Revision #4

A New Diagnostic Approach using Regional Analysis of Anterior Knee Laxity in Patients with Anterior Cruciate Ligament Deficiency

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Abstract

Purpose

The first purpose of this study was to analyze the characteristics of the anterior knee laxity in the three regions of different stiffness in the force-displacement curve, which was obtained from a frequently used arthrometer for quantifying knee joint stability in the patients with anterior cruciate ligament (ACL) rupture and the healthy controls. The second purpose was to compare the characteristics from the regional analysis of the anterior knee laxity between two subject groups in order to explore proper diagnosis criteria.

Methods

Seventy-one patients with unilateral ACL tear and eighty healthy controls were enrolled and their anterior knee laxities were tested using the KT-2000 arthrometer. The displacements and stiffness of the three regions were extracted separately and compared between groups to further develop the diagnostic criteria.

Results

The results indicated that the laxity behavior was mostly affected in Region 2 and Region 3 after ACL tear. Two good indicators for ACL tear were found in the receiver operating characteristic (ROC) curve analysis: Region 2 with the displacement larger than 3.7 mm and Region 3 with the stiffness smaller than 22 N/mm. These two criteria provided better diagnostic accuracy with increased sensitivity.

Conclusions

The regional analysis method developed in this study could provide more information for understanding the characteristics of the anterior knee laxity and help increase the diagnostic accuracy for ACL rupture.

Key words: *Knee, Diagnostic criteria, Anterior cruciate ligament injury, KT-2000 arthrometer*

The level of evidence: Level II

Diagnostic studies – Development of diagnostic criteria in a consecutive series of patients and a universally applied “gold” standard

Introduction

Anterior cruciate ligament (ACL) is the most frequently injured structure in acute traumatic hemarthrosis of the knee [31]. The incidences of ACL tears range from 0.21 to 2.78 per 1000 exposures to various sports participations, such as soccer, basketball, skiing and wrestling [34]. Accurate diagnosis of ACL tear, which is vital to the following patient care, relies on injury history, clinical examinations [5,23], MR imaging and arthroscopy [8]. In clinical diagnosis, three examinations are commonly used: the Lachman, the anterior drawer, and the pivot shift tests [23,33]. These tests reportedly had a high level of specificity (range: 92-98%) but a relatively low level of sensitivity in the pivot shift test (24%) and the anterior drawer test (55%) without anesthesia [5]. The Lachman test is considered reliable [44] and having the greatest validity and highest diagnostic accuracy (sensitivity: 85%) [5,33]. Henning et al. [16] have demonstrated the positive correlation between the ACL strain and the applied forces during the Lachmen test, and established the relative ACL strain in the Lachmen test for various functional activities and rehabilitation exercises. However, the testing acuity could be affected by several examiner-related variables such as the hand position in force application [17], method of charting, level of experience, and degree of specialization [33]. Therefore, instrumented measurements of knee laxity are frequently used as assisting diagnosis tools [4,9,10].

KT-1000 or KT-2000 arthrometer (MEDmetric Co., San Diego, USA) is a popular instrument for knee laxity measurements [20,21,32,37,41] and has been proven to have good clinical validity and reliability [14,19,29,30,35,38]. The clinical diagnostic criteria for ACL injuries were established by selecting proper parameters in the measured anterior forces and corresponding tibia displacements with the same testing position as the Lachman test [36]. Because of the larger variation in the absolute values of anterior displacements at specific applied forces from one knee, most clinicians consider the side-to-side differences between the injured and the contralateral uninjured knees would provide better discrimination in identifying ACL injuries [2,4,10,30]. The diagnostic criteria for the side-to-side differences of displacement at 89 N (20 lb) and 134 N (30 lb) forces have been reported to have an anterior displacement difference (ADD) larger than 3 millimeter (ADD20 ≥ 3 mm and ADD30 ≥ 3 mm) [9,42]. Another parameter is the compliance index (CI), the difference of the displacements between 89 N and 67 N forces from one knee [9,10], and its diagnostic criterion is suggested to be larger than 3 millimeters (CI ≥ 3 mm) [10]. The CI side-to-side difference (CID) larger than 1.5 mm (CID ≥ 1.5 mm) was considered a better indicator than CI because of the higher sensitivity level [10,13]. However, the parameters using side-to-side differences require an uninjured contralateral knee, and therefore may be unsuitable for those suffering from bilateral knee pathologies.

When the examination is limited to only one knee, the stiffness can be used to help discriminate the ACL injury [24,26,27]. The stiffness, defined by the slope of the applied force to the displacement of the tibia [26], reportedly varied with different knee flexion angles and the smallest value is found at flexion 20-30° [11,26]. Changes of stiffness in different regions of the force-displacement curve represented changes in restraining properties of the knee joint under various loading conditions [24,26,27]. Two in vitro studies analyzed the stiffness in the initial and terminal loading regions and found significantly smaller values in the ACL-deficient knees when compared with the normal ones [11,26]. However, according to the diagrams in the literature and our tested data, the anterior force-displacement curve in the KT-2000 arthrometer test showed a pattern with three different stiffness [22,24,27].

Moreover, to our best knowledge, no specific diagnostic criterion for the stiffness parameter has been proposed. Therefore, the purposes of this study were (1) to analyze the stiffness characteristics of anterior knee laxity in three regions of the anterior force-displacement curve in the KT-2000 arthrometer test, and (2) to compare the characteristics between healthy controls and patients with ACL rupture in order to explore proper diagnosis criteria for the stiffness parameter. The hypotheses of this study are (1) the mechanical properties of three regions in force-displacement diagram are different between normal and ACL-deficient knees, and (2) the testing results from one knee could be used to establish proper diagnostic criteria for stiffness parameter to accurately distinguish the ACL injury.

Materials and Methods

Seventy-one patients with ACL rupture from China Medical University Hospital were enrolled. They were diagnosed by an experienced orthopedic surgeon as unilateral ACL complete tear with physical examinations and confirmed either by arthroscopy or MRI examination. Eighty healthy adults from the university campus were recruited voluntarily for comparison. They were aged 18 to 45 years and had no pathology in their lower extremities. All participants signed the consent form and then received routine medical history taking and physical examination to ensure the intact structures around the knees. Firstly, 40 ACL patients and 40 healthy adults were selected randomly to establish the diagnostic criteria. Secondly, cross-validation was performed by the data from the remaining 31 patients, and 40 healthy adults to examine the accuracy of the diagnostic criteria. These 31 patients were further divided into acute and chronic subgroups by the post-injury duration of three months. There were 6 patients in the acute subgroup and 25 in the chronic subgroup.

KT-2000 arthrometer was used to investigate the responses of the knee laxity to various loading conditions. The applied force and corresponding displacement data were recorded into a laptop via a data acquisition A/D card (DaqCard 216B, IOtech, USA) with the measurement resolutions of 0.14 N and 0.012 mm at 1000 Hz. Then, the displacement parameters, including ADD20, ADD30, CI, and CID, and also the displacement and stiffness in each of the three regions would be extracted from the force-displacement curve. To avoid inter-rater variability, one experienced tester with KT-2000 performed all the tests. The tester demonstrated high level of intra-rater reliability ($ICC_{(3,1)} > 0.76$) and clinical validity ($ICC_{(3,3)} > 0.86$), by comparing among repeated trials and comparing the computed maximum displacement with the reading from the dial.

The basic data of each participant, such as age, height, weight and dominant leg, was collected firstly (Table 1). Although there were significant differences in the comparisons of the age, body height and weight between groups, no difference in the body mass index (BMI) suggested similar body figures. The KT-2000 arthrometer was fastened on the lower leg and perpendicular loads were applied to the tibia. The test was performed at 30° of knee flexion with the right knee tested first in the control group, and the uninjured knee first in the patient group. A pre-test trial was necessary to ensure the relaxation of the surrounding muscles and to obtain the starting reference position. A successful trial consisted of an anterior pull (up to 134 N), a posterior push (up to 134 N) and then a release. The trial should end with the indicator of the dial returning to ± 0.5 mm of the starting reference position. Patient relaxation must be maintained throughout the entire test because the muscle contraction could cause significant measuring errors. The examiners would periodically check the patient’s thighs to make sure there is no muscle contraction or guarding. If the dial needle was noted to shift unsteadily or any muscle contraction or guarding was detected during the trial, the trial would be considered a failure. Moreover, any sudden distortion in the force-displacement curve display immediately after each trial would also be considered a failure as well. Three successful trials would be obtained to calculate the mean value of the variables for each knee.

The applied force and corresponding displacement data formed a force-displacement curve that was then analyzed with a self-written MATLAB (MathWorks, USA) program. The curve was first approximated using a 5-order polynomial function [24], and two turning points of the curve were selected manually by a same operator. These two turning points separated the curve into three regions, each of which was then fitted with a straight line using simple linear regression (Figure 1). The slope of the line in each region represented its stiffness.

Statistical Analysis

Intraclass correlation coefficient (ICC) for the results from each region of the three successful trials was calculated to investigate the inter-trial and inter-rater reliability. For the inter-rater reliability, another operator was enrolled and performed the same data management procedure on the 40 controls and 40 ACL patients. Paired t-test was used to compare the forces, displacements and stiffness of the three regions between dominant and non-dominant sides in the control group. The independent t-test was used to compare all the variables between genders in the control group, and between the control and patient groups. The comparing results between groups were then used to select suitable variables to establish proper diagnostic criteria. Receiver operating characteristic (ROC) curve was constructed for each selected variable, and the area under the ROC curve (AUC) was calculated to acquire the diagnostic accuracy. The point with maximal summation of sensitivity and specificity on the ROC curve was considered the proper diagnostic criterion. The specificity, sensitivity, positive and negative likelihood ratios (LR+, LR-) of all the diagnostic criteria were further calculated using the testing data from the additional 40 healthy participants and the two subgroups of the 31 ACL patients. The differences of AUCs between regions were tested with MedCalc statistical software (Mariakerke, Belgium), and all other statistical analyses were conducted using SPSS software (SPSS Inc., Chicago, IL, USA) with significant level at 0.05.

Results

A high level of inter-trial reliability for each region was demonstrated for both operators ($ICC_{(3,1)}$=0.72-0.96, *P*<0.001), and also the inter-rater reliability ($ICC_{(3,3)}$= 0.92-0.99, *P*<0.001) (Table 2). The force-displacement curves in the control and patient groups were constructed from the mean force and displacement data listed in Table 3, and the two turning points were also shown in Figure 2. In the control group, no significant differences between dominant and non-dominant sides were found for the displacements, forces and stiffness of the three regions. Comparisons between genders showed no significant differences except that females had a larger displacement (female: 2.5 ± 0.8 mm, male: 1.8 ±0.9 mm, *P*= 0.02) and smaller stiffness (female: 29.2 ± 11.1 N/mm, male: 40.3 ± 14.0 N/mm, *P*= 0.03) in Region 3.

Comparisons between the control and patient groups showed significantly differences in the displacement and stiffness parameters but not in the force parameters (Table 3). The forces of the two turning points have similar mean values around 46 N and 82 N in both groups. Interestingly, if converting the forces of the first turning points into percentage of individual’s body weight (%BW), the forces of

46 N were found equivalent to an average value of 6%BW approximately. The displacements of all three regions were significantly larger (*P* <0.001), and the stiffness were significantly smaller in the patient group (*P* <0.001) than those in the control group. Therefore, these two variables were treated as possible diagnostic parameters and used to establish their clinical diagnostic criteria.

The ROC curves of the possible diagnostic parameters were shown in Figure 3. The AUCs for the displacements were similar between the three regions (area: 0.837-0.894). The point closer to the upper-left corner was selected as the diagnostic criterion, with 3.7 mm displacement of Region 2 (specificity: 85%, sensitivity: 75%) (Figure 3A). For the stiffness of the three regions, Region 3 had the largest AUC (area: 0.945), and the best diagnostic criterion would be at 22 N/mm (specificity: 88%, sensitivity: 90%) (Figure 3B). The estimated specificity, sensitivity, LR+, and LR- of these two criteria and several other criteria suggested in the literature were shown in Table 3.

Discussion

The most important finding of the present study was to establish two diagnostic criteria for ACL deficiency by using regional analysis of the anterior knee laxity test, which was proved to have high levels of intra- and inter-rater reliability. Our results indicated that the ACL group had significantly larger displacements and smaller stiffness than the control group in both Region 2 and Region 3, suggesting the important roles of the ACL in these two regions. Previous studies have also reported a larger anterior tibial translation at 134 N in the ACL injured knee than in the normal knee [4,10,25,30]. The ACL strain in daily activities seldom exceeded 4.5% (or 1.4

mm estimated elongation approximately) [6,7,12], and the ACL elongation would have less than 50% relative to the Lachman test (or under the applied forces of 20 lb) [15]. The average force at the end point of Region 2 was 82 N (18.4 lb) and the corresponding displacements were 2.6 mm and 5.5 mm in the two groups of this study (Table 3). So the characteristics of Region 2 would be closely correlated to the knee stability in daily activities. For Region 3, the amount of the applied forces and corresponding tibial translations would make the ACL strain or elongation exceed far beyond those in daily activities and therefore should be considered in discussions about strenuous or sport-related movements. Matsumoto et al. also reported that the terminal stiffness, defined as the stiffness between 89 N and 134 N, of the ACL-injured knee was significantly smaller than the normal knee [27]. Although the force leading to ACL rupture might be higher than 134 N, the laxity characteristics beyond 134 N reportedly had similar linear relationships with those just below 134 N [30]. Therefore, the stiffness of Region 3 may play a more significant role than the displacement in the reference of ACL injury.

Two diagnostic criteria were developed based on our results: Region 2 with a displacement larger than 3.7 mm and Region 3 with stiffness smaller than 22 N/mm. Specificity refers to the correct rate of negative results (indicating normals) in a true normal group, while sensitivity is the correct rate of positive results (indicating injuries) in a true injury group. The previous diagnosis criteria (i.e. ADD20, ADD30, CI, and CID) work excellently only in indicating normals with high specificity [4,5,39] and most of them required a contralateral intact knee. When compared with the previous criteria, the criteria developed in this study needed testing data from only one knee, and could have good performances in both indicating the ACL injury with 73-83% sensitivity and indicating normal with 70-80% specificity (Table 4). Different levels of LRs suggested the clinical importance for the test results. They were defined as large (LR+ > 10, LR- < 0.1), moderate (LR+: 5-10, LR-: 0.1-0.2), small (LR+: 2-5, LR-: 0.2-0.5) and rarely important (LR+: 1-2, LR-: 0.5-1) levels [18]. The previous diagnosis criteria generated moderate to large importance for LR+, but rarely to small importance for LR-. Our diagnostic criteria generated small clinical importance for both LRs, but better performances were noticed for LR- when compared with the previous diagnostic criteria. These results suggested that our diagnosis criteria could be useful for recognizing the ACL-injured knees from possible ACL patients, especially for the stiffness in Region 3.

The comparison within the control group showed that females had significantly larger displacements and smaller stiffness than males in Region 3. Similar gender difference had already been discussed in several studies, but most of them only revealed smaller knee anterior displacements in male subjects [1,16,43]. Hinton et al. [16] reported that the differences between genders in the knee anterior displacement emerged at the loadings of 89 N and 134 N, which agreed with our results in Region 3. For Region 1, the applied forces worked to orient and tighten the collagen fibers of surrounding structures and counteracted the weight of the lower leg [24,28]. According to the anthropometric data, the weight of the lower leg is nearly 6.1% of the body weight [45]. The mean loading of the first turning point was around 6.6% of the body weight for both groups in this study. The result supported the statement that Region 1 represented the counteraction of the gravity forces (weights) from the lower leg and the instrument.

In this study, there were some limitations needing to be addressed regarding the selection of the participants. The ACL group consisted of the consecutive patients during a period of time and the control group was the convenient sample from the university campus. This may lead to the first limitation of the heterogeneity in the age, body height and weight between two subject groups. However, Anderson et al. had studied the correlation between anthropometric data and ACL size, and found that the ACL size was correlated to the lean body mass (i.e. BMI) only [3]. Previous studies showed that the anterior knee translation would decrease with age for subjects between 11 and 18 years old [1,16,40], but the subjects in our study have all passed their adolescence. Therefore, the differences of the demographic data between groups would not significantly influence the characteristics of the anterior knee laxity. The second limitation is the small subject number in the acute subgroup, and it may influence the diagnostic accuracy in the acute subgroup. The results of diagnostic accuracy in this study demonstrated minor incongruousness with the results in Bach et al. [4], in which they reported poorer accuracy of these diagnosis criteria for the patients with acute ACL tear than for those with chronic tear, but the opposite result was demonstrated in this study. This disagreement may be caused by the small subject number of the acute subgroup in this study. Another explanation is the possible discrepancy in the severity of symptom (e.g. joint swelling) and the post-injury duration, because presence of the acute symptoms may influence the general knee laxity and the adaptations on the mechanical property of the surrounding tissues after ACL tear would gradually increase with the post-injury duration. For clinical relevance, a simpler analysis method could be developed according to our results, by setting the loadings of Region 2 from 46 N to 82 N and those of Region 3 from 82 N to 134 N. Then, this analysis method could be used to easily analyze the force-displacement curve region-wise to acquire detailed and valuable information about the mechanical characteristics of the knee joint. It also provides another means to assist the diagnosis of the ACL injuries before the invasive arthroscopic or extensive MRI examination.

Conclusion

A new diagnostic approach with regional analysis of the anterior knee laxity for ACL deficiency was presented in this study. The reliability of this analysis method showed high levels of inter-trial and inter-rater reliability, which would support the future application of this method. The results suggested the crucial restraint role played by the ACL in Region 2 and Region 3. Two diagnostic criteria were developed based on our results: Region 2 with a displacement larger than 3.7 mm and Region 3 with stiffness smaller than 22 N/mm. They were shown to have good levels of both sensitivity and specificity. The simplified regional analysis method could be developed according to the results of this study and provide a means to acquire detailed information about the mechanical characteristics of the knee joint and could be used as a diagnostic means for ACL rupture before the invasive arthroscopic or expensive MRI examination.

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Table 1: The demography of the control and patient groups

	For establishing diagnostic criteria (N=80)					For validating diagnostic accuracy (N=71)				
	Control		ACL patient			Control		ACL patient		
Gender	Male	Female	Male	Female		Male	Female	Male	Female	
	30	10	30	10		10	30	8	23	
Injury subgroup			Acute	Chronic				Acute	Chronic	
			9	31				6	25	
	Mean ± SD		Mean ± SD		*P* value	Mean ± SD		Mean ± SD		*P* value
Age (year)	21.1 ± 2.5		24.5 ± 6.3		0.003*	21.9 ± 3.0		25.5 ± 6.1		0.005*
Body height (cm)	168.2 ± 6.6		171.8 ± 8.3		0.04*	162.3 ± 7.2		173.6 ± 6.4		<0.001*
Body weight (kg)	65.9 ± 12.3		73.0 ± 14.0		0.02*	55.7 ± 10.5		74.0 ± 14.2		<0.001*
BMI (kg/m^2)	23.2 ± 3.8		24.6 ± 3.9		NS	21.1 ± 2.8		24.4 ± 4.6		0.001*

NS non-significant

* $P < 0.05$

Table 2: The intraclass correlation coefficient (ICC) of intra-rater and inter-rater reliability for regional analysis of anterior knee laxity in 40 ACLD and 40 control subjects.

		Intra-rater		Inter-rater	
		ICC$_{(3,1)}$	95% CI	ICC$_{(3,3)}$	95% CI
Displacement of region one (mm)	Rater 1	0.75	0.69-0.80	0.97	0.95-0.98
	Rater 2	0.72	0.65-0.77		
Displacement of region two (mm)	Rater 1	0.93	0.91-0.95	0.93	0.91-0.95
	Rater 2	0.90	0.87-0.82		
Displacement of region three (mm)	Rater 1	0.83	0.79-0.87	0.92	0.89-0.94
	Rater 2	0.89	0.86-0.92		
Stiffness of region one (N/mm)	Rater 1	0.86	0.83-0.89	0.99	0.99-0.99
	Rater 2	0.86	0.83-0.89		
Stiffness of region two (N/mm)	Rater 1	0.75	0.69-0.80	0.98	0.97-0.99
	Rater 2	0.73	0.67-0.79		
Stiffness of region three (N/mm)	Rater 1	0.89	0.86-0.91	0.99	0.99-0.99
	Rater 2	0.86	0.83-0.89		

Table 3: The displacement and stiffness of each region between groups

		Control (N=40)	Patient (N=40)	*P*-value
		Mean ± SD	Mean ± SD	
Force (N)	at turning point 1	44.2 ± 12.3	48.6 ± 11.9	n.s.
	at turning point 2	80.8 ± 18.0	83.5 ± 20.0	n.s.
Displacement (mm)	Region 1	1.4 ± 0.5	2.1 ± 0.7	<0.001**
	Region 2	2.6 ± 1.1	5.5 ± 3.0	<0.001**
	Region 3	2.1 ± 1.4	4.1 ± 1.9	<0.001**
Stiffness (N/mm)	Region 1	36.5 ± 11.4	25.6 ± 11.8	<0.001**
	Region 2	14.6 ± 8.4	6.6 ± 3.7	<0.001**
	Region 3	35.8 ± 13.6	14.3 ± 6.5	<0.001**

** $P<0.001$

n.s. non-significant

Table 4: The sensitivity, specificity, positive and negative likelihood ratio (LR+, and LR-) of the diagnosis criteria in both acute and chronic subgroups (N=71)

Diagnostic criteria	Specificity (%)	Sensitivity (%)			LR+			LR-		
		Both	Acute	Chronic	Both	Acute	Chronic	Both	Acute	Chronic
Side-to-side difference at 134 N > 3mm	93	45	67	40	6.0	8.9	5.3	0.6	0.4	0.7
Side-to-side difference at 89 N > 3mm	93	45	67	36	6.4	9.5	5.1	0.6	0.4	0.7
Compliance index > 3mm	98	55	15	40	22.0	6.0	16.0	0.5	0.9	0.6
Compliance index difference > 1.5mm	98	29	33	28	11.6	13.3	11.2	0.7	0.7	0.7
Displacement of region 2 > 3.7mm	70	81	83	72	2.7	2.8	2.4	0.3	0.2	0.4
Stiffness of region 3 < 22 N/mm	68	90	100	80	2.8	3.1	2.5	0.1	0	0.3

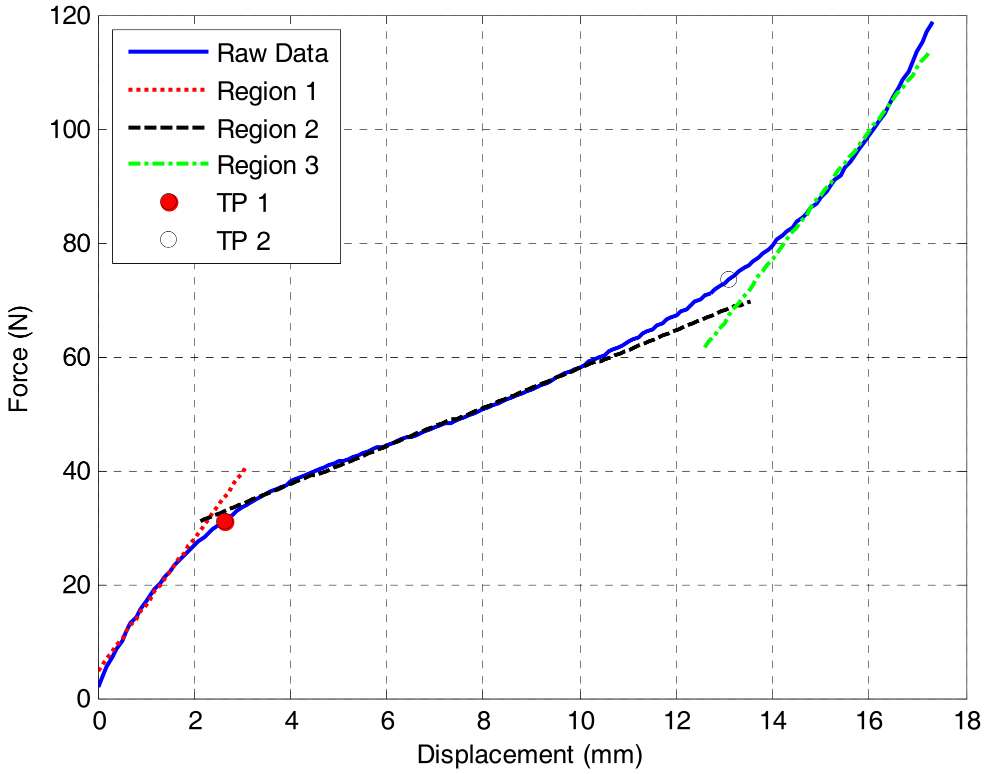


Figure 1: The three regions of the force-displacement curve; TP: turning point

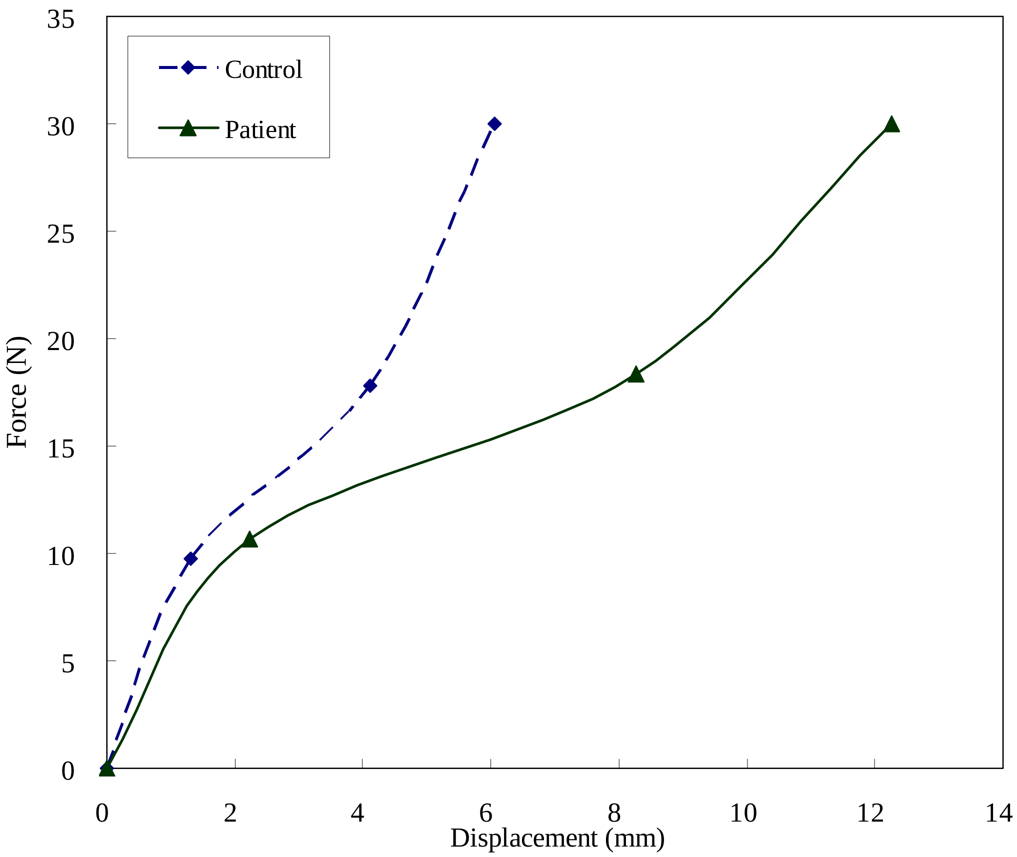
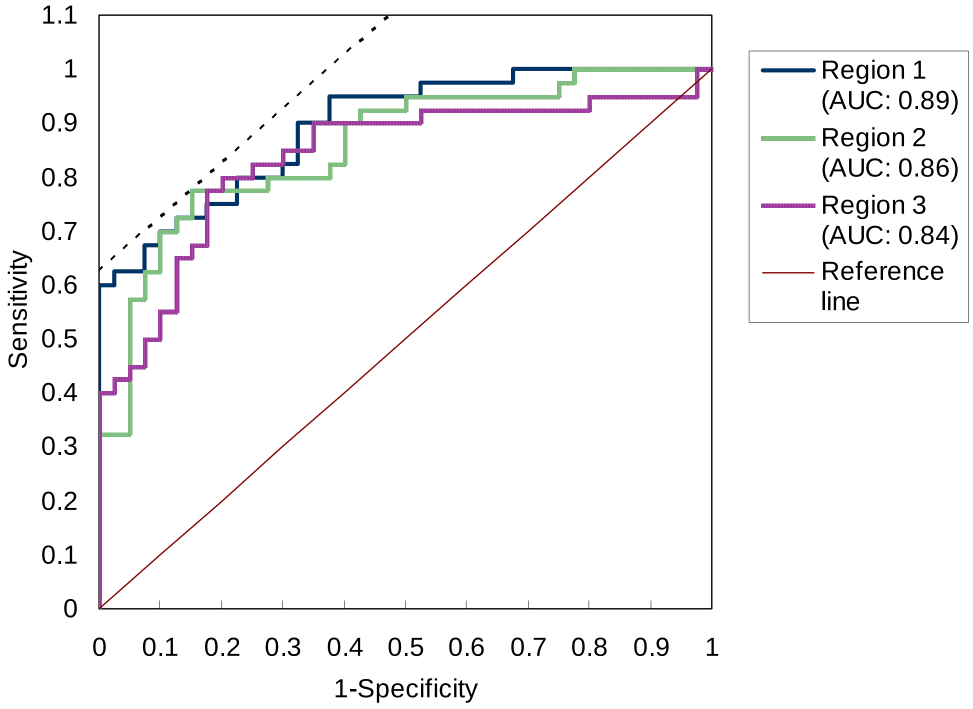
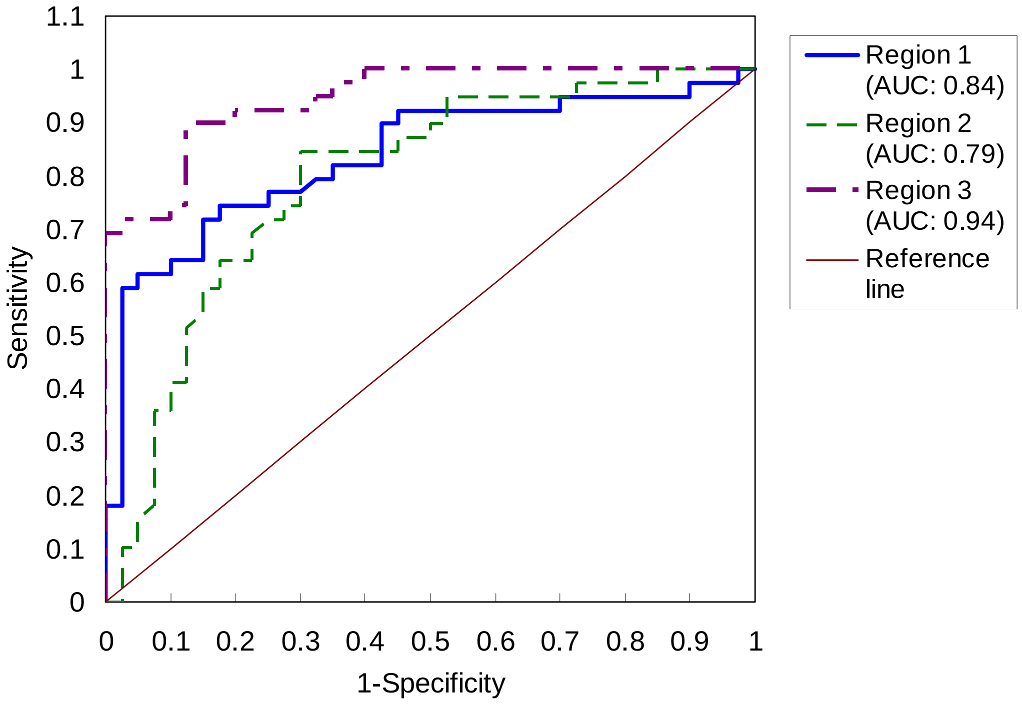


Figure 2: The average force-displacement curves of the control (N =40) and patient (N=40) groups.



(A)



(B)

Figure 3: The ROC curve of diagnosis variables (A) displacement variables, the dash oblique line is parallel with reference line; (B) stiffness variables (N=80)