRS15 - D0	**Frequency**	**Percentage**	**Cumulative frequency**	**Cumulative percentage**
-5	1	2.17	1	2.17
-4	3	6.52	4	8.70
-3	9	19.57	13	28.26
-2	18	39.13	31	67.39
-1	9	19.57	40	86.96
0	4	8.70	44	95.65
1	1	2.17	45	97.83
3	1	2.17	46	100.00

Table 4 : Difference in Ferretti scores between DRS30 and DRS15

Difference in Ferretti scores between DRS30 and DRS15				
DRS30 - DRS15	**Frequency**	**Percentage**	**Cumulative frequency**	**Cumulative percentage**
-4	1	2.13	1	2.13
-3	1	2.13	2	4.26
-2	2	4.26	4	8.51
-1	10	21.28	14	29.79
0	25	53.19	39	82.98
1	2	4.26	41	87.23
2	4	8.51	45	95.74
3	2	4.26	47	100.00