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► A tele-assessment system for monitoring treatment effects in subjects with spinal cord injury

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Summary

We developed a method for remote measurement of balance and leg force in patients with spinal cord injury (SCI). In a group of 21 patients, both telemedicine and conventional clinical assessments were conducted at baseline and six months later. Telemedicine assessments were successfully acquired and transmitted at first attempt. The time required to set up the telemedicine equipment, position the subject, perform the measurements, and then send the data to the university laboratory was approximately 30 minutes. After six months, several motor and sensory functions showed significant changes. There were significant correlations between changes in remotely-measured leg force and changes in several of the American Spinal Injury Association (ASIA) sensory and motor scores. Changes in balance did not show any significant correlations with changes in the ASIA scores. Intra-rater reliability was better than inter-rater reliability. Use of telemedicine to remotely monitor changes in patients with SCI appears promising.

Introduction

Telemedicine may be useful in patients with spinal cord injury (SCI), where impaired mobility can make access to medical professionals difficult.¹ Patients with SCI are at risk of developing various complications such as pressure ulcers, hypertension, obesity, bladder infections, type 2 diabetes and cardiopulmonary diseases.² By remotely monitoring musculoskeletal function it may be possible to prevent these complications. Several telemedicine studies have been conducted in patients with SCI, particularly in the prevention and treatment of pressure ulcers.^{3,4} Studies have also been performed to improve post-discharge support⁵ and follow-up care.⁶ However, there appear to have been no previous long-term studies of remote monitoring in patients with SCI.

We have examined two functions, balance and leg strength. These functions are often a focus of post-SCI training programmes. After SCI, balance is directly related to motor performance, postural control and injury prevention;⁷ and leg strength is related to function and

quality of life.⁸ Also, measuring leg strength and related musculoskeletal functions after SCI can help to prevent pressure ulcers⁹ and improve insulin sensitivity.¹⁰ The primary aim of our study was to construct a system for the remote assessment of balance and leg strength in patients with SCI. We also examined its reliability and validity.

Methods

We evaluated patients with a chronic SCI, first at baseline and then again six months later. At each evaluation, conventional clinical measures and telemedicine measures were made.

Patients received treatment at an outpatient facility (Project Walk, Carlsbad, California, USA) and their telemedicine assessments were performed at this facility and the resulting data sent via the Internet to a university laboratory 90 km away. The treatment programme has been described in more detail elsewhere.¹¹

Patients were recruited from the facility where they had received treatment prior to study enrolment. The inclusion criteria were a SCI of more than two months' duration, injury level above T12, non-ventilator dependence, no major active psychiatric illness, and no other major

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neurological disorder such as traumatic brain injury, epilepsy, stroke, Parkinson's disease or severe peripheral neuropathy. The study was approved by the appropriate ethics committee.

Clinical measures

Conventional clinical measures were performed at the beginning and end of the six-month period, all by the same researcher. The tests administered were the American Spinal Injury Association (ASIA) motor and sensory scores,¹² which have proven validity and reliability for longitudinal evaluations.^{12,13} Additional clinical measures were the ASIA Impairment scale, Modified Ashworth Scale¹⁴ to measure spasticity in each elbow, the Craig Handicap Assessment and Reporting Technique (CHART),¹⁵ Center for Epidemiologic Studies Depression Scale (CES-D)¹⁶ and the Satisfaction with Life Scale (SWLS).¹⁷

Telemedicine equipment

A specially modified computer was used to record and transmit balance and lower extremity force. The computer was a laptop computer interfaced to a data acquisition board (Labjack, Lakewood, Colorado, USA). The data acquisition board was connected to the assessment devices described below.

During testing, visual waveform graphs and auditory beeps were used to provide real-time feedback during each trial. Using a web camera connected to the laptop, the program captured images of the subject during each assessment task, at a frequency of 1 Hz. Tilt and force signals from the assessment devices were sampled at a rate of 20 Hz and stored in a file. Immediately after each assessment, a copy of all data was transmitted to the university laboratory via a wireless connection. The data were then reviewed. Pictures were reviewed to confirm overall compliance, and motor performances were measured from the assessment devices as described below. The data transmissions were anonymized by using a patient-identifying number rather than a name.

Device for measuring balance

The device for measuring balance (Figure 1) was an inclinometer (CXTA02 Tilt Sensor, Crossbow Technology Inc, San Jose, California, USA) attached to a shoulder harness (Rolyan Clavicle Posture Support, Sammons Preston, Bolingbrook, Illinois, USA). The inclinometer provided angular measurements of tilt, up to a maximum of 75°, in two orthogonal axes. The inclinometer sat on the subject's back, at the T6 vertebral level.

Device for measuring leg force

The leg force device provided support for the foot. It consisted of two parallel stainless steel tracks with a cross member. Two parallel stainless steel tracks were then welded to the cross member perpendicular to the other tracks.



Figure 1 The device for testing balance. The two straps (indicated by white arrows) hold the inclinometer, which sits on the subject's back at the T6 spinal level

A linear actuator (Firgelli Automations Inc) was attached at the centre of the cross member. A force sensor (SML-100, Interface Mfg Inc., Scottsdale, Arizona, USA) was attached between the end of the actuator and the base plate of the foot binding (Drake F-60 Snowboard binding). The base plate rode on the stainless tracks via four nylon wheels (Figure 2A).

Telemedicine measures

Subjects were tested by one of three specialists who had been trained to use the testing equipment and who were also involved in the subject's treatment. Six remote assessments were conducted, to measure balance (static and dynamic) and the force of leg pressing (four types).

Balance

- (1) **Static balance.** For static balance the subjects were seated at the edge of a table, without back support, with their arms resting at the side of the body and with their feet placed flat on the floor. Participants were instructed to find a comfortable position to sit in order to maintain balance. Displacement was recorded in two axes (left/right and anterior/posterior) for 30 seconds. After transmission, the measurements were analyzed to determine the mean displacement (in degrees);
- (2) **Dynamic balance.** Dynamic balance was measured using a similar method. However, during balance testing, subjects were instructed to alternately raise each arm as high as possible, up to 90° of shoulder flexion, to the beat of a 1 Hz metronome. Testing lasted 15 seconds. Displacement in the same two axes was recorded and analyzed to provide mean displacement over 15 seconds.

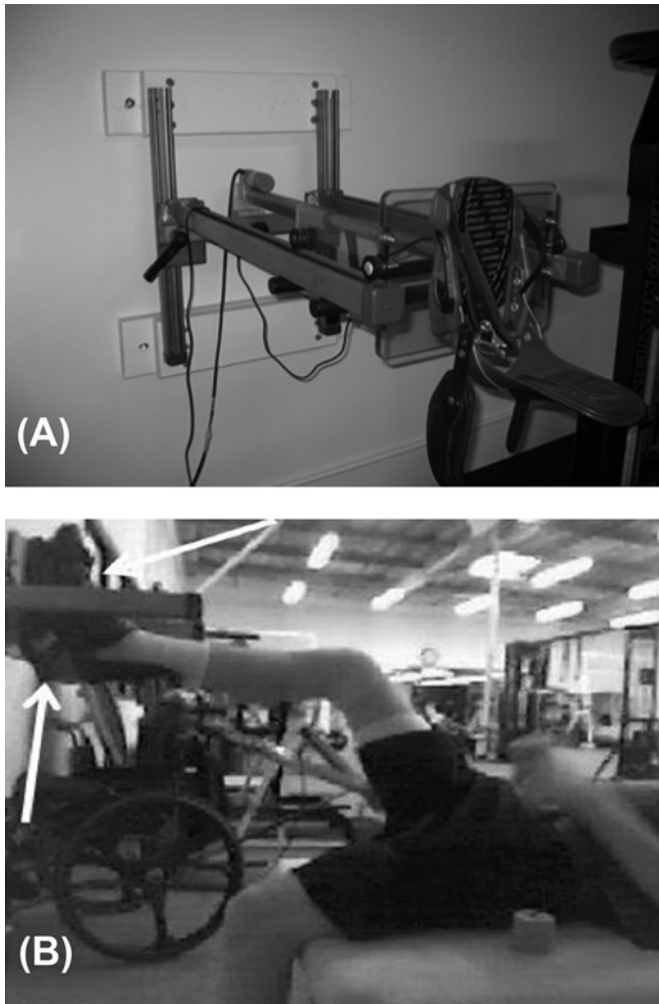


Figure 2 (A) The device for testing leg force. (B) Image taken during tele-assessment of leg force. The white arrows indicate the device. When testing leg force at maximum extension, the starting position was approximately 140° for both right knee extension and right hip extension

Leg force

Voluntary lower limb force was measured, primarily at knee and hip extensors. Using the leg press device, the subject was placed in a supine position, with the hip/knee at various degrees of flexion. Subjects lay on a table with the right foot strapped into the device, with the entire sole of the shoe in contact with the device base plate. The left leg was in line with the torso, with the knee and lower leg off the edge of the table (Figure 2). The pelvis was secured with a belt across the anterior superior iliac spines in order to eliminate any compensation (i.e. pelvic elevation). The shoulders were blocked to prevent the subject from sliding backwards on the table. Four leg force tests were performed and the level of force over time was recorded. The resultant data file was analyzed to determine the maximum force exerted.

- (3) Leg force at maximum flexion. Subjects performed an isometric contraction in a fully flexed position. The right knee and hip were each fixed in 90° of

flexion, confirmed using a goniometer, with the right calf parallel with the floor. This posture was achieved by adjusting the leg press device;

- (4) Leg force at maximum extension. Subjects performed an isometric contraction in a fully extended position. Testing was identical to that used during maximal flexion, except that the starting position was approximately 140° of right knee and hip extension (see Figure 2B). If either of these tests showed a force >32 kg, the next two tests were omitted, as they would have caused the fuse in the actuator to trip. This occurred in four subjects;
- (5) Leg force during passive flexion. The latent force of the leg was measured, when moved by the actuator, without any resistance supplied by the subject. A 3-second baseline force was measured and then the actuator moved the leg to 90 degrees of knee flexion;
- (6) Leg force during eccentric contraction. The eccentric force generated by the leg was measured, starting in the maximum extension position. After a 3-second baseline force measurement the actuator moved the leg to 90° of knee flexion while the subject attempted to resist the movement.

Validity and reliability

The validity and reliability of the telemedicine measures were evaluated. Not all subjects were available to perform the repeat testing required for reliability assessments.

The validity of the telemedicine measures was examined by comparing the changes in the six values with the changes in the four main ASIA scores (total motor score, total sensory score, upper extremity motor score and lower extremity motor score). This was a pilot study, and no correction for multiple comparisons was applied.

In addition, leg force during passive flexion was examined in relation to the Ashworth spasticity scale.

Inter-observer and intra-observer reliability were estimated in two ways. For inter-rater reliability, two different specialists, each blinded to the test results of the other, made their own measurements, always during the same test session. The Spearman rank correlation coefficient was calculated for the two groups of measures. For intra-rater reliability, a single specialist repeated measurements for a given patient, twice over a 30-minute period. The correlation was calculated for these two groups of measures. In addition, the intraclass correlation coefficient (ICC) was calculated. All six telemedicine measures were examined.

Statistics

A standard package was used for data analyses (JMP, SAS Institute, Cary, North Carolina). The data were analyzed using non-parametric tests (Wilcoxon rank sum test for categorical data and Spearman’s rho for continuous data) because they were not normally distributed. Paired testing (Wilcoxon

signed rank test) was used to assess significance of change over the six-month interval for each tele-assessment, as well as for each behavioural test.

Results

A total of 22 subjects with chronic SCI were recruited. One subject was not able to return for the six-month follow-up testing, leaving 21 subjects. The mean time between making the clinical measures and making the remote assessments was 15.7 days (SD 10.7) at baseline, and 12.3 days (SD 9.2) at month six.

After six months, several motor and sensory functions showed significant changes (see Table 1). More details have been described elsewhere.¹¹

The skill to successfully administer each of the tele-assessment methods was mastered in a few minutes by all assessors. Tele-assessments were successfully acquired and transmitted at first attempt. The time required to set up the tele-assessment computer, position the subject, perform the tele-assessments, and then send the data to the university laboratory was approximately 30 minutes.

The results of tele-assessments at baseline and after six months are shown in Table 2. At baseline, the displacement during dynamic balance was significantly greater ($P < 0.05$) than during static balance. There were significant changes for several measures of leg force. The largest change was in leg force at maximum extension, whether expressed as amount of change (as in Table 2), or as percentage change.

Validity

There were significant correlations between changes in leg force tele-assessments and changes in several of the ASIA

Table 2 Telemedicine measures. The values are mean (SD). For the static and dynamic balance measures, a decrease in mean displacement indicates greater stability and thus improved balance over time

	Baseline	Change after six months
Static balance, mean displacement (degrees)	0.5 (0.3)	0.0 (0.3)
Dynamic balance, mean displacement (degrees)	1.9 (0.7)	-1.5 (0.6)
Leg force at maximum flexion (kg)	6.8 (10.0)	7.3 (15.0)
Leg force at maximum extension (kg)	6.4 (11.3)	19.1 (19.1)***
Leg force during passive flexion (kg)	5.4 (3.2)	8.2 (5.9)**
Leg force during eccentric contraction (kg)	7.7 (5.4)	9.5 (10.4)*

* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$

sensory and motor assessments (Table 3 and Figure 3). Changes in balance did not show any significant correlations with change in any of the ASIA assessments. The change in force at maximum extension correlated significantly with more ASIA assessments than the other tele-assessments did (for example, see Figure 3). Leg force during passive flexion showed a trend towards correlation with the Ashworth scale of spasticity on the right ($r = -0.43$, $P < 0.09$) but not the left.

Reliability

Inter-rater reliability (Table 4) was less often significant as compared to intra-rater reliability (Table 5). Inter-rater reliability was significant only for force at maximum flexion, and not for any of the other five tele-assessments. Intra-rater reliability was significant for two of the force measures evaluated, but not for either balance measure. The intra-rater reliability was highest for force at maximum flexion. The ICC for inter-rater reliability was excellent¹⁸ for two force measures (force during maximum flexion and during maximum extension) and substantial¹⁸ for one balance measure (static balance), while ICC for intra-rater reliability was substantial to excellent for two force measures.

Table 1 Clinical measures. The values are mean (SD)

	Baseline	Change after six months
Age (years)	34 (13)	
Gender (m/f)	18/3	
Handedness (r/l/am)	19/1/2	
Footedness (r/l/am)	16/0/6	
Time post-injury (days)	1082 (856)	
ASIA impairment scale (A/B/C/D)	6/6/8/1	
Level of spinal cord injury (no. of subjects)	C4 (4)/C5 (11)/C6 (2)/C8 (2)/T3 (1)/T11 (1)	
ASIA total sensory score (0–224)	97 (31)	8.2 (14.2)
ASIA total light touch score (0–112)	59 (19)	4.7 (11.3)
ASIA total pinprick score (0–112)	36 (19)	3.8 (8.9)
ASIA total motor score (0–100)	39 (16)	4.8 (4.5)
ASIA UEMS bilateral score (0–50)	31 (10)	1.5 (2.2)
ASIA LEMS bilateral score (0–50)	8.8 (11)	3.5 (3.9)
Modified Ashworth right score (0–5)	1.6 (1.7)	0.04 (1.3)
Modified Ashworth left score (0–5)	1.7 (1.6)	-0.3 (1.5)
CHART score (0–600)	441 (91)	12.5 (69)
CES-D score (0–60)	11 (7)	-0.6 (9.5)
SWLS score (5–35)	17 (7)	0.8 (4.4)

r, right, l, left, am, ambidextrous/ambipedal; Total sensory score, ASIA light touch plus ASIA pinprick scores combined; UEMS, upper extremity ASIA motor score; LEMS, lower extremity ASIA motor score; CHART, Craig Handicap Assessment and Reporting Technique; CES-D, Center for Epidemiologic Studies Depression; SWLS, Satisfaction with Life Scale

Discussion

Implementation of telemedicine methods for patients with SCI could improve musculoskeletal function and skin

Table 3 Relation between changes measured by telemedicine and changes measured by conventional clinical scores. Only the significant relationships are shown

Telemedicine measure	Clinical measure	n	r	P
Force at maximum extension	ASIA total motor score	16	0.78	0.0003
Force at maximum extension	ASIA total sensory score	16	0.49	0.04
Force at maximum extension	ASIA bilateral UEMS	16	0.51	0.03
Force at maximum extension	ASIA bilateral LEMS	16	0.68	0.004
Force during eccentric contraction	ASIA total motor score	9	0.70	0.03

UEMS, Upper Extremity Motor Score; LEMS, Lower Extremity Motor Score

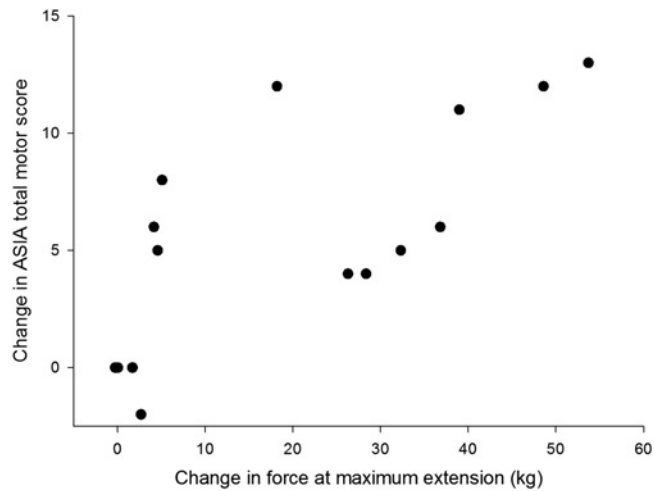


Figure 3 Change in the remotely-measured force at maximum extension and the change in ASIA total motor score in the 16 available subjects ($r = 0.78$, $P = 0.0003$). This was the highest correlation observed

care.¹⁻⁶ The aim of the present study was to evaluate a system for remotely measuring changes in leg strength and balance in subjects with SCI. The method was easy for assessors to learn, and it worked in a rapid and consistent

manner. Most of the tele-assessment measurements of force performed well, documenting significant gains over time, although tele-assessment of balance did not show such changes. Force measures also performed better than balance measures in terms of reliability and validity.

All the subjects had substantial neurological deficits at baseline, and most had a motor complete injury (ASIA A or B) due to a cervical lesion. Subjects showed improvement on several clinical measures over the six-month time course, as described previously.⁷ In parallel, the tele-assessments also identified significant improvement in three of the four leg force measures that were studied (Table 2). The change over time in leg force at maximum extension was the largest among the tele-assessment measures. The reason why is unknown. One explanation is that leg extension is the position assumed by the chronically plegic leg, and so force exerted in this position might show the greatest and most consistent improvement with treatment.

Balance measures performed less well in the present study. The device was able to determine that dynamic balance was associated with greater displacement as compared to static balance, as expected. This suggests that the mechanism for measuring balance worked as intended, consistent with a prior study.¹⁹ The change in balance was not significant over time for either measure. The absence of change in

Table 4 Inter-rater reliability for the six telemedicine measures

	Maximum flexion		Maximum extension		Passive flexion		Eccentric contraction	
Examiner:	1	2	1	2	1	2	1	2
<i>n</i>	9	9	9	9	8	8	8	8
Mean force (SD), kg	5.9 (9.5)	5.9 (6.4)	5.4 (11.8)	7.7 (11.8)	6.4 (4.0)	7.3 (5.0)	8.6 (6.8)	11.8 (9.1)
<i>r</i>		0.68*		0.38		-0.17		0.31
ICC		0.87		0.81		-0.06		-0.17
	Static balance				Dynamic balance			
Examiner:	1		2		1		2	
<i>n</i>	9		9		9		9	
Mean displacement (SD), degrees	0.4 (0.1)		0.4 (0.1)		2.0 (0.7)		2.1 (0.5)	
<i>r</i>			0.46				0.16	
ICC			0.73				0.12	

ICC, intraclass correlation coefficient
* $P < 0.05$ (Spearman's rho)

Table 5 Intra-rater reliability for the six telemedicine measures

	Maximum flexion		Maximum extension		Passive flexion		Eccentric contraction	
Examination:	1	2	1	2	1	2	1	2
<i>n</i>	9	9	9	9	7	7	8	8
Mean force (SD), kg	5.4 (9.1)	12.2 (10.4)	5.0 (10.9)	7.3 (6.8)	6.8 (4.1)	11.3 (7.3)	9.5 (6.8)	10.0 (9.1)
<i>r</i>		0.88**		0.68*		0.71		0.50
ICC		0.97		0.73		0.25		-0.01
	Static balance				Dynamic balance			
Examination	1		2		1		2	
<i>n</i>	9		9		9		9	
Mean displacement (SD), degrees	0.4 (0.1)		0.4 (0.1)		2.0 (0.7)		2.1 (0.5)	
<i>r</i>			0.57				0.16	
ICC			0.44				0.12	

ICC, intraclass correlation coefficient
* $P < 0.05$, ** $P = 0.001$ (Spearman's rho). Note that a trend was present for passive flexion ($P = 0.07$)

balance measures might have reflected content of treatment. This absence of change could theoretically also be due to limited sensitivity of this tele-assessment method, though this seems less likely given its ability to detect significant within-subject differences in dynamic vs. static balance. The absence of significant change over time in either balance measure probably impeded attempts to validate these in relation to clinical measures.

The present study also provided an assessment of reliability and validity. Intra-rater reliability was better than inter-rater reliability. Force measures were more reliable than balance measures were. Leg force at maximum extension had the strongest validity, i.e. correlated with the most number of clinical measures. This measure also showed the most significant change over time; indeed, the tele-assessments methods that were best at identifying change over time showed the greatest validity (see Figure 3). Good reliability and validity are important in putting tele-assessments into effective use.

The present study had several weaknesses. Treatment was associated with more effect on force than balance, and so study hypotheses were less well tested on the balance measures. The contribution of spasticity to the leg force measures, especially leg force during passive flexion, is uncertain. Unfortunately, spasticity was only measured in the elbow, and showed only a weak trend towards correlating with leg force during passive flexion. On the other hand, leg force during passive flexion might represent a means to tele-assess spasticity in subjects with SCI, a suggestion that requires further study. The need for the pelvis strap, and the use of a therapist to safeguard against the subject sliding, during force testing meant that an examiner had to be present for tele-assessment testing.

Use of telemedicine to remotely monitor changes in patients with SCI appears promising.

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