

# EVALUATING THE INJURY RISK IN FOOTBALL BY ASSESSING THE HAMSTRINGS ARCHITECTURAL AND STRUCTURAL CHARACTERISTICS

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## LIST OF ABBREVIATIONS

AA: aponeurosis angle ACL: anterior cruciate ligament AD: Amber Daver ADC: Amber De Coessemaeker BFIh: biceps Femoris long head CI: confidence interval FL: fascicle length HSI: hamstring strain injury MD: mean difference MT: muscle thickness NHE: Nordic hamstring exercise OR: odds ratio PA: pennation angle RR: relative risk RTP: return to play SDC: Sofie De Clerck ST: semitendinosus US: ultrasound imaging



### **ABSTRACT**

**Objective:** The objective of this study was to evaluate the risk of hamstring strain injury (HSI) by assessing the Biceps Femoris long head (BFIh) and Semitendinosus (ST) architectural and structural characteristics (fascicle length, muscle thickness and pennation angle) in male football players. However, due to the lack of HSI occurrence during the football season 2018-2019, the association between lower limb injury incidence and muscle architecture of BFIh and ST was examined. Next to this prospective research, this study aimed to examine the association between hamstring injury history and retrospective parameters.

<u>Method:</u> Non-elite football players (n=49) participated in the study. The subjects completed a retrospective injury questionnaire that collected demographic data, sport-related data and medical and sport-related injury history (especially HSI). Fascicle length, muscle thickness and pennation angle from the BFIh and ST were determined using ultrasonography (US) at the beginning of preseason. The occurrences of HSI and other injuries were recorded via a monthly questionnaire. Relative risk (RR) was determined for univariate data, and logistic regressions were employed for multivariate data.

**<u>Results</u>**: Twenty-one out of the 49 (42,9%) participants sustained a football related lower limb injury during the first part of the 2018-2019 football season. The odds of having a general injury is 12,07 times higher in attackers than midfield players and defenders (p=0,015, 95% CI: 1,628-89,413). Next to the playing position, participants with HSI history were significantly more likely to sustain another injury during follow up (p=0,046). Univariate analyses revealed that participants sustaining a lower limb injury during follow up, demonstrated significantly shorter fascicles (p=0,006) of the ST as well as the muscle thickness of the ST was significantly smaller in this group (p=0,028, MD=0,24, 95% CI: 0,027-0,447). No significant differences in muscle characteristics were found between the previously HSI group and non-HSI group.

**Conclusions:** Position on the field, previous HSI and muscle characteristics (fascicle length and muscle tickness) can contribute to new football related injuries.

Key words: Hamstring strain injury, muscle characteristics, lower limb injury, football players, ultrasonography



## **ABSTRACT - DUTCH**

**Doelstelling:** De doelstelling van dit onderzoek was het risico op een hamstringblessure nagaan door de architecturale en structurele karakteristieken (vezellengte, spierdikte en pennatiehoek) van de Biceps Femoris lange kop (BFlh) en Semitendendinosus (ST) in mannelijke voetbalspelers te onderzoeken. Door het tekort aan nieuwe hamstringblessures bij de deelnemers tijdens het voetbalseizoen 2018-2019, werd de associatie gemaakt tussen nieuwe sport-gerelateerde blessures van de onderste ledematen met de spierkarakteristieken van de BFlh en ST. Naast dit prospectieve onderzoek, bestudeerde deze studie de associatie tussen hamstringblessure historiek en retrospectieve parameters

**Methode:** Niet-professionele voetbalspelers (n=49) namen deel in deze studie. De deelnemers vulden een retrospectieve vragenlijst in welke peilde naar de demografische data, sportgerelateerde data en medische- en sport-gerelateerde blessure verleden (specifiek hamstringblessure verleden). Voor de start van het voetbalseizoen (augustus 2018) werden spiervezellengte, spierdikte en pennatiehoek van de BFIh en ST onderzocht, gebruik makend van ultrasonografie (US). Het optreden van hamstringblessures en andere sport-gerelateerde blessures werd vastgelegd via een maandelijkse vragenlijst. Relatief risico werd bepaald voor univariate data en logistische regressies werden uitgevoerd voor multivariate data.

**Resultaten:** 21 van de 49 deelnemers liepen een sport-gerelateerde blessure op van de onderste ledematen tijdens de eerste helft van het voetbalseizoen. De kans op een nieuwe blessure was 12,07 keer hoger bij aanvallers in vergelijking met middenvelders en verdedigers (p=0,015, 95% CI: 1,628-89,413). Verder bemerkt deze studie dat voetballers met een verleden van een hamstringblessure significant meer kans hadden op een nieuwe blessure tijdens de follow-up (p=0,046). Univariate analyses onthulden dat deelnemers die een letsel aan de onderste ledematen hadden opgelopen tijdens de follow-up, significant kortere spiervezellengtes en kleinere spierdiktes van de ST vertoonden (p=0,028, MD=0,24, 95% CI: 0,027-0,447).

**Conclusie:** Positie op het veld, HSI verleden en spierkarakteristieken (spierdikte en spiervezellengte) kunnen bijdragen tot nieuwe voetbal-gerelateerde blessures.

<u>Sleutelwoorden</u>: Hamstring blessure, spier karakteristieken, onderste lidmaat blessure, voetbalspelers, ultrasonografie



#### **INTRODUCTION**

Hamstring strain injuries (HSI) are the most common muscle injuries in football. In this context 80% of the HSI involve the Biceps Femoris long head (BFIh).<sup>1-4</sup> Next to their high occurrence (12% of all injuries per season, 5-6 injuries per team per season)<sup>5,6</sup> they are associated with astonishing recurrence rates (up to 35% of injuries recur within the same season after Return to Play (RTP)). <sup>7,8</sup> HSI occur mostly during high-speed running activities. In the terminal swing phase of the gait cycle in running, the hamstrings reach their maximum length and are required to eccentrically decelerate the torque towards knee extension and hip flexion.<sup>9</sup> Subsequently, eccentric stress is maximized, putting the hamstring unit at risk of strain injury due to excessive loading. To reduce HSI incidence rates in football players, it is important to acknowledge the possible presence of intrinsic risk factors when customizing prevention programs, next to taking into account the specific injury mechanism (as mentioned above).

Previous research, investigating intrinsic risk profiles in association with running related HSI, has identified several factors associated with an increased HSI risk. These can be categorized in modifiable and non-modifiable risk factors. Increasing age and injury history have been identified as non-modifiable intrinsic risk factors that increase the risk of future HSI in football players. Recently, different studies have focused on changing modifiable risk factors to reduce HSI. Eccentric knee flexor strength, lower limb muscle imbalances and BFIh fascicle length are some of the modifiable risk factors which have been associated with HSI susceptibility repeatedly.<sup>10</sup> Regarding the lower limb muscle imbalances, there is no consistent evidence that lower limb eccentric muscle strength imbalance between the legs (objectified by means of isokinetic dynamometry) increases the risk of HSI. On the other hand, functional eccentric knee flexor weakness, observed during the Nordic Hamstring Exercise (NHE) could be identified as a risk factor for future HSI in football players.<sup>10</sup> Low levels of eccentric hamstring strength may reduce the ability to control the terminal swing phase of the gait cycle and potentially lead to acute injuries.<sup>10</sup> Next to these functional strength deficits, hamstring muscle architecture is believed to play a role in HSI as well. Previous studies investigated the role of BFIh muscle characteristics in the aetiology of HSI in football players. One study reported that shorter BFIh fascicles in the subsequently injured limbs may have increased the susceptibility of the BFIh muscle to injure.<sup>10</sup> Powerful eccentric contractions of the hamstring muscles during the terminal swing phase of high-speed running may damage the shorter fascicles (consisting of fewer sarcomeres in-series) by overstretching these fascicles. Today, research on the correlation between HSI and muscle architecture, such as fascicle length, mainly focusses on



the BFIh. However, there is still a lack of evidence in order to generalize these findings for the Semitendinosus muscle (ST). Therefore, this study will assess the muscle architecture of both these muscles.

Muscle architecture can be assessed with two-dimensional ultrasound imaging (US). In contrast to MRI, US is less expensive, more accessible and more time efficient. Previous studies compared different techniques for muscle architectural determination in a number of muscle groups (from cadaveric samples), including the hamstring muscles.<sup>11,12</sup> From these reports it is clear that US is a reliable and valid technique, in order to determine muscle architecture. This method is able to visualize aponeurosis and pennation angles as well as muscle thickness, which allows deduction of the fascicular length.<sup>13</sup>

A lot of research has been conducted to determine the correlation between HSI and architecture of the hamstrings, where the main focus was on the BFIh. It is unclear if the architecture of the ST contributes as much to HSI as the muscle architecture of the BFIh. Also, most research studied the correlation between muscle architecture and HSI retrospectively. The question if shorter fascicle lengths is a consequence or rather a cause of HSI currently remains unclear. The purpose of this study is to examine how muscle architecture of BFIh and ST (fascicle length, muscle thickness and pennation angle) correlate with the risk of HSI in male football players in a retro- and prospective study design. This study hypothesizes that football players with shorter fascicle lengths and greater pennation angles of both the ST and BFIh have a greater risk of HSI.



#### **METHOD**

#### **Study design**

A retro- and prospective cohort study was performed to evaluate the correlation between muscle architecture and the incidence of HSI in non-elite football players. Following muscle characteristics were measured in the BFIh and ST using US: fascicle length, muscle thickness and pennation angle. US evaluation was performed at the department of physical therapy and motor rehabilitation of the Ghent University, Belgium. It was impossible to blind the researchers because they were involved in both testing and analysing. Ethical approval for the study was given by Ghent University Human Research Ethics Committee (approval number: EC/2018/1409 – Document A, EC/2018/1410 - Amber De Coessemaeker (ADC), EC/2018/1411 - Sofie De Clerck (SDC), EC/2018/1412 - Amber Daver (AD)). The study was performed during the preseason (July 2018- August 2018) of the 2018-2019 Belgian Football competition.

#### **Participants**

Forty-nine male non-elite football players aged 18-30 were included in the study. Participants were personally addressed to participate in this study. E-mailing trainers and coaches of football clubs, visiting football clubs and face to face communication with football players and coaches were the most common ways to recruit possible participants. They were approached independently and provided written, informed consent before collecting any data. The subjects completed a retrospective injury questionnaire that collected demographic data, sport-related data and medical and sport-related injury history (especially HSI). None of the participants performed lower limb strength or flexibility training more than one hour a week. Exclusion criteria included (1) HSI in the last 3 months, (2) low back pain, (3) history of ACL-injury, (4) goalkeepers and (5) the presence of physical injury or complaints at the moment of recruitment. According to these exclusion criteria, football players were in- or excluded in the study. After the testing session, participants were asked to fulfil a monthly questionnaire to report injury due to football activities.



#### Assessment of BFIh and ST architecture

To conduct the measurements of the fascicle length, muscle thickness and pennation angle of both the BFIh and the ST, the method of Timmes et al. was applied.<sup>10</sup> The description of the method is given in the following paragraph.

All assessments were performed with participants in a prone position, the hip in neutral position and the knee fully extended with both malleoli just over the edge of the table so the angle between the feet and the leg remained constant at 90°, as seen in the pictures below (Figure 1 and 2).



Figure 1: Positioning of participant



Figure 2: US imaging

The participants were assessed after a period of inactivity. The scanning site of both the BFIh and ST was determined as the halfway point between the ischial tuberosity and the knee joint fold, along the line of the examined muscle.

Muscle architecture parameters were determined from US taken along the longitudinal axis of the muscle belly using a two-dimensional B-mode ultrasound (TELEMED UAB, US medical systems, Vilnius LT-02189, Lithuania). To acquire US images, the linear array US probe (frequency: 12MHZ, Linear 60 mm, field of view: 59 mm) was placed on the skin over the scanning site, with a layer of conductive gel, aligned longitudinally and perpendicular to the posterior thigh. The examiner ensured minimal pressure on the skin by the probe because this might influence the accuracy of the measurements.<sup>14</sup> Finally, the orientation of the probe was manipulated slightly by the examiner if the superficial and intermediate aponeuroses were not parallel. For each acquired US image (Figure 3 and 4), six points were digitized, as described by Blazevich et al.<sup>15</sup> The following parameters were calculated from the US images: fascicle



length, muscle thickness, pennation angle and aponeurosis angle. A fascicle of interest was outlined and marked on the image (Figure 3 and 4). Muscle thickness was defined as the distance between the superficial and intermediate aponeurosis. The pennation angle was appointed as the angle between the marked fascicle and the intermediate aponeurosis. The aponeurosis angle for both aponeuroses was determined as the angle between the line marked as the aponeurosis and an intersecting horizontal line across the captured image.<sup>12,15</sup> Fascicle length was estimated from the length of the outlined fascicle between the aponeuroses. Because the entire fascicle was not visible in the field of the probe, its length was estimated using the following validated equation from Blazevich et al. and Kellis et al. <sup>12,15</sup>

#### FL=sin (AA+90°)×MT/sin (180° -(AA+180° -PA))

Where FL=fascicle length, AA=aponeurosis angle, MT=muscle thickness, and PA=pennation angle.

Fascicle length was reported in absolute terms (cm). All images were collected and analysed by three researchers (AD, SDC, ADC) who are members of the University of Ghent, department Rehabilitation Sciences and Physiotherapy.



Figure 3: US image of right ST MT: 2,17cm - AA: 5,7°- PA: 6,8°



Figure 4: US image of right BF MT: 2,17cm - AA: 5,7°- PA: 6,8°

MT: (3+4)/2

AA: angle between 1 and 2

PA: angle between 2 and 5



#### Follow up

After the testing session, participating football players were monitored for the registration of injury incidence throughout the first half of the 2018-2019 competition season. During the winter break, prospective data collection was terminated, after which the architectural parameters were assessed on possible associations with injury susceptibility (both retro- and prospectively). For all injuries that occurred, the players completed a standardized injury report to specify details regarding injury mechanism and location. These reports were forwarded to the investigators throughout the first part of the football season.

#### Data analyse

This study included retro- and prospective data collecting activities. To collect the retrospective data, a questionnaire that contains elements about anthropometrics, sport characteristics, training and competition exposure (in hours), injury history and current injuries, was completed by each participant before the testing sessions. During the testing session, several variables were measured based on US. Muscle thickness (cm), pennation angle (°) and aponeurosis angle(°) were objectified on the US images after data acquisition, using the metric US tools in a specific sequence. To determine the fascicle length, reported in absolute terms (cm), the equation of Blazevich et al. was used.<sup>15</sup> These measurements were repeated bilaterally for the ST and BFlh muscle. Prospective data were collected on a monthly basis using online questionnaires. Injury incidence, injury location, type of injury and duration of absence from training or competition (in weeks) were recorded and included in the data collection.

#### Statistical analyses

All statistical analyses were performed using the Statistical Package for the Social Sciences, version 25 (SPSS 25, IBM corporation). Where appropriate, data were screened for normal distribution using the Shapiro-Wilk test and by evaluating the Q-Q plots and histograms. Descriptive statistics of the demographic data are represented in Table 3 (see attachment). Other administrative data, including weekly football exposure (training and competition), alternative sports exposure (e.g. specific strength or participation in alternative sports), level of competition, field position, foot dominance, years of experience, hamstring injury history (year, side) and general injury history, were collected for all participants (Table 3). Statistical analyses were performed both retro- and prospectively. Participants were divided into different groups based on hamstring injury history during prospective monitoring. Univariate analyses were performed to compare the retrospective data between the group with history of HSI and



the non-HSI group, as well as comparing the hamstring architectural and structural characteristics between those groups. Univariate comparisons were undertaken using the Independent-Samples T-test and the Mann-Whitney U-test to determine significance. Because of the small sample size, averages of both limbs were calculated and implemented in the univariate analyses to compare the US measurements between the injured and noninjured group. Subsequently, univariate logistic regressions were performed to clarify the most defining variables that influence the odds of a lower limb injury during the first part of the football season. Variables that showed significance (p<0.05) in the Independent-Samples Ttest and the Mann-Whitney U-test were included in the regression as continuous or dummy independent variables. For the architectural parameters, the same methodological approach for the univariate analyses was used during the logistic regression. The first model included (1) muscle thickness of the ST. (2) player position and (3) hamstring injury history. The second model included (1) muscle fascicle length of ST, (2) player position and (3) hamstring injury history. The third model included (1) the muscle fascicle length of the ST. The Nagelkerke R Square coefficient, specificity and sensitivity were determined to identify the strength of each model with a prospective lower limb injury occurrence.

#### **RESULTS**

#### Retrospective participant and injury details

Forty-nine male football players (age:  $21,6 \pm 1,92$  y, height:  $180,6 \pm 6,38$  cm, weight:  $73,4 \pm 7,23$  kg, BMI:  $22,5 \pm 1,77$ ), competing in the recreational competition series in the East and West of Flanders, were included in this study and assessed before the beginning of the Belgian football competition 2018-2019. Twenty of the 49 participants suffered from a previous HSI in the past 7 years (age:  $21,9 \pm 1,85$ y, height:  $180,2 \pm 7,01$ cm, weight:  $74,9 \pm 6,94$ kg, BMI:  $23,1 \pm 1,82$ ) and 29 did not (age:  $21,5 \pm 1,20$ y, height:  $180,8 \pm 6,02$ cm, weight:  $72,5 \pm 7,39$ kg, BMI:  $22,1 \pm 1,66$ ). There was no significant difference (p>0,05) in anthropometrical parameters between the participants who sustained a previous HSI and those who did not. Player position did differ significantly (p= 0,024) between groups, with less attacking players in the previous non-HSI group (non-injured group: attacker: 13,8%, midfielder: 41,4%, defender 44,8%; history of HSI group: attacker: 40,0%, midfielder 20,0%, defender 40,0%) (Figure 5).







Additionally, the composition of players level in competition in the non-HSI group (1<sup>st</sup>: 13,8%, 2<sup>nd</sup>: 13,8%, 3th: 44,8%, 4<sup>th</sup>27,6%) compared to the group with HSI history (1<sup>st</sup>: 35,0%, 2<sup>nd</sup>: 25,0%, 3th: 15,0%, 4<sup>th</sup>: 25,0%) indicates (p>0,05) that more than 70% of the non-HSI group plays at the lowest two levels (Figure 6). Regarding the football exposure, no significant group differences could be established (p>0,05).





The football players in the non-HSI group had  $13,7 \pm 4,09$  y of experience, participated  $3,7 \pm 1,02$ h/week in football training and  $1,8 \pm 0,43$ h/week in competition. These data are comparable to the previously HSI group where the football players presented  $13,9 \pm 4,79$ y of experience and participated  $3,4 \pm 0,72$ h/week in football training and  $1,8 \pm 0,40$ h/week in competition. Before the testing period, 20 out of 49 participants had suffered from HSI. Six out of 20 hamstring injuries were medical imaging negative strain injuries, 14 participants suffered from an actual hamstring muscle tear. Next to the hamstring injuries, lower limb retrospective injuries were recorded and added to the univariate analyses. Thirty-four out of 49 participants reported having suffered from (any) sports-related musculoskeletal injury in the past.



#### Prospective follow up and injury details

Due to the lack of new HSI occurrence, the link with any lower limb injury during the football season 2018-2019 was examined. To execute the prospective univariate analyses, the division of the injured and non-injured group was based on lower limb new football season injury during the first half of the football competition. Of the 49 participants, 21 participants sustained a football related lower limb injury (42,9%). Attackers (38,1%) and midfield players (38,1%) sustained significantly more lower limb injuries during the first part of the competition season than defenders (23,8%) (p=0,014), as seen in Figure 7. When comparing new season lower limb injury with hamstring injury history, it can be concluded that participants with a hamstring injury history were significantly more likely to sustain another injury during follow up (p=0,046). Within this hamstring injury group, it was established that the lower limb injury risk increased when the timeframe between this study's US investigation and prior HSI was shorter (p=0,005).



Figure 7: Pie chart of position by new lower limb injury

#### Univariate analyses

Retrospective univariate analyses that contains anthropometrical parameters, sport characteristics, training and competition exposure, information about injury history, hamstring architectural and structural characteristics, for both the group with history of HSI and the non-HSI group can be found in table 3. Prospective univariate analyses are based on lower limb injuries the participants sustained during the first part of the season. Next to the parameters of the retrospective analyses, injury characteristics of the lower limb new football season injuries were also included. Within the new lower limb injuries group a distinction was made between participants with or without HSI history. These results can be found in Table 1.



Table 1: Lower limb injuries

NEW LOWER LIMB INJURIES				
Non-HSI history		HSI history		
Type of injury	Amount	Type of injury	Amount	
HSI	2	HSI	2	
Ankle sprain	2	Ankle sprain	3	
MCL strain	1	MCL strain	1	
Pubalgia	2	CAM hip	1	
Quadriceps contusion	1	Fracture metatarsal	2	
		Overload injury of calf	4	
		Quadriceps contusion	1	

#### **BFIh and ST architectural characteristics**

The collected data of the BFIh and ST architectural characteristics in this study are visualised in the box plots below (Figure 8-11). This study found no significant differences between previously HSI group and non-HSI group (p>0,05) regarding muscle characteristics. This result is in contrast to the association between muscle architectural characteristics and new season lower limb injuries where significant differences were found between prospectively lower limb injured and non-injured group (p<0,05). Participants sustaining a lower limb injury during follow up, demonstrated significantly shorter fascicles of the ST than participants remaining injury-free (p=0,006). The muscle thickness of the ST in the prospective injury group was significantly smaller than the muscle thickness in the non-injured group (p=0,028, MD=0,24, 95% CI: 0,027-0,447). Other averages of muscle architectural and structural characteristics were not significantly different between the two groups in the prospective analysis (p>0,05). All parameters can be found in Table 4 (see attachment).









Figure 9: Mean pennation angles



#### Multivariate (of binary) logistic regression

Results of all binary logistic regression models can be found in Table 2. The Nagelkerke R square varied between 22,6% (model 3) and 47,4% (model 1). Model 2, consisting of (1) muscle fascicle length of ST (2) player position and (3) hamstring injury history shows the highest sensitivity (71,4%).





Regression model	P-value	Nagelkerke R square (%)	Model fit	Sensitivity (%)	Specificity (%)
Model 1 Whole model ST MT Players position Hamstring injury history	0,004* 0,015* 0,019*	47,4	0,897	66,7	82,1
Model 2 Whole model ST FL Players position Hamstring injury history	0,009* 0,112 0,029*	45,9	0,807	71,4	82,1
Model 3 Whole model ST FL	0,012*	22,6	0,495	66,7	71,4

Table 2: Binary logistic regression model outputs

\*p<0,05

## BFIh and ST muscle characteristics, participant details and the risk of new index injury

To determine the odds ratio (OR) of sustaining a lower limb injury during follow up, binary logistic regressions were executed in three different models consisting of the independent variables as previously described. The odds of having a lower limb injury is 12,07 times higher in attackers than midfield players and defenders (p=0,015, 95% CI: 1,628-89,413). In comparison to participants without hamstring injury history, participants with a hamstring injury history have a 7,16 times higher OR to sustain a new season lower limb injury (p=0,019, 95% CI: 1,376-37,297). Muscle thickness of the ST has a significant inverse relationship with the incidence of a new lower limb injury (p=0,048, 95% CI: 0,72-0,99). For every 1,0 cm increase in ST muscle thickness, the odds of having a new season lower limb injury are reduced by 96,8%. The same significant relationship was found between a lower limb injury and the fascicle length of the ST. The odds of having a new lower limb injury decreases with 22,8% if the fascicle length of the ST increases with 1,0 cm (p=0,009, 95% CI: 0,635-0,938). The Nagelkerke R square coefficient was calculated to determine the variability of the dependent variable (new season lower limb injury) that is predicted by model 3. A coefficient of 0,226 means that 22,6% of the variability is explained by the average of the ST fascicle length.



## **DISCUSSION**

The purpose of this study was to investigate the correlation between muscle characteristics (. fascicle length, muscle thickness and pennation angle) of both the ST and BFIh and HSI. To the authors knowledge, similar studies have not yet been reported. Previous research showed that athletes with a unilateral history of BFIh strain injury have shorter fascicles lengths and greater pennation angles in the previously injured limb compared to the contralateral limb.<sup>16</sup> It remains unclear whether this can be generalised for the ST. Additionally, no prior work has examined the correlation between overall injury susceptibility and hamstring muscle characteristics in a prospective manner. The intention of this study was to examine how muscle architecture of BFIh and ST correlate with HSI in male football players in a retro- and prospective study design. However due to the lack of new HSI occurrence in this study's cohort, the association between any lower limb injury occurrence during the football season 2018-2019 and muscle architecture of BFIh and ST was examined. Subsequently the hypothesis of this study could not be confirmed, nor denied.

#### Main findings

The main findings of this study were that; (1) no significant differences in muscle characteristics between the previously HSI group and non-HSI group were found; (2) muscle thickness of the ST in the prospective injured group was significantly smaller than the muscle thickness in the non-injured group; (3) participants sustaining an injury during follow up have significantly shorter ST fascicles compared to participants remaining injury-free during follow up; (4) the risk of having a lower limb injury is 12,07 times higher in attackers compared to midfield players and defenders; (5) football players with a previous HSI have a 7,6 higher chance of having a new lower limb injury.

#### Muscle characteristics and hamstring injury history

No significant differences in ST and BFIh structural and architectural characteristics were found between the previously HSI group and non-HSI group in this study. Muscle fascicle length and pennation angle of both hamstring muscles did not differ between the previously HSI and non-HSI group (Table 3). The results of the current study are in contradiction with Timmins et al. regarding the association between muscle characteristics and HSI within the preceding 18 months.<sup>16</sup> In the aforementioned study BFIh fascicles were shorter and pennation angles were larger in the previously injured BF compared to the contralateral



homonymous muscle belly.<sup>16</sup> This architectural difference was suggested to potentially increase the muscle's injury risk, as shorter fascicles imply the presence of fewer in-series sarcomeres which would make the muscle more susceptible to damage caused by powerful eccentric contractions.<sup>16</sup> A number of potential explanations can be applied to illustrate the association between HSI and altered muscle characteristics. Firstly, intramuscular nerve branch damages at the injury site can lead to neuromuscular inhibition whereby shortening of muscle fascicle length appears.<sup>17-19</sup> Secondly, a reduced level of eccentric contraction was noticed in the injured BFIh compared to the non-injured BFIh muscle.<sup>19,20</sup> This reduced activation in combination with avoiding stretch of the injured muscle during the early phase of the rehabilitation can possibly alter muscle structural and architectural characteristics.<sup>18</sup> The current study included 20 participants with a HSI history of which 13 injuries occurred more than two years ago. Muscle characteristics adaptations due to training exposure or other anthropometrical parameters such as growth could be underlying causes that this study could not reproduce the same findings. Subsequently, the theory of Fyfe et al which suggests that reduction in fascicle length persists in participants with HSI history after RTP, could not be confirmed.18

Apart from fascicle length and pennation angle, the present study found no significant differences in muscle thickness of both ST and BFIh between the previously HSI and non-HSI group either. Recently published research shows inconsistent conclusions concerning muscle thickness in participants with HSI history. Timmins et al. reported no findings of associations between muscle thickness and HSI.<sup>10</sup> This could be related to a number of different reasons. Firstly, reductions in muscle thickness can be countered by greater pennation angles in the injured BFIh compared to the contralateral uninjured limb whereby potential muscle atrophy could be masked. Secondly, the alterations of muscle thickness and cross-sectional area due to HSI history may be fluctuating along the length of the muscle belly what could influence the assessments of the muscle thickness. The muscle thickness measurements in this current study could have been performed in a part of the BFlh where muscle atrophy was limited. A more recent investigation also found no evidence of atrophy in previously injured hamstring muscles.<sup>21</sup> In contrast to previous described researches, significant reductions in BFIh volumes and compensatory increasements in BF short head volumes were observed in the injured limb in contrast to the contralateral non-injured limb measured by MRI.<sup>22</sup> Because of the different measurements methods and outcome variables (volume vs muscle thickness), results of this study can not be linked to this current study.



#### Muscle characteristics and new season lower limb injury

Investigating the architectural muscle characteristics in function of overall lower limb injury incidence during the follow up period revealed that ST muscle thickness was significantly associated with the risk of sustaining a lower limb injury during follow up. Specifically, the injury risk appeared to reduce with 96,8% with every 1cm increasement in ST muscle thickness as measured by US. A possible explanation for this finding could be that the maximum torque produced by a muscle is proportional to its physiological cross-sectional area.<sup>23</sup> A greater muscle thickness leads to a greater cross-sectional area and therefore to a higher maximum torque. The capacity to generate a higher torque is suggested to reduce strain and potentially diminish micro traumata caused by intermittent high-intensity exercise. This could render the muscle less susceptible to strain injury. However, the systematic review of Freckleton et al describes that neither concentric, nor eccentric hamstring peak torque is a risk factor for HSI.<sup>24</sup> Another plausible explanation could be that increasements in muscle thickness are considered to represent an increase of myofibrils in parallel, which enables a greater transmission of force developed through the muscle-tendon unit.<sup>25</sup> This could reduce the risk of mechanical damage and therefore reduce the risk of HSI. Further research is needed to confirm this hypothesis.

Next to the ST muscle thickness, the fascicle length was also significantly associated with prospective injury occurrence. Regression analysis demonstrated that the risk of sustaining a lower limb injury during follow up decreased with 22,8% if the fascicle length of the ST increased with 1cm. The study of Alsonso-Fernandez reported changes in the fascicle length of the BFIh after an 8-weeks eccentric training program and a significant reduction in fascicle length after a detraining period of 4weeks.<sup>26</sup> Several authors agreed that the fascicle length increases after a period of eccentric strength training, possibly due to an increase in serial sarcomeres.<sup>26-28</sup> The responses to eccentric training and subsequent detraining may be of interest for the prevention and rehabilitation of injuries to the hamstring muscles as, like the findings in this study stated, shorter fascicles are more prone to injury than longer fascicles. Possessing shorter fascicles has been suggested to increase the likelihood of microscopic muscle damage as a consequence of repetitive eccentric actions and, when coupled with a high frequency of training sessions, may result in an accumulation of damage. Subsequently this might induce premature hamstring muscle fatigue and therefore alter lower limb biomechanics during running activities.<sup>28</sup> These biomechanical alterations could potentially increase the risk of soft tissue sprains and muscle strains in the lower limb during sustained activity. More so, the accumulation of eccentrically induced muscle damage would leave the



muscle more vulnerable to strain injury when it encounters a potentially injurious situation, increasing the probability of re-injury.<sup>28</sup>

The most common new season lower limb injuries in this study were calf strains, ankle sprains and groin injuries (Table 1). The greater part of the injuries in the previously injured (HSI) group were overload injuries of the calf muscle (28,57%). This could be explained by the concept of myofascial chains.<sup>29</sup> Myers et al. described 11 myofascial meridians existing of muscles and fascial tissues that connect distant parts of the body.<sup>30</sup> As a part of the superficial back line, one of the described myofascial meridians, the hamstring muscles and the gastrocnemius muscle are connected by the femur condyles.<sup>30</sup> The study of Cruz-Montecino et al. identified the force transfer between the pelvic movement/hamstrings and the gastrocnemius muscle.<sup>31</sup> Results of this study showed that decrease in hamstring flexibility is related to a lower deep fascia displacement of the gastrocnemius muscle. The effects of eccentric training on muscle characteristics and lower limb flexibility were described by a review of O'Sullivan et al.<sup>32</sup> As a consequence of eccentric training, muscle flexibility increases due to sarcomerogenesis. This statement could be explained by studies included in the review of O'Sullivan et al.<sup>32</sup> Four researches identified significant increases in muscle fascicle length and subsequently more in-series sarcomeres following eccentric training, indicating structural adaptations within the muscle.<sup>15,27,33,34</sup> This explanation can lead to the hypothesis that a lower hamstring flexibility is related to a lower amount of in serie-sarcomeres and decreases in muscle fascicle lengths. This makes the hamstring muscle weak links in superficial back line whereby athletes could be more susceptible for overuse injuries within this myofascial chain, for example calf strains.

Ankle injuries are among the most common in football with previous studies indicating that they account for 11 up to 20% of all injuries.<sup>5</sup> In this study 21,43% of all new lower limb injuries in the previously HSI group were ankle sprains. The following hypothesis could be an explanation: due to smaller muscle thickness and fascicle length in the ST, this muscle has less myofibrils in parallel and less in-series sarcomeres, resulting in respectively less transmission of force and decrease in optimum length for force production, as described previously. Due to this aberrant activation of the ST, excessive load is placed on the BFIh.<sup>35</sup> The BFIh attempts to compensate for the functional deficit of the ST whereas BFIh is less stretch tolerant and less suited to control the hip and knee torques in the end range during running.<sup>35</sup> As a consequence the BFIh has to work harder, which increases the muscle tension. Due to this increase in muscle tension and the attachment of the BFIh on the head of the fibula, the fibula gets pulled upwards, putting the talofibular ligaments and the calcaneofibular



ligament under more tension. This impairs the proprioception, alters the neuromuscular control and increases the incidence of ankle sprains. Further research should be executed to confirm this hypothesis.

The other lower limb injuries are listed in Table 1. The finding that injury history is such a predominant risk factor for muscle strains, demonstrates that thisshould be considered as a risk factor when other variables are studied. Although numerous prospective studies have found an association between low hamstring muscle strength and hamstring injury, injury history has also been associated with low hamstring muscle strength and may be a confounder for new season lower limb injuries.

#### **Practical implications**

Based on the results of this study, it could be suggested that future injury prevention should consider the effect of exercise on muscle characteristics, as these might be related to injury risk. If greater ST muscle thickness and a greater fascicle length are associated with a lower injury risk, then composing a prevention program that alters these muscle characteristics could be of great value. The question remains how preventive training programs may lead to architectural changes and which exercises exactly are best suited to serve these goals. Eccentric hamstring exercise programs, such as the NHE have proven effective in multiple studies.<sup>10,26,36,37</sup> The NHE is able to increase the BFIh fascicle length and thereby decrease the risk of sustaining an injury whereas concentric training of the hamstrings shortens the fascicle length of the BFIh and should not be the key focus. In the study of Alonso Fernandez et al., an 8-week NHE based eccentric training program was followed by male soccer players which resulted in increases of the BFIh fascicle length and muscle thickness.<sup>26</sup> Despite the high-level evidence concerning NHE-programs that would be effective to reduce hamstring injuries, the incidence of hamstring injuries has increased annually by 4% in UEFA professional men football players.<sup>38</sup> It could be stated that long-term compliance of NHE prevention programs is limited in professional and amateur soccer players which lowers the effectiveness of these interventions.<sup>39</sup> One of the main reasons of not consistently implementing NHE to training programs is the lack of sport specificity (eccentric contraction in a shortened position) of these exercises which could be lowering the motivation of players and coaches.<sup>40</sup> It could be suggested that other prevention programs, next to eccentric strength training, can be effective to enhance muscle fascicle length and muscle thickness and subsequently reduce hamstring injuries in soccer players. For example, Bourne et al. reported significant increases in BFIh fascicle length in both eccentric and isometric training



programs.<sup>21</sup> More so, a recent study demonstrated that isometric training has the possibility to enlarge the hamstring endurance capacity (more than eccentric training) and therefore reduce the hamstring injury risk.<sup>41</sup> In contrast to most literature, Van Hooren et al. mentioned a rather predominantly isometric contraction of the hamstrings during the swing phase of the high-speed running.<sup>42</sup> If it could be stated that hamstrings contracts especially isometrically, prevention programs should be implementing isometric exercises to condition the hamstrings for high-speed running.<sup>42</sup> Further research is necessary to explore the pathophysiology of hamstring injuries and to examine the effects of different prevention programs on hamstring muscle architecture and injury incidence. As most studies have focussed on the BFIh architecture and the association with lower limb injuries in general, next to looking at the BFIh and the specific hamstring injury risk) cannot be collided with those of previous work.

#### Exposure training details and risk of injury

In the current study the odds of sustaining a football related injury during follow up were 12,07 times higher in attackers compared to midfield players and defenders. Three previous retrospective investigations reported a greater general injury risk in attackers compared to defenders and goal keepers.<sup>43-45</sup> Most of the studies reported some association between forward position and injury risk, indicating that attackers may be at higher risk of injuries when compared to other playing positions. There are different possible explanations for this finding. Firstly, it has been demonstrated that the majority of football incidents happen in the middefensive zone and in the "core box", i.e. the 2 typical attackers' zones, where most of the duels and tackles may occur. Therefore, attackers may have a higher tendency of sustaining injuries, due to the intensity of match play in the aforementioned playing zones. <sup>46</sup> More so, fast kicking and acceleration/deceleration activities of the attackers may predispose for hamstring muscle injuries, accounting up to 25% of the total lay off time in professional football.<sup>46</sup> Nonetheless, it should be noted that it may be difficult to give a clear cut answer about injury risk and playing position, due to the variability of the playing styles and players at each position.<sup>46</sup>



#### Hamstring injury history and injury susceptibility

The present study findings demonstrated that football players with a history of HSI have a 7,16 times higher chance to sustain a new lower limb injury. These findings are in accordance with what has been reported in former studies, stating that previous HSI are a significant risk factor for new injuries in male football players.<sup>47,48</sup> In the study of Arnason et al, a previous HSI was found to be a strong predictor for a new hamstring injury in the same leg<sup>47</sup>. Sigurdsson et al.<sup>47</sup> discovered that hamstring strains, groin strains, knee sprains, and ankle sprains are the most frequent types of injuries in football. Previous HSI on the same side creates structural muscle changes or scar tissue formation in the muscle and/or tendon caused by inadequate tissue healing, inadequate rehabilitation or premature/unjustified RTP after injury.<sup>47</sup> Due to this inadequate healing is the only reason for re-injury or if inherent characteristics of the subject play a role as well. More research should focus on the recurrence of HSI in sport.<sup>49</sup> Further research has to be conducted to generalize these findings for lower limb injuries.

#### Limitations

Due to the fact that this was the first study investigating US characteristics of both the BFIh and ST muscles in function of (hamstring) injuries in male football players, there are some options for more underlying research. First of all, due to organisational issues, not all US measurements were taken by the same examiner. In general, US has proven to be a reliable and valid method to measure muscle characteristics.<sup>12,50</sup> Despite these conclusions, the reliability depends mostly on the examiner's competence. A change in orientation and rotation of the US probe can result in a 12% difference in reported pennation angle.<sup>13</sup> In future research, measurements should be taken by one examiner only. Secondly, because of the lack of participants who sustained a new HSI, the focus of this study shifted from prospective to retrospective and from HSI to lower limb injury. In the future a larger cohort of participants should be included. Thirdly, the participants who suffered from a previous HSI did not know if this injury occurred in the BFIh or ST. Further research should try to collect information about the location of the HSI to give more precise information about its correlation between muscle architecture and injury incidence. Last, the fascicle length was estimated based on the mathematic formula suggested by Blazevich et al .and Kellis et al. and not measured precisely.<sup>12,15</sup> Therefore, small errors in each of the parameters included could result in fairly



large within-group variability for this outcome measure. These issues should definitely be taken into account when interpreting the present findings.

#### Conclusion

This research intended to give more insight in the correlation between hamstring muscle architecture and HSI in a retro- and prospective manner. Due to a small population the focus of the study shifted and the association between hamstring muscle architecture and lower limb injury incidence was investigated. No significant differences in muscle architectural characteristics were found between the previously HSI group and non-HSI group. Besides this, results demonstrated that increments in ST muscle thickness and fascicle length were significantly associated with lower injury occurrence during follow up. In addition the odds of sustaining any injury during follow were significantly higher in participants playing in attacking positions and in presence of a hamstring injury history.





## **ATTACHMENTS**

#### Table 3: Retrospective data

Variable	Total (n=49):mean	95% CI	Non-injured (n=29):	Injured group	P- value
	± SD		mean ± SD	(n=20): mean ± SD	
Age (y)	21,6 ±1,92	20,20 - 22,90	21,5 ± 1,20	21,9 ± 1,85	0,596
BMI	22,5 ± 1,77	20,30 – 25,44	22,1 ± 1,66	23,1 ± 1,82	0,069
Weight (kg)	73,4 ± 7,23	65,94 – 84,56	72,5 ± 7,39	74,9 ± 6,94	0,264
Height (cm)	180,6 ± 6,38	172,48 – 190,52	180,8 ± 6,02	180,2 ± 7,01	0,719
Flexibility and strength training (h)	0,3 ± 0,39	-0,09 – 0,37	$0,3 \pm 0,45$	0,3 ± 0,28	0,400
Hours of competition (h)	1,8 ± 0,41	1,40 – 1,94	1,8 ± 0,43	1,8 ± 0,40	0,894
Football training (h)	3,5 ± 0,90	2,21 – 4,70	3,7 ± 1,02	3,4±0,72	0,414
Sports per week (h)	7,2 ± 2,28	4,11 – 12,97	7,1 ± 1,90	7,4 ± 2,78	0,903
Position <sup>1</sup>	2,18 ± 0,81	1,27 - 2,54	2,3 ± 0,71	2,0 ± 0,92	0,024*
Level <sup>2</sup>	0,8 ± 0,42	1,77 – 3,50	$2,9 \pm 0,99$	2,0 ± 0,92	0,102
Dominance <sup>3</sup>	0,8 ± 0,42	0,71 – 1,11	0,8 ± 0,41	$0,8 \pm 0,44$	0,725
Experience (y)	13,8 ± 4,34	13,65-16,89	13,7 ± 4,09	13,9 ± 4,79	0,587
HSI left or right <sup>4</sup>	0,9 ± 76	0,44 – 1,38	1	0,9 ± 76	1
Year of HSI	2015,8 ± 1,94	2013,73 – 2013,45	1	2015,8 ± 1,94	1
Type of HSI <sup>5</sup>	1,7 ± 0,47	1,30 – 1,98	1	1,7 ± 0,47	1
Other injury history <sup>6</sup>	0,7 ± 0,47	1,00 – 1,00	0,8 ± 0,41	0,6 ± 0,51	0,038*
Injury history left or right <sup>4</sup>	1,0 ± 0,76	0,82 – 1,91	0,8 ± 0,67	1,4 ± 0,81	0,098*
Year of other injury	2016,4 ± 1,56	2014,80 - 2017,75	2016,3 ± 1,17	2016,4 ± 2,15	0,217
Pennation angle ST mean (°)	11,9 ± 2,67	11,16 – 12,69	11,8 ± 2,62	12,1 ± 2,80	0,745
Aponeurosis angle ST mean(°)	2,4 ± 1,35	1,99 – 2,77	2,2 ± 1,44	2,6 ± 1,20	0,214
Muscle thickness ST mean (cm)	2,3 ± 0,38	2,16 – 2,38	2,2 ± 0,38	2,4 ± 0,35	0,127
Fascicle length ST mean (cm)	15,8 ± 5,77	14,15 – 17,47	14,9 ± 5,18	17,1 ± 6,45	0,194



Variable	Total (n=49):mean	95% CI	Non-injured (n=29):	Injured group (n-20): mean + SD	P- value
Pennation angle BF mean (°)	$13,0 \pm 2,60$	12,24 – 13,73	13,3 ± 2,57	12,5 ± 2,63	0,218
Aponeurosis angle BF mean (°)	2,0 ± 1,13	1,69 – 2,34	2,1 ± 1,14	1,9 ± 1,13	0,669
Muscle thickness BF mean (cm)	2,8 ± 0,41	14,93 – 17,24	2,8 ± 0,39	$2,8 \pm 0,44$	0,892
Fascicle length BF mean (cm)	16,1 ± 4,02	14,93 – 17,24	$15,6 \pm 4,04$	16,8 ± 3,98	0,282

\* p<0,05

<sup>1</sup> 1= attacker, 2= midfielder, 3= defender

<sup>2</sup> 1= 1<sup>st</sup> provincial, 2= 2<sup>nd</sup> provincial, 3= 3th provincial

<sup>3</sup> 3 0= left, 1= right

<sup>4</sup> 0= left, 1= right, 2= both

<sup>5</sup> 0= overload, 2= strain, 3= tear

<sup>6</sup> 0= no, 1= yes

#### Table 4: Prospective data

Variable	No lower limb injury (n=28): mean ± SD	Lower limb injury (n=21): mean ± SD	P- value
Age (y)	21,8 ± 1,98	21,4 ± 1,86	0,342
BMI	22,3 ± 1,62	22,8 ± 1,95	0,292
Weight (kg)	72,9 ± 7,15	74,1 ± 7,46	0,580
Height (cm)	180,8 ± 6,04	180,2 ± 6,95	0,736
Flexibility and strength training (h)	$0,3 \pm 0,43$	0,3 ± 0,32	0,860
Hours of competition (h)	1,8 ± 0,39	1,8 ± 0,46	0,894
Football training (h)	$3,4 \pm 0,80$	3,7 ± 1,04	0,282
Sports per week (h)	7,0 ± 1,88	7,5±2,75	0,670
Position <sup>1</sup>	$2,4 \pm 0,74$	1,9 ± 0,79	0,014*
Level <sup>2</sup>	2,8 ± 1,11	2,5 ± 1,12	0,390



Variable	No lower limb injury (n=28): mean ± SD	Lower limb injury (n=21): mean ± SD	P- value
Dominance <sup>3</sup>	$0.8 \pm 0.44$	$0,8 \pm 0,40$	0,625
Experience (y)	14,1 ± 4,00	13,3 ± 4,83	0,669
HSI history	$0,3 \pm 0,46$	0,6 ± 0,51	0,046*
HSI left or right <sup>4</sup>	1,3 ± 0,71	0,8 ± 0,75	0,147
Year of HSI	2014,3 ± 1,83	2016,8 ± 1,29	0,005*
Type of HSI <sup>5</sup>	1,8 ± 0,46	1,7 ± 0,49	0,042*
Other injury history <sup>6</sup>	$0,8 \pm 0,44$	0,6 ± 0,50	0,330
Injury history left or right 4	0,7 ± 0,72	1,2 ± 0,80	0,271
Year of other injury	2016,3 ± 1,65	2016,5 ± 1,45	0,794
Type of new HSI5	1	1,0 ± 0,81	/
Duration of new HSI	1	5,1 ± 4,49	1
Pennation angle ST mean (°)	11,7 ± 2,72	12,3 ± 2,62	0,455
Aponeurosis angle ST mean(°)	2,7 ± 1,50	2,0 ± 1,03	0,093
Muscle thickness ST mean (cm)	2,4 ± 0,31	2,1 ± 0,42	0,034*
Fascicle length ST mean (cm)	17,8 ± 6,36	13,2 ± 3,60	0,003*
Pennation angle BF mean (°)	12,6 ± 2,49	13,5 ± 2,72	0,127
Aponeurosis angle BF mean (°)	1,9 ± 1,17	2,1 ± 1,08	0,486
Muscle thickness BF mean (cm)	2,7 ± 0,42	2,8 ± 0,40	0,542
Fascicle length BF mean (cm)	16,5 ± 4,36	15,5 ± 3,54	0,401

\*p<0,05

<sup>1</sup> 1= attacker, 2= midfielder, 3= defender

<sup>2</sup> 1= 1<sup>st</sup> provincial, 2= 2<sup>nd</sup> provincial, 3= 3th provincial

<sup>3</sup> 0= left, 1= right

<sup>4</sup> 0= left, 1= right, 2= both

<sup>5</sup> 0= overload, 2= strain, 3= tear

<sup>6</sup> 0= no, 1= yes



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## **ABSTRACT IN LEKENTAAL**

**Doelstelling:** Het risico op blessures bij voetballers evalueren aan de hand van architecturale en structurele karakteristieken (spierdikte, spiervezellengte en pennatiehoek) van de hamstrings.

**Methode:** Niet-professionele voetbalspelers namen deel in deze studie (n=49). De deelnemers vulden een vragenlijst in die peilde naar zaken uit het verleden zoals sportgerelateerde, demografische en blessure gerelateerde data. Voor de start van het voetbalseizoen (augustus 2018) werden spierdikte, spiervezellengte en pennatiehoek van 2 spierbuiken van de hamstrings onderzocht, gebruik makend van een echografie toestel. Het optreden van hamstringblessures en andere sport-gerelateerde blessures werd vastgelegd via een maandelijkse vragenlijst.

**Resultaten:** 21 van de 49 deelnemers liepen een sport-gerelateerde blessure op tijdens de eerste helft van het voetbalseizoen. De kans op een nieuwe blessure was 12,07 keer hoger bij aanvallers in vergelijking met middenvelders en verdedigers. Verder bemerkt deze studie dat voetballers met een verleden van hamstringblessure significant meer kans hadden op een nieuwe blessure tijdens de follow-up. Daarnaast ontdekte dit onderzoek dat deelnemers die een letsel aan de benen hadden opgelopen tijdens de follow-up, significant kortere spiervezellengtes en kleinere spierdiktes van de hamstrings vertoonden

**Conclusie:** De positie op het veld, de hamstringblessurehistoriek en de spierkarakteristieken (spierdikte en spiervezellengte) kunnen bijdragen tot nieuwe voetbal-gerelateerde blessures.





## PROOF OF SUBMISSION TO ETHICAL COMMITTEE





Pagina 2/2	
Vervolg b	blz. 2 van het adviesformulier betreffende project EC UZG 2018/1409
° ° ° ° ° ° ° ° °	Het Ethisch Comité beklemtoont det een gunstig advies niet betekent dat het Comité de verantwoordelijkheid voor het onderzoek op zich neemt. Bovendien dient U er over te waken dat Uw mening als betrokken onderzoeker wordt weergegeven in publicaties, rapporten voor de overheid enz., die het resultaat zijn van dit onderzoek. In het kader van 'Good Clinical Practice' moet de mogelijkheid bestaen dat het farmaceutisch bedrijf en de autoriteiten inzage krijgen van de originele data. In dit verband dienen de onderzoekers erover te waken dat dit gebeurt zonder schending van de privacy van de proefpersonen. Het Ethisch Comité benadrukt dat het de promotor is die garant dient te staan voor de conformiteit van de anderstalige informatie- en toestemmingsformulieren met de nederlandstalige documenten. Geen enkele onderzoeker betrokken bij deze studie is lid van het Ethisch Comité. Alle leden van het Ethisch Comité hebben dit project beoordeeld. (De ledenlijst is bijgevoegd) The Ethics Committee is organized and operates according to the 'ICH Good Clinical Practice' rules. The Ethics Committee stresses that approvel of a study does not meen that the Committee accepts responsibility for it. Moreover, please keep in mind that your opinion as investigator is presented in the publications, reports to the government, etc., that are a result of this research. In the framework of 'Good Clinical Practice', the pharmaceutical company and the authorities have the right to inspect the original date. The investigators have to essure that the privacy of the subjects is respected. The Ethics Committee stresses that it is the responsibility of the promotor to guarantee the conformity of the non-dutch informed consent forms with the dutch documents. None of the investigators involved in this study is a member of the Ethics Committee. All members of the Ethics Committee have reviewed this project. (The list of the members is enclosed)
Ppdi, dr. Voorzitt	D. MATTHYS ter / Chairman
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