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FUNCTIONAL ELECTRICAL STIMULATION-ASSISTED WALKING FOR PERSONS WITH INCOMPLETE SPINAL INJURIES: LONGITUDINAL CHANGES IN MAXIMAL OVERGROUND WALKING SPEED

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This study investigated the changes in maximal overground walking speed (MOWS) that occurred during walking training with a functional electrical stimulation (FES) orthosis by chronic spinal cord injured persons with incomplete motor function loss. The average walking speed over a distance of 10 m was calculated while the participants ($n = 14$) used their FES orthosis with and without power as well as with the various ambulatory assistive devices available. Within the first year of use, walking with an FES orthosis facilitated use of more advanced ambulatory assistive devices (10/14), improvements in functional mobility (12/14) and increases in the combined (0.26 m/s) and therapeutic (0.25 m/s) MOWS that were correlated (combined: $r = 0.57$; therapeutic: $r = 0.69$) with their respective initial MOWS. A longitudinal analysis showed that increases in MOWS followed a pattern of changes best described by either an exponential association (8/12) or a linear (4/12) model. These changes were similar for the combined and therapeutic MOWS (7/11) as well as for the different ambulatory assistive devices (8/9). It is concluded that the increased MOWS during walking training using the FES orthosis is mostly due to a therapeutic effect, implying that mechanisms of plasticity occur during such a training paradigm.

Key words: rehabilitation, electric stimulation therapy, paraplegia, gait, locomotion.

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INTRODUCTION

Until recently, a spinal cord injury usually resulted in the loss of all motor and sensory functions below the injury site. With improvements in primary care, as well as other factors, a greater proportion of spinal cord injured persons retains some motor and/or sensory function. The epidemiology of spinal cord injury has resulted in an increase in the percentage of spinal cord injured persons with incomplete motor function loss (SCI-IMFL) (1). Restoration of walking is possible for a greater proportion of the spinal cord injured population because of this rise in SCI-IMFL percentage. Electrical stimulation of the common peroneal nerve, eliciting a motor response from the tibialis anterior muscle as well as a flexion withdrawal reflex, can be used like an active orthosis to assist the swing phase of walking.

Functional electrical stimulation (FES) was developed more than 30 years ago to prevent "foot drop" in hemiplegic (2) or SCI (3) persons. FES has been used to restore a variety of movements, including walking (4), and was first reported for SCI-IMFL in 1989 (5). Simple systems utilizing FES-assisted walking with common peroneal nerve stimulation were efficacious for the hemiparetic population (6, 7), but showed a minimal effect for SCI-IMFL (8, 9). Walking speed was increased on average by 0.08 m/s, independent of initial walking speed, whereas oxygen consumption during gait decreased by 3%. Furthermore, studies of gait modulation with the orthosis turned off showed a therapeutic effect in participants who had suffered a stroke or head trauma (for a review see (10)). Such an effect has also been reported for the SCI-IMFL population (11, 12), which showed a minimal effect during a 12-week FES-assisted walking programme (range: 0.0–0.1 m/s) (12).

The objective of this study was to characterize the magnitude and time course of the changes in maximal overground walking speed (MOWS) resulting from the use of FES-assisted walking for SCI-IMFL. Preliminary results of this study have been reported previously (13–15).

METHODOLOGY

Fourteen SCI-IMFL patients, with an average age of 33 years (range: 25–48.9) participated in the study and constituted a sample of convenience. The time interval between the injury and the start of the FES-assisted walking program ranged from 1.8–19.1 years. Participants' lesions ranged in neurological level from the fifth cervical vertebra (C5) to the first lumbar vertebra (L1). According to the International Medical Society of Paraplegia (IMSOP) classification (16), the participants were in either the C category (5/14) or the D category (9/14). Furthermore, the participants spanned the range of functional categories from community ($n = 4$) to least community ($n = 3$) and household walkers ($n = 6$) (17).

All participants required an ambulatory assistive device at the onset of the study. The ambulatory assistive devices used were either a walker ($n = 6$), a forearm crutch ($n = 4$) or a cane ($n = 3$). Mobility was evaluated on a functional scale consisting of 13 items scored on a 7-point scale (maximum score: 84 points). The psychometric properties of the scale have been tested and some modifications made (18). The mobility score ranged from 45–83 points.

FES-assisted walking was accomplished by stimulating the common

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Table I. *Characteristics of the participants*

Participants	Neurological level of lesion	IMSOP	Time post-injury (years)	Age (years)	FES orthosis (start) Mobility score	AAD (initial)	Qr	Ql	Pr	Pl	FES orthosis (end of first year) Mobility Score	AAD (end)	Qr	Ql	Pr	Pl
AC	T12–L1	P_D	12.3	34.0	80	1C			S	S	81	1C			S	S
DB	T8	P_D	6.6	36.0	74	2K			S	S	82	N/A			S	S
DT	T11	P_C	3.1	31.8	45	W			S	S	58	W			S	S
FG	C5–C6	T_D	3.7	48.9	62	2C			S	S	71	2C			S	
JB	T10	P_D	2.5	37.8	78	2C			S		81	2C			S	
LR	T10	P_D	19.1	32.4	63	2K			S	S	73	2C			S	S
LS	T9–T12	P_C	9.9	36.3	60	W	S	S	S	S	64	2K	S	S	S	S
MA	C5–C6	T_C	6.1	36.3	54	W			S	S	61	2K			S	S
MR	C3–C6	T_D	6.3	26.8	83	1C				S′	84	N/A				S′
MS	C6	T_D	8.8	27.6	73	2K			S	S	76	2K			S	
RL	C5	T_D	1.8	29.1	59	2K			S		66	2K			S	
RP	C5–C6	T_C	4.3	28.5	58	W	S	S	S	S	67	2K			S	S
SH	C7	P_C	6.1	30.8	64	W			S	S	70	W			S	S
SM	C5–C6	T_D	4.3	25.0	66	W				S	75	2K				S

IMSOP: International Medical Society of Paraplegia; AAD: ambulatory assistive device; C: cane; K: forearm crutches; W: walker; N/A: no AAD; Qr, Ql: stimulation of the right and left quadriceps; Pr, Pl: stimulation of the right and left common peroneal nerve; S′: stimulation of the tibial nerve.

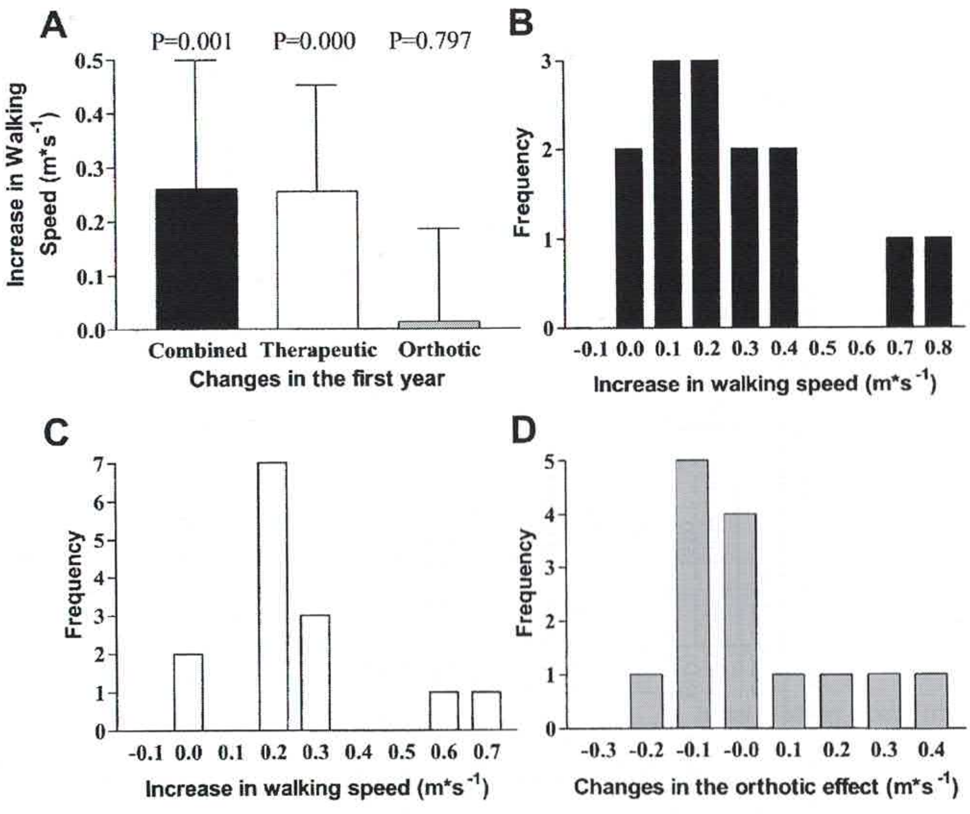

Fig. 1. Changes in the combined, therapeutic and orthotic parameters within the first year of FES-assisted walking. (A) Average increases for the three parameters. (B) Frequency distribution of the increases in maximal overground walking speed in the combined condition. (C) Frequency distribution of the increases in maximal overground walking speed in the therapeutic condition. (D) Frequency distribution of the changes in the orthotic effect.

Table II. *Changes in maximal overground walking speed occurring within the first year of FES-assisted walking*

		Combined effect				Therapeutic effect				Orthotic effect			Comparison	
Participant	AAD	Init(C) m/s (SD)	End(C) m/s (SD)	D(C) m/s	R(C) %	Init(T) m/s (SD)	End(T) m/s (SD)	D(T) m/s	R(T) %	Init(O) m/s	End(O) m/s	D(O) m/s	D(C)–D(T) m/s	D(T)/D(C) %
AC	2C	1.11 (0.07)	1.32 (0.04)	0.19	19	1.11 (0.03)	1.28 (0.02)	0.17	15	0.00	0.04	0.04	0.02	89
DB	2K	0.97 (0.01)	1.76 (0.07)	0.79	81	1.02 (0.08)	1.71 (0.04)	0.69	68	−0.05	0.05	0.10	0.10	87
DT	W	0.19 (0.02)	0.39 (0.05)	0.20	105	0.05 (0.02)	0.24 (0.02)	0.19	380	0.14	0.15	0.01	0.01	95
FG	2C	0.55 (0.03)	0.67 (0.02)	0.12	22	0.48 (0.01)	0.70 (0.02)	0.22	46	0.07	−0.03	−0.10	−0.10	183
JB	2C	0.85 (0.03)	1.56 (0.04)	0.71	84	1.15 (0.06)	1.47 (0.02)	0.32	28	−0.30	0.09	0.39	0.39	45
LR	2K	0.57 (0.01)	0.82 (0.04)	0.25	44	0.57 (0.01)	0.82 (0.02)	0.25	44	0.00	0.00	0.00	0.00	100
LS	2K	0.13	0.22	0.09	69	0.00	0.20	0.20	N/A	0.13	0.02	−0.11	−0.11	222
MA	2K	0.17 (0.01)	0.15 (0.00)	−0.02	−12	0.16 (0.00)	0.17 (0.00)	0.01	06	0.01	−0.02	−0.03	−0.03	−50
MR	1C	1.54 (0.02)	1.97 (0.08)	0.37	24	1.60 (0.01)	2.25 (0.13)	0.65	41	−0.06	−0.28	−0.22	−0.28	176
MS	2K	0.50 (0.03)	0.61 (0.01)	0.11	22	0.45 (0.07)	0.63 (0.02)	0.18	40	0.05	−0.02	−0.07	−0.07	164
RL	2K	0.18	0.43	0.25	139	0.10	0.10	0.00	00	0.08	0.33	0.25	0.25	00
RP	W	0.10	0.25 (0.02)	0.15	150	0.00	0.30 (0.01)	0.30	N/A	0.10	−0.05	−0.15	−0.15	200
SH	W	0.13	0.17	0.04	31	0.00	0.19	0.19	N/A	0.13	−0.02	−0.15	−0.15	475
SM	2K	0.18	0.58	0.40	222	0.18	0.37	0.19	106	0.00	0.21	0.21	0.21	48
Mean		0.51	0.78	0.26	71	0.49	0.74	0.25	70	0.02	0.03	0.01	0.01	131
SD		0.45	0.62	0.24	65	0.53	0.68	0.20	107	0.11	0.14	0.17	0.18	126
p				0.0012				0.0003				0.7971		0.0019

AAD: ambulatory assistive device; C: cane; K: forearm crutches; W: walker; Init(C), Init(T): initial walking speed in the combined and therapeutic conditions; Init(O): initial orthotic effect; End(C), End(T): maximal walking speed obtained within the first year in the combined and therapeutic conditions; End(O): maximal orthotic effect; D(C), D(T), D(O): difference between initial and maximal values in the combined and therapeutic conditions and the orthotic effect; R(C), R(T): ratio of increase of improvement during the first year.

peroneal nerve to help initiate and accomplish the swing phase and quadriceps stimulation was provided to help maintain the extension of the knee during the stance phase (12). The common peroneal nerve and quadriceps stimulations were generated by one of three stimulators depending on the required number of channels and availability of the device. When stimulation of the quadriceps and the common peroneal nerve was required, the participants used a Quadstim stimulator (Biomotion, Inc.), which was capable of providing monophasic stimulation with a constant current. The parameters of stimulation were adjustable for the output current (0–150 mA), stimulus frequency (10–30 Hz) and stimulus pulse width (50–500 μs). When the participants required only one channel of stimulation, they were fitted with either a Unistim (Biomech Engineering Ltd.) or MikroFES (Institut Jozef Stefan) device. The Unistim stimulator provided monophasic stimulation with a constant voltage output. The output voltage was adjustable from 0–100 V, whereas the stimulus frequency and pulse width were constant (23 Hz and 300 μs, respectively). The MikroFES stimulator also provided monophasic stimulation, with a constant voltage output that could be adjusted from 10 to 130 V. The frequency of stimulation was fixed at 25 Hz with a pulse width of 150 μs. The triggering of the common peroneal nerve stimulation with these devices could be made either with hand or foot switches that used either force-sensing resistors (Interlink, Inc.) or mechanical contacts. Details of the participants, ambulatory assistive devices and channels of stimulation used in this study can be found in Table I.

Prior to the start of FES-assisted walking all the participants signed a consent form. Following a 4-week initiation program on the proper use of the FES stimulator, the participants were asked to use FES-assisted walking as much as possible in their activities of daily living.

To evaluate the MOWS, the participants were asked to walk as fast as possible on a 15-m walkway. The surface of the walkway was an industrial carpet with a high coefficient of friction. Participants were allowed to start walking before the starting line in order to accelerate and reach a steady speed before the start of the timing of the performance. The performance in the middle 10 m of the walkway was timed with a handheld stopwatch and the values transformed into an average MOWS. This outcome measure had good reliability for a sample of persons suffering from rheumatism (19). The participants were asked to perform under different randomized conditions: with the use of the FES orthosis, without orthosis, and with their various ambulatory assistive devices. Measures of the MOWS with or without the FES orthosis determined the combined and therapeutic values, respectively. The difference in MOWS between the combined and therapeutic values established the orthotic effect (20).

The time course of the changes in MOWS was fitted with two models, a linear model (Ymodel = A + BX) and a model of exponential association:

$$(\text{Ymodel} = \text{Ystart} + \text{Yspan} \times (1 - e^{-\text{K}\times\text{DELTA\_X}})$$

where Ystart = MOWS at the start of FES-assisted walking, Ymax = MOWS reached during the period of FES-assisted walking, Yspan = Ymax − Ystart, Xstart = week during which FES-assisted walking was done using a particular ambulatory assistive device and DELTA_X = X − Xstart. Some variables of the equation were determined and kept constant (Ystart, Xstart), whereas others were calculated using non-linear regression (Prism v3.0, GraphPad Software). Richardson's method was used to evaluate the derivatives during the fitting of the non-linear regression. The model with the lowest residual sum-of-squares was used to represent the experimental data.

RESULTS

Changes within the first year

When possible, measures of the MOWS were done repeatedly to establish a baseline measure of spontaneously occurring changes. No changes in MOWS were found in participants that were evaluated at least three times prior to the start of the FES-assisted walking study. This result indicates that no spontaneous recovery had occurred prior to the start of FES-assisted walking.

FES-assisted walking has a functional impact, as seen by the increase in functional mobility within the first year (t-test = 6.702, df = 13, $p < 0.000$). This increase in functional mobility is dependent on many factors, but changes according to which ambulatory assistive device is used during walking (Table I) and when walking speed increases. Table I also reports changes within the first year in the orthosis appropriate for each participant. Some participants (3/14) needed a simpler system of stimulation within the first year of FES-assisted walking.

Within the first year of FES-assisted walking, the combined MOWS increased on average by 0.26 m/s (standard deviation (SD): 0.24; Fig. 1A) and the therapeutic MOWS increased by 0.25 m/s (SD: 0.18; Fig. 1A). Both were significantly different from zero ($t = 4.106$, df = 13, $p = 0.0012$ and $t = 4.821$, df = 13, $p = 0.0003$, respectively). The increases in MOWS for the combined condition ranged from −0.02 to 0.79 m/s (Fig. 1B) and from 0.00 to 0.69 m/s for the therapeutic condition (Fig. 1C). The changes in the orthotic effect were not significant ($t = 0.2624$, df = 13, $p = 0.7971$), ranging from −0.22 to 0.39 m/s (Fig. 1D). These increases were normally distributed as tested by the Kolmogorov-Smirnov (KS) distance test (21)

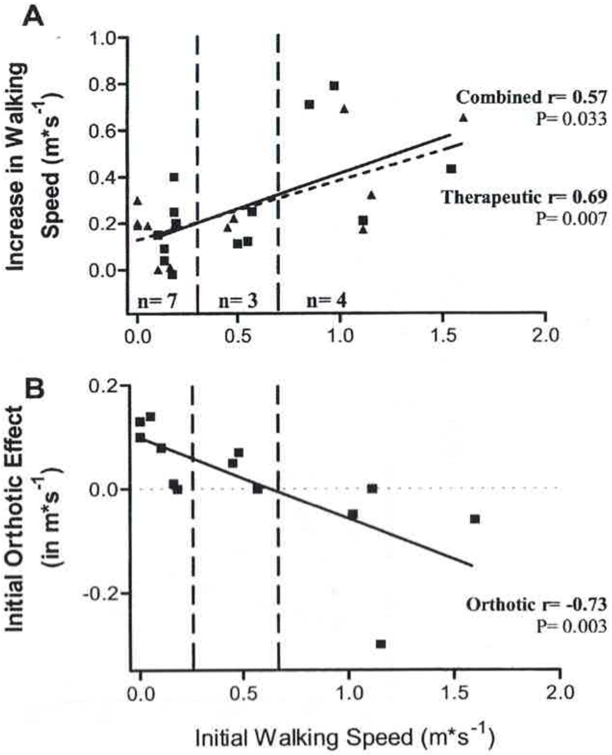

Fig. 2. Relations with the initial maximal overground walking speed. (A) Relations between the increases found in the combined and therapeutic conditions and the initial walking speed (combined condition: triangle, therapeutic: squares). (B) Relation between the initial orthotic effect and the initial therapeutic maximal overground walking speed. The vertical lines represent the boundaries between functional categories of walkers (see text for explanation).

($KS_{combined}$: 0.2323, $p > 0.10$; $KS_{therapeutic}$: 0.2267, $p > 0.10$; $KS_{orthotic}$: 0.1504, $p > 0.10$). The values of the MOWS for all the conditions of each participant as well as their changes can be found in Table II. These increases in MOWS were correlated to the initial value of MOWS for both the combined ($r = 0.57$, $p = 0.033$) and therapeutic conditions ($r = 0.69$, $p = 0.007$), as shown in Fig. 2 (panel A). However, the initial orthotic effect was inversely correlated to the initial therapeutic walking speed, as shown in panel B of Fig. 2 ($r = 0.73$, $p = 0.003$).

Longitudinal changes in MOWS

The increases in MOWS were not instantaneous, but followed a longitudinal progression for both combined and therapeutic conditions. Fig. 3 shows the changes in MOWS for the participants in the combined condition. Changes in MOWS occurred for the three functional categories of walkers (A: Community walkers; B: Least community walkers; C and D: Household walkers) with no striking difference between categories in terms of the model that best described the longitudinal changes. The increase in MOWS in the combined condition was a percentage of the initial MOWS (71%, SD: 65). This idea is supported by the fact that the ratio of increase (R(C) from Table II) was not correlated to the initial MOWS ($r = -0.02$, $p = 0.944$). In addition, as reported above, the magnitude of change correlated to the initial walking speed, showing a greater increase for the participants that were community walkers at the onset of the study. Of the 14 participants, 2 had no changes in MOWS in the combined condition. Of the remaining 12 participants, the longitudinal changes of 4 were best described with a linear model, whereas those of the other 8 participants were best described with an exponential association model. This difference in the qualitative aspect of the increase in MOWS, as represented by the different models of change, demonstrates the variety of longitudinal changes. The values of the parameters of change (either K or B) for each participant can be found in Table III.

Like the longitudinal changes in MOWS in the combined condition, the increases in the therapeutic condition were not instantaneous, but depended on the time since the start of FES-assisted walking. Furthermore, as seen in Fig. 4 and in the longitudinal changes in MOWS of the combined condition, the longitudinal changes were similar in many aspects between functional categories of walkers (A: Community walkers; B: Least community walkers; C and D: Household walkers). These

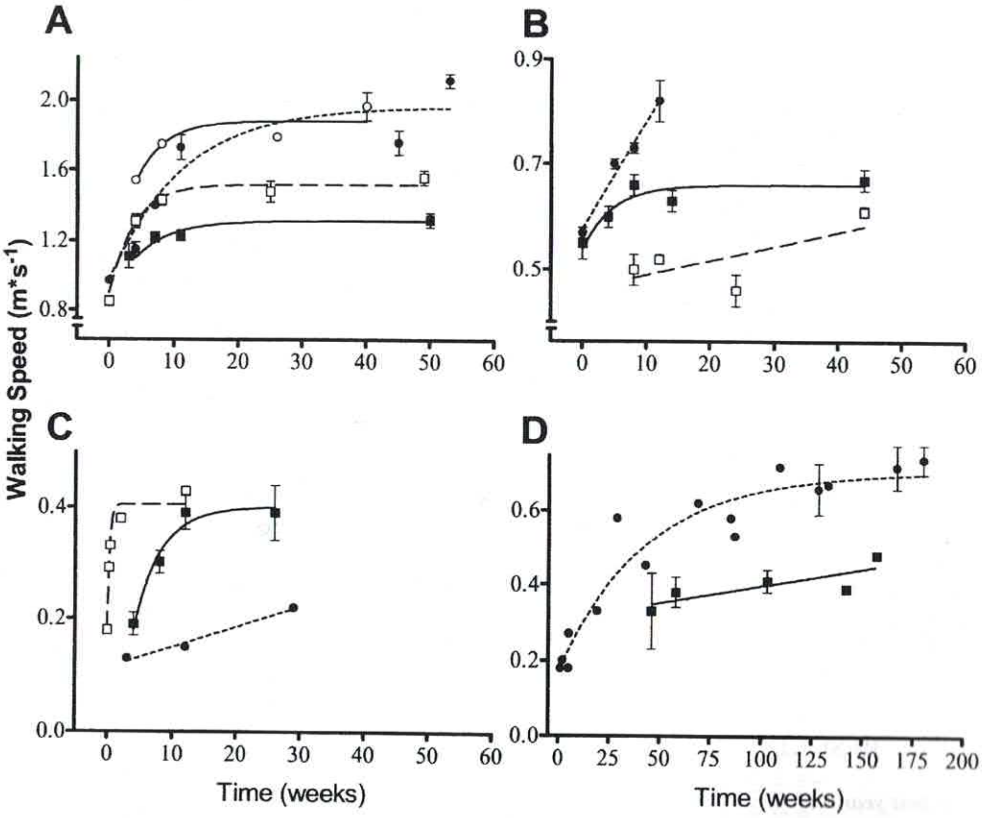

Fig. 3. Longitudinal changes in the combined maximal overground walking speed. (A) Results of subjects with unlimited walking ability in the community: AC (filled squares, full line), DB (filled circles, small dotted line), JB (open squares, long dotted line), MR (open circles, full line). (B) Results of subjects with least walking ability within the community: FG (filled squares, full line), LR (filled circles, small dotted line), MS (open squares, long dotted line). (C) Results of subjects with household walking ability: DT (filled squares, full line), LS (filled circles, small dotted line), RL (open squares, long dotted line). (D) Results of subjects with household walking ability: RP (filled squares, full line), SM (filled circles, small dotted line).

Table III. *Parameters of the models of longitudinal changes occurring using FES-assisted walking (combined and therapeutic effects for AAD)*

		Combined			Therapeutic		
Participant	AAD	Model	K or B	R^2	Model	K or B	R^2
AC	2C	Exp. Ass.	0.187 (0.067)	0.93	Exp. Ass.	0.238 (0.017)	0.99
DB	2K	Exp. Ass.	0.085 (0.032)	0.89	Exp. Ass.	0.100 (0.027)	0.93
	NA		NA		Exp. Ass.	0.116 (0.039)	0.87
DT	W	Exp. Ass.	0.241 (0.075)	0.97	Exp. Ass.	0.056 (0.040)	0.92
FG	2C	Exp. Ass.	0.212 (0.105)	0.86	Exp. Ass.	0.705 (1.011)	0.81
	1C	Exp. Ass.	0.160 (0.013)	0.99	Exp. Ass.	0.580 (0.392)	0.96
JB	2C	Exp. Ass.	0.261 (0.051)	0.98	Exp. Ass.	0.181 (0.006)	0.99
	1C	Exp. Ass.	0.198 (0.091)	0.56	Exp. Ass.	0.217 (0.272)	0.40
LR	2K	Linear	0.021 (0.001)	0.99	Linear	0.020 (0.003)	0.97
LS	2K	Linear	0.004 (0.000)	0.98	Linear	0.006 (0.000)	0.99
MA	2K		NA			NA	
MR	1C	Exp. Ass.	0.229 (0.176)	0.83	Exp. Ass.	0.018 (0.028)	0.93
	NA	Exp. Ass.	0.556 (0.335)	0.98	Linear	0.022 (0.003)	0.96
MS	2K		0.003 (0.002)	0.48	Exp. Ass.	0.500 (*N/A*)	0.36
RL	2K	Exp. Ass.	2.992 (0.674)	0.96		NA	
RP	2K	Linear	0.001 (0.000)	0.67	Linear	0.001 (0.000)	0.81
SH	W		NA		Exp. Ass.	2.169 (0.834)	0.96
SM	2K	Exp. Ass.	0.023 (0.006)	0.92	Linear	0.002 (0.000)	0.81
	2K(a)	Linear	0.002 (0.000)	0.74	Linear	0.002 (0.001)	0.76
	2C	Linear	0.001(0.000)	0.90	Linear	0.001 (0.000)	0.88
Mean (SD)		Exp. Ass.	0.215 (0.140)			0.271 (0.238)	
		Linear	0.005 (0.007)			0.008 (0.009)	

2K(a) = time-adjusted function. NA = Not applicable. See Table I for other abbreviations.

changes consisted of a percentage of the initial MOWS (70%, SD: 107) as seen by the fact that the ratio of increase (R(T) from Table II) was not correlated to the initial walking speed ($r = -0.35$, $p = 0.288$), whereas the absolute increase in MOWS was correlated. Fig. 4 reports the longitudinal changes of the 12 participants for whom there was a change in therapeutic MOWS. Like the combined MOWS, the longitudinal changes for eight participants were best described with an exponential association model of increase, whereas the changes in four participants were best described using a linear model. Individual values of the parameter of change can be found in Table III.

Comparison of the parameters of change (Table III) for the combined and therapeutic conditions, when the participants used the same ambulatory assistive device, shows that the parameters were similar for half of the participants (7/14) in the two conditions. Two had different parameters of changes (participants DT and MR) that remained similar qualitatively, whereas for two participants, different models were necessary (participants MS and SM). Their changes were best described using a linear model for one condition and an exponential association model for the other. Three of the 14 participants could not be compared because in one or both conditions, combined or therapeutic, there were no changes with FES-assisted walking. Parameters of longitudinal changes for the participants that were able to use different ambulatory assistive devices were calculated. Comparison between devices revealed a difference for only one participant (MR) out of nine (Table III) between the parameters of changes for the combined and therapeutic conditions.

The orthotic effect varied according to both the participant and the time since the start of FES-assisted walking. Some participants (4/14) had an increase in the orthotic effect over time (Fig. 5A), others (4/14) decreased over time (Fig. 5B), and some participants (4/14) showed no change in the orthotic effect with time (Fig. 5C). For two participants the results were mixed: there was an increase in the orthotic effect for the first year, followed by a time-dependent decrease (Fig. 5D). It should be noted that the orthotic effect ranged widely, from −0.30 to 0.35 m/s.

In summary, longitudinal changes in MOWS showed a wide variety of responses. Most participants showed increases in both the combined and therapeutic conditions that were qualitatively and quantitatively similar for the different conditions and according to the ambulatory assistive device used. However, the longitudinal parameters of change differed in magnitude for some participants, as did the qualitative models of change. It should also be noted that one participant exhibited changes in only the combined condition (RL) and showed no therapeutic effect, whereas another showed changes in the therapeutic condition (SH) alone, with no change in the combined condition.

DISCUSSION

The aim of this study was to characterize the magnitude and time course of the changes in MOWS using FES-assisted walking for

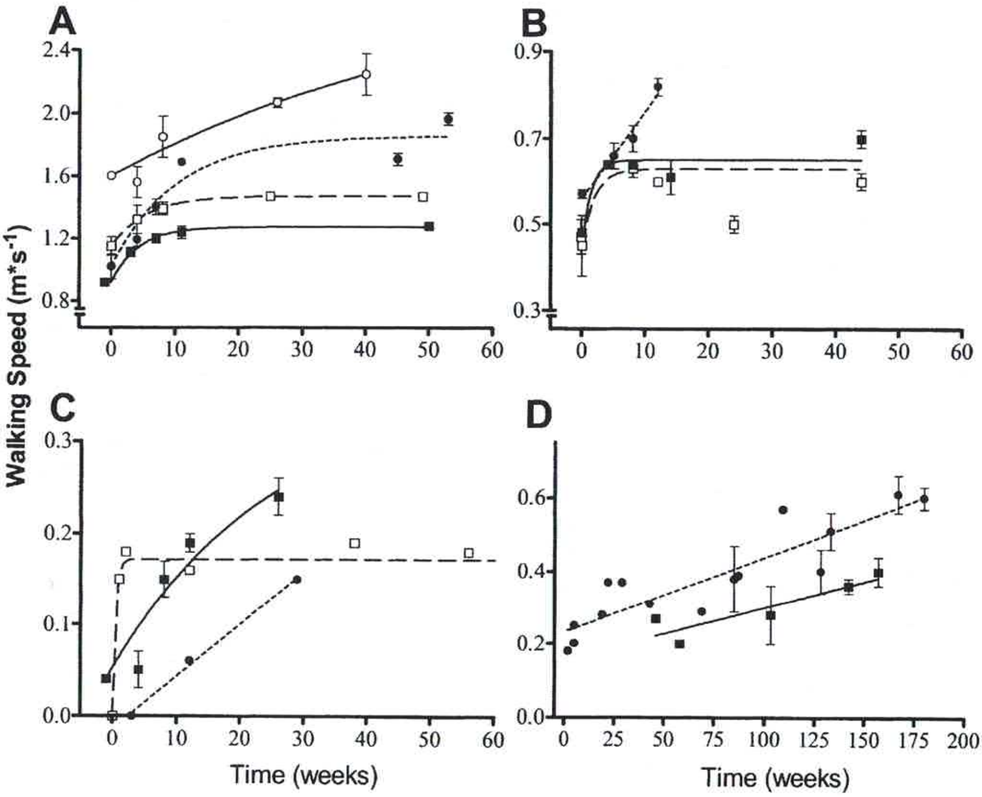

Fig. 4. Longitudinal changes in the therapeutic maximal overground walking speed. (A) Results of subjects with unlimited walking ability in the community: AC (filled squares, full line), DB (filled circles, small dotted line), JB (open squares, long dotted line), MR (open circles, full line). (B) Results of subjects with least walking ability within the community: FG (filled squares, full line), LR (filled circles, small dotted line), MS (open squares, long dotted line). (C) Results of subjects with household walking ability: DT (filled squares, full line), LS (filled circles, small dotted line), SH (open squares, long dotted line). (D) Results of subjects with household walking ability: RP (filled squares, full line), SM (filled circles, small dotted line).

SCI-IMFL. The main result is that SCI-IMFL patients who use an FES orthosis have improved mobility scores due to increased MOWS and to the change in the type of ambulatory assistive device used. This increase is also seen during the same time course when the FES orthosis is turned off.

Unlike previous studies of the effect of simple systems of FES-assisted walking for SCI-IMFL (8, 9, 11), which showed a minimal effect on walking speed, this study showed an average increase in walking speed three orders of magnitude higher than previously reported for the whole spectrum of SCI-IMFL. This greater increase can be explained by two factors. First, we used the MOWS instead of the comfortable walking speed used in other studies. Secondly, the duration of our study was longer. In previous studies, the time since the start of FES-assisted walking was either not taken into account (9) or was controlled with only a relatively short duration (8, 11). The models fitted to the experimental data in the present study reveal that time since the start of FES-assisted walking is a factor in the increase in MOWS. Even the effect of the orthosis was dependent on the time since the start of FES-assisted walking.

Most of the increase in MOWS in the combined condition stems from the therapeutic effect of FES-assisted walking, showing that plasticity in walking behaviour is possible for chronic stage SCI-IMFL. This therapeutic effect may be due to factors such as plasticity of the peripheral system and within the central nervous system. Activating muscles by electrical or voluntary means incurs changes in the properties of their fibres (22). No study so far has reported the effect of FES-assisted walking using common peroneal nerve stimulation on changes to the muscle fibre properties of either the tibialis anterior or triceps surae. However, studies of electrical stimulation of the peroneal nerve have shown stimulus-dependent changes in muscle properties (23, 24). Our participants reported that lower leg muscles hypertrophied while using FES-assisted walking, probably from an increased cross-sectional area of the muscles related to the increased muscular activity.

Plasticity is characteristic of many sites within the nervous system. Changes in synaptic activity have been shown from connections in the monosynaptic stretch reflex (25) to cortical sensorimotor maps (26). More important for this study is the fact that electrical stimulation of the common peroneal nerve has been shown to reduce the amplitude of the H-reflex in the soleus muscle (27). Furthermore, some participants reported fewer spasms and better bowel and bladder control. These changes in

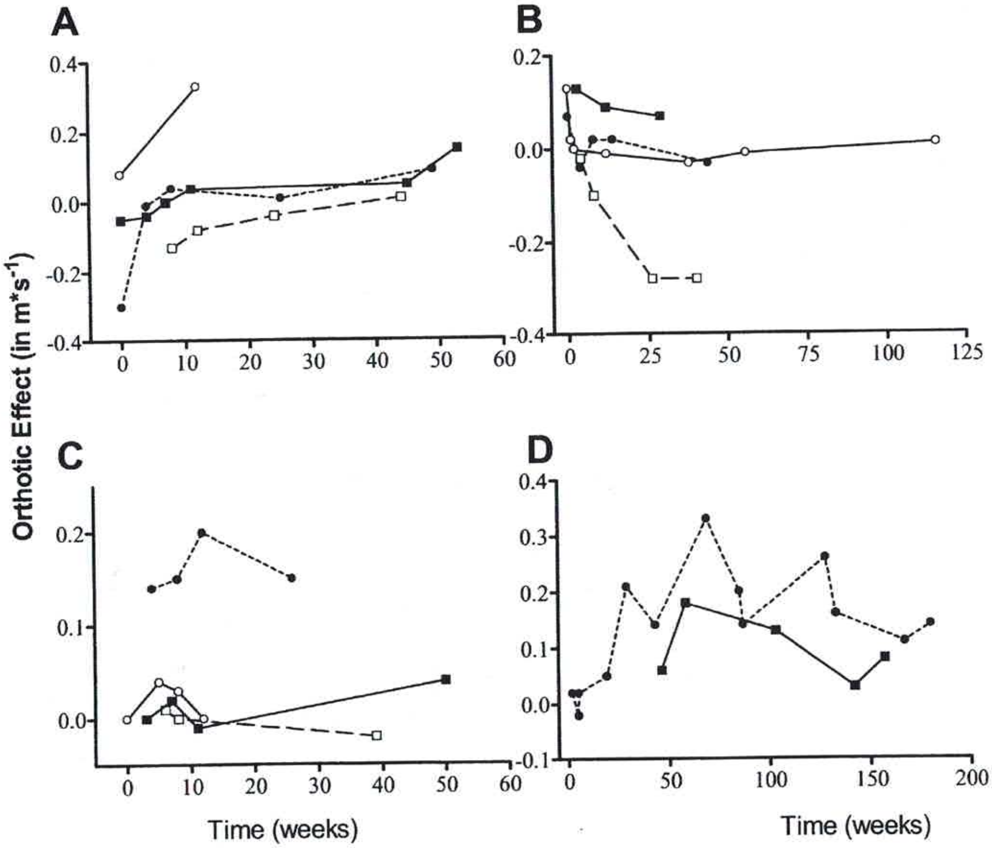

Fig. 5. Longitudinal changes in the orthotic effect. (A) Results of subjects that learned to use the effect of the orthosis: DB (filled squares, full line), JB (filled circles, small dotted line), MS (open squares, long dotted line), RL (open circles, full line). (B) Results of subjects who used the orthosis less with time: LS (filled squares, full line), FG (filled circles, small dotted line), MR (open square, long dotted line), SH (open circles, full line). (C) Results of subjects who did not change their use of the orthosis over time: AC (filled squares, full line), DT (filled circles, small dotted line), MA (open squares, long dotted line), LR (open circles, full line). (D) Results of subjects who improved with the orthosis, but for whom the effect was reduced after a certain time: RP (filled squares, full line), SM (filled circles, small dotted line).

the activity-dependent feedback from all the receptors coupled with changes in the muscles could trigger a reorganization of the planning and generation of walking behaviour.

Behavioural modifications can be seen in the increased strength of the lower limbs and changes in the output of the motor patterns. An increase in ankle dorsiflexion strength has been reported for hemiparetics that received common peroneal nerve stimulation while walking or sitting (28). Three types of responses to a programme of electrical stimulation of the quadriceps have been shown in SCI-IMFL: some participants experience increases in both their voluntary and electrically-activated strength, others only in their electrically-activated strength and some showed no changes in either condition (12). These three types of changes in lower limb strength are similar to the changes reported above for MOWS in our participants. Changes in walking behaviour using FES-assisted walking have been reported in the population of persons who have experienced cerebrovascular accidents. One case study of a person who had experienced a cerebrovascular accident and was using FES-assisted walking showed an improvement in the control of weight acceptance on the paretic side, changes in the kinematic pattern of walking with a return to normal knee flexion at toe-off, and peak knee flexion and knee extension at heel strike (29).

An increase in walking speed fitting an exponential association model has also been seen in SCI persons with complete motor function loss who used FES-assisted walking (30), as well as in participants in a computer-assisted gait training program for hemiparetic persons (31). Because the changes were similar in all conditions, it is hypothesized that changes occurring using FES-assisted walking are systemic changes that could also be used in other motor activities.

Because of the heterogeneity of our sample, the results of this study have many functional implications relevant to the whole spectrum of SCI-IMFL. Improvements in MOWS were seen in the whole spectrum of SCI-IMFL with greater absolute effects for the participants that were walking faster at the onset of the study. Furthermore, the reported time courses of the changes in MOWS allow us to suggest that clinical trials on the effect of an FES orthosis for SCI-IMFL should use a period longer than 12 weeks of training and should evaluate the therapeutic effect of the orthosis. Due to discrepancies between the results of this study and those of previous studies (8, 9, 11) of the effects of

FES-assisted walking in SCI-IMFL, we propose that evaluation of the changes in walking behaviour occurring with an intervention should take into account at least two factors, such as control and capacity of the walking behaviour (32). These factors can be evaluated using walking tasks that demand variation of the walking pattern from the usual comfortable speed on a flat, overground surface. Furthermore, this study shows that the FES orthosis has potential as a training tool in the rehabilitation of walking for SCI-IMFL patients, and that it will help in restoring walking behaviour.

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QUADRICEPS STRENGTH IN WOMEN WITH A PREVIOUS HIP FRACTURE: RELATIONSHIPS TO PHYSICAL ABILITY AND BONE MASS

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Associations between physical ability, level of current physical activity and bone mass were examined in 47 elderly women (mean age 80 years) who had suffered from a hip fracture 3–36 months (mean 17 months) previously. Measures of physical ability included isokinetic quadriceps strength of both the non-fractured and fractured leg, and walking and stair climbing speed. An estimate of current physical activity was made using the Northwick Park activity index questionnaire specifically designed for hip fracture patients. Bone mineral density of the spine and hip (Ward's triangle, femoral neck and trochanter) was assessed by dual energy X-ray absorptiometry. Relationships between the measured parameters were analysed using multiple regression analyses, taking into account the confounding effects of age, height, weight and months since fracture. Quadriceps strength of the fractured leg was on average 18% lower than that of the contralateral leg ($p < 0.001$). Quadriceps strength of the fractured leg proved to be the most robust predictor of walking speed ($R_{partial} = 0.69$, $p < 0.0001$), stair climbing speed ($R_{partial} = 0.46$, $p < 0.001$) and the activity index ($R_{partial} = 0.56$, $p < 0.0001$). Bone mineral density was independently predicted only by body weight ($R_{partial}$ range: 0.45–0.72, $p < 0.001$), not by any of the parameters of physical ability or by the Northwick Park activity index. In conclusion, quadriceps strength is markedly affected in women with a previous hip fracture and is associated with walking ability and level of physical activity. This study showed that bone mass is linked to body weight, not to physical ability and activity. Thus, the main benefit of muscle strengthening exercises in these women may be to promote mobility.

Key words: physical activity, bone mineral density, hip fracture, muscle strength.

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INTRODUCTION

The number of hip fractures occurring in the world in 1990 has been estimated at 1.3 million. With the ageing of the population the annual number of hip fractures is expected to increase by more than 250% by the middle of the next century (1).

Disability and dependency are common after hip fracture (2–4). The risk of a new hip fracture is increased six times in women who have already sustained one (5). This tendency to fracture could reflect reduced bone strength or increased risk of falling due to diminished neuromuscular response. In fact, bone mass is lower in hip fracture patients than in age-matched controls (6), and during the first year after the fracture, bone loss is accelerated (7). Lean mass after hip fracture has been shown to decrease by 10% during the first year, suggesting that focus on muscle strengthening exercises may facilitate the rehabilitation process (7). Enhancement of muscle strength and physical activity may also have a positive effect on bone mass. Numerous studies have demonstrated positive associations of bone mass with muscle strength and physical activity in young as well as in elderly healthy subjects (8–13). Such associations, however, have not yet been examined in elderly osteoporotic and/or disabled women.

It is unlikely that present efforts to prevent hip fractures will have a substantial effect in the foreseeable future (14). Therefore, there is a need for a better understanding of the relationship between muscle strength, physical function and bone mass with the goal of improving the outcome of rehabilitation. The purpose of this study was to examine relationships between constitutional parameters, physical ability and current level of physical activity, and bone mineral density (BMD) in women with a previous hip fracture.

METHODS

Subjects

Forty-seven consecutive women with previous hip fractures were examined. The mean age was 80.3 ± 7.0 (±1 SD) years. Only women who were otherwise healthy were included. None were on medication known to influence bone metabolism. Forty-two cases concerned cervical fractures and five trochanteric fractures. The fractures were of fragility type. The measurements were carried out 6–36 months (mean 17 months) after the time of surgery. At the time of examination, all women were able to walk with or without a walking aid.

The study was performed in accordance with the Helsinki Declaration and with approval of the Ethics Committee of Copenhagen County. Written consent was obtained from all the women.

Muscle strength measurements

Quadriceps strength (Nm) of the fractured and non-fractured legs was measured at 30°/second by an isokinetic dynamometer (Cybex 6000, Ronkonkoma, NY, USA) as previously described in detail (15).

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Table I. *Characteristics of the study group*

	Mean ± 1 SD	Range
Age (years)	80.3 ± 7.0	62–96
Height (cm)	156 ± 6	144–176
Weight (kg)	60.0 ± 11.3	42–88
Bone mineral density (g/cm^2)		
Neck	0.55 ± 0.10	0.30–0.76
Trochanter	0.44 ± 0.10	0.21–0.68
Ward's triangle	0.34 ± 0.08	0.19–0.55
Spine	0.81 ± 0.16	0.54–1.16
Walking speed (km/h)	3.3 ± 1.0	0.9–6.2
Stair climbing speed (steps/min)	51 ± 22	12–103
Activity index (%)	43 ± 19	7–86
Quadriceps strength (Nm)		
Non-fractured leg	66 ± 22	31–118
Fractured leg	54 ± 22	18–107

Walking and stair climbing speed

The women were free to use a stick. Assessment of walking speed (km/h) was performed while the women walked a distance of 50 m in a corridor as fast as possible. Stair climbing speed (steps/min) was measured on a staircase with 30 steps. The women were asked to climb up and down as quickly as they could. Time was measured using a stopwatch.

Physical activity

The Northwick Park activity index questionnaire was used to determine the level of physical activity undertaken on a daily basis, with special regard to social circumstances (16). This questionnaire has been developed specifically for patients with previous hip fractures. The questionnaire includes questions regarding employment, shopping, walking aids, walking distance, stair climbing and home help. The index is expressed in percent. A low index indicates functional dependency and a low level of physical activity.

Measurements of BMD

BMD of the femoral neck, the trochanter and Ward's triangle of the non-fractured leg and BMD of the spine (L2–L4) were measured using a Norland XR-26 dual energy X-ray absorptiometer (DXA). Precision errors for BMD measurements at our laboratory are similar to those reported by other investigators and have been presented elsewhere (17).

Statistics

All data were uniformly distributed. Results are given as mean ± 1 standard deviation (SD) and range. The difference in quadriceps strength between the non-fractured and fractured legs was evaluated with a two-tailed Student's *t*-test for paired observations. Pearson's correlation analysis was used to express the strength of the association between two variables. The predictability of a single variable from several variables was assessed by multiple regression analysis (stepwise selection), from which partial correlation coefficients ($R_{partial}$) were derived. The significance level was set at $p < 0.05$ for all tests. Analyses were performed using the software programme SPSS Statistics V. 4.01 (SPSS International BV, Chicago, IL, USA).

RESULTS

Subject characteristics are presented in Table I. Quadriceps strength was on average 18% lower in the fractured leg than in the contralateral leg ($p < 0.0001$).

Several significant linear inter-correlations were found between the measures of physical ability, the Northwick Park activity index, BMD, age, weight, height and months since fracture (data not shown). Consequently, multiple regression analyses were used to examine the predictability of one variable from several variables. Table II shows the results of multiple regression analyses with the Northwick Park activity index, walking speed or stair climbing speed as the dependent variable and age, height, weight, months since fracture and quadriceps strength of both legs as the independent variables. Quadriceps strength of the fractured leg was the most important determinant of walking speed, stair climbing speed and the Northwick Park activity index. Quadriceps strength of the non-fractured leg did not independently predict any of these three parameters. However, when excluding quadriceps strength of the fractured leg from the analyses, quadriceps strength of the non-fractured leg predicted the activity index ($R_{partial} = 0.45$, $p < 0.001$), walking speed ($R_{partial} = 0.52$, $p < 0.001$) and stair climbing speed ($R_{partial} = 0.29$, $p < 0.05$) independently of age, height, weight and months since fracture.

The Northwick Park activity index was independently correlated with months since fracture ($p < 0.001$). Walking speed and stair climbing speed were positively correlated with body height ($p < 0.05$) and negatively correlated with body weight ($p < 0.05$) (Table II). In multiple regression analyses adjusting for age, height, weight and months since fracture, the Northwick Park activity index was positively associated with walking speed ($R_{partial} = 0.64$, $p < 0.0001$) and with stair climbing speed ($R_{partial} = 0.71$, $p < 0.0001$).

Table III shows the results of multiple regression analyses with BMD as the dependent variable and age, height, weight, months since fracture, the activity index and quadriceps strength as independent variables. Body weight was the only independent predictor of BMD at any measurement site ($R_{partial}$ range:

Table II. *Partial correlation coefficients derived from multiple regression analyses with the Northwick Park activity index, walking speed or stair climbing speed as the dependent variable and age, height, weight, months since fracture and quadriceps strength as the independent variables in 47 women with previous hip fractures*

	Age	Height	Weight	Months since fracture	Quadriceps strength	
					Non-fractured leg	Fractured leg
Activity index	−0.17	0.17	−0.04	**−0.48********	0.02	**0.56********
Walking speed	−0.24	**0.30***	**−0.41****	0.10	−0.10	**0.69********
Stair climbing speed	0.00	**0.40****	**−0.31***	0.14	−0.17	**0.46******

**** $p < 0.0001$, *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$.

Table III. *Partial correlation coefficients derived from multiple regression analyses with bone mineral density (BMD) of the femoral neck, trochanter, Ward's triangle or spine as the dependent variable and age, height, weight, months since fracture, the Northwick Park activity index and quadriceps strength as the independent variables in 47 women with previous hip fractures*

						Quadriceps strength	
	Age	Height	Weight	Months since fracture	Activity index	Non-fractured leg	Fractured leg
BMD							
Neck	−0.23	0.20	**0.65********	−0.23	0.08	0.19	−0.02
Trochanter	−0.16	0.19	**0.72********	−0.26	−0.01	−0.11	0.06
Ward's triangle	−0.23	0.12	**0.45******	−0.08	−0.04	0.24	0.08
Spine	0.00	0.09	**0.47******	−0.12	0.11	0.08	0.17

**** $p < 0.0001$, *** $p < 0.001$.

0.45–0.72, $p < 0.001$). No correlations were found between BMD and walking speed or stair climbing speed (data not shown).

DISCUSSION

Studies of elderly, generally healthy subjects without fractures have reported relationships between muscle strength and functional status (18), chair rising ability (19), and walking and stair climbing speed (19–21). Furthermore, an association between muscle strength and the risk of recurrent falls (22, 23) and fractures (10, 24, 25) has been demonstrated. Although hip fracture patients with mental disorders and coexisting medical conditions known to influence bone mass or muscle function were not included in this study, the mean activity index was only 43%, indicating a low level of physical activity (16). Quadriceps strength was markedly reduced (18%) in the fractured leg compared to the non-fractured one. It this context, it should be taken into consideration that quadriceps strength of the *non-fractured* leg in women with previous hip fractures may be reduced by 25% compared to that in healthy age-matched controls (26). In the present study of women with previous hip fractures, we showed that quadriceps strength of the fractured leg was positively and independently associated with walking and stair climbing speed and with the current level of physical activity. Moreover, the level of physical activity was dependent on walking and stair climbing ability. Although the degrees of explanation (R^2) were only moderate (for example, $0.69^2 = 48\%$ of the variability in walking speed was independently explained by quadriceps strength (Table I)), the findings illustrate the need for improved rehabilitation of muscle function after hip fracture.

Body weight seemed to be an independent contributor to problems related to walking and stair climbing. This is also the case for women suffering from osteoarthritis of the knees (27). Body height, which may associate with the distance covered in a step, was positively related to walking and stair climbing speed.

Several studies of young and elderly women with no physical handicaps have demonstrated independent relationships between BMD and muscle strength (8, 11, 28, 29). Only one previous study has focused on hip fracture patients. Wand et al. (16) examined 12 hip fracture patients rehabilitated 6–33 months previously. The patients had a mean activity index (Northwick Park) of 40% similar to the one found here (43%). A significant inverse relationship between hydroxyproline excretion and the activity index was reported. Based on this finding an association between bone mass and physical activity was suggested for hip fracture patients. However, in the present somewhat larger study, independent associations of BMD at the Ward's triangle, trochanter, femoral neck and spine with the activity index as well as with walking and stair climbing speed were not demonstrated. Consequently, we cannot confirm the suggestion of Wand et al. (16) that physical activity may have a positive effect on bone mass in women with previous hip fractures. Using multiple regression analysis, we found that body weight was the most important determinant of BMD in these women. Reduced muscle strength and a low level of physical activity in women with previous hip fractures possibly make the effect of body weight on bone mass more important. Body weight may mediate effects on bone mass through increased weight-loading on the skeleton. Fatty tissue, a major contributor to body weight, may also mediate positive effects on bone mass via conversion of adrenal steroid precursors to estrogens (30).

A reference population of healthy age-matched women was not available. Bone mass, however, has been shown to be lower in patients with a recent hip fracture than in age-matched controls (6). Furthermore, there is an increased rate of bone loss following the fracture (7). Accordingly, the BMD values found by us were considerably lower than those demonstrated in women who had sustained a hip fracture a few days previously (6). We did not find associations between BMD and months since fracture. The reason may be that total BMD, not the change in BMD, was measured. Moreover, BMD decreases mainly during the first year following the fracture (7), indicating that a linear correlation between bone loss and time since fracture may not be present.

Notwithstanding the limitations of the cross-sectional study design, we conclude that quadriceps strength in women with previous hip fractures is markedly reduced and is associated with walking ability and level of physical activity. Bone mass is linked most closely to body weight, not to age, disease duration, quadriceps strength or current level of physical activity. Thus, the main benefit of muscle strengthening exercises in these women may be to promote mobility, not to reduce bone loss.

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IMPACT OF AGE ON IMPROVEMENT IN HEALTH-RELATED QUALITY OF LIFE 5 YEARS AFTER CORONARY ARTERY BYPASS GRAFTING

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The aim of this study was to describe the relief of symptoms and improvement in other aspects of health-related quality of life 5 years after coronary artery by-pass grafting in relation to age. Patients in western Sweden were approached with an inquiry prior to surgery and 5 years after the operation. Health-related quality of life was estimated with 3 different instruments: Physical Activity Score (PAS), Nottingham Health Profile (NHP), Psychological General Well-Being Index (PGWB). Prior to surgery patients were approached either in the ward or by post and 5 years after surgery they were approached by post. A total of 1719 patients were available for the survey, of whom 876 (51%) responded to the survey both prior to and after 5 years. Among the 876 respondents 287 were <60 years, 331 were 60–67 years and 258 were >67 years. In terms of physical activity, chest pain and dyspnoea, a similar improvement was observed regardless of age. In terms of health-related quality of life questionnaires, there was an inverse association between age and improvement when using PAS and a similar trend was observed with NHP and PGWB. In conclusion, 5 years after coronary artery bypass grafting relief of symptoms and improvement in physical activity was not associated with age, whereas improvement in other aspects of health-related quality of life tended to be less marked in elderly people. Overall age seemed to have a small impact on the improved well-being 5 years after coronary surgery. However, due to the limited response rate the results may not be applicable to a non-selected coronary artery bypass grafting population.

Key words: age, coronary surgery, quality of life.

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INTRODUCTION

Severe coronary artery disease can be treated successfully with coronary artery bypass grafting (CABG) with a considerable improvement in terms of the relief of angina pectoris.

Approximately 3 out of 4 patients are free from ischaemic events for 5 years (1). However, increased survival is demonstrated only in selected subgroups with advanced coronary artery disease (2) and this effect has not been established in elderly patients. The outcome in terms of increased physical activity, symptom relief and other aspects of quality of life (QoL) is of major importance in severely symptomatic patients and particularly if a prognostic gain cannot be expected. Health-related QoL constitutes the individual's perception of symptoms, well-being, and physical and mental functional capacity. However, reports on the influence of age on long-term outcome after CABG in terms of health-related QoL are scarce.

This study evaluates the effect of CABG on health-related QoL for 5 years after the procedure in relation to age. In a shorter perspective age has not been shown to substantially influence health-related QoL after CABG (3, 4).

MATERIAL AND METHODS

Patients

All patients from all 15 hospitals in the western region of Sweden (1.6 million inhabitants), who underwent CABG at the 2 referral centres for CABG in western Sweden, Sahlgrenska University Hospital and the Scandinavian Heart Center, both in Göteborg, between June 1988 and June 1991, received a questionnaire regarding health-related QoL symptoms at the time of coronary angiography prior to the operation and at 5 years after the operation. The pre-operative questionnaires were administered prior to coronary angiography to all patients on the waiting-list who were scheduled for an elective angiography. Patients undergoing emergency coronary evaluation received the questionnaires in the ward prior to angiography.

The demographic data were collected through review of medical charts, interviews, and physical examination of the patients by a physician of the research team, when the patient was hospitalized for CABG. The functional classification was made according to the New York Heart Association.

In total, 2365 patients underwent CABG during the inclusion period. Out of these 244 were excluded due to concomitant valve surgery and 121 patients were excluded due to previous CABG. Of the remaining 2000 patients 281 (14%) died during the subsequent 5 years. Five-year mortality in the 3 age groups (youngest first) were: 8%, 12% and 22%, respectively ($p < 0.0001$ for correlation with actual age). Thus, there were 1719 patients available for this survey, of whom 876 (51%) answered the inquiry both prior to the procedure and 5 years later. Among the 876 respondents 287 were <60 years, 331 were 60–67 years and 258 were >67 years.

In Table I responders are compared with non-responders. Responders included fewer females, they had a less severe angina pectoris, a lower prevalence of previous AMI, congestive heart failure, renal dysfunction and percutanous transluminal coronary angioplasty (PTCA).

In Table II responders are compared with non-responders in the 3 age-groups with regard to previous history and observations at cardioangiography. An interaction with age was found for gender and a history of hypertension.

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Table I. *Clinical characteristics at operation in all patients alive at 5 years after operation in relation to whether patients answered the questionnaire both prior to and at 5 years after operation (%)*

	Responders $n = 876$	Non-responders $n = 843$	p*
Female sex/male	16/84	21/79	0.005
Age (years) (mean)	62.4	62.0	
NYHA class (7)#			0.01
1	2	3	
2	12	14	
3	65	52	
4	21	32	
Previous MI	55	63	0.0006
Angina pectoris	98	97	
Congestive heart failure	11	14	0.05
Hypertension (2)#	36	36	
Diabetes mellitus	10	11	
Renal dysfunction (3)#	22	27	0.01
Cerebrovascular disease	8	7	
Claudication (1)#	10	11	
Obesity	12	12	
Current smoker (2)#	11	14	
Previous PTCA	4	8	0.0003
3-vessel disease (6)#	66	63	
EF <0.40 (77)#	7	9	

NYHA, New York Heart Association; MI, myocardial infarction; PTCA, percutaneous transluminal coronary angioplasty; EF, ejection fraction.
*Given if below 0.05.
Number of patients with missing information.

Symptom scores; single item questions

All of the questionnaires were administered to the patients and collected by 1 person. The study was approved by the local ethics committee in Göteborg. The patients were approached with the first questionnaire at the time of coronary angiography (mean of 3.6 months prior to the operation) and then approached with the same inquiry, by post, 5 years after the operation. The questionnaire included questions about physical activity, the reasons for limitation of physical activity, the occurrence of various types of chest pain, the frequency of chest pain and the occurrence of various types of dyspnoea. Examples are: Have you had symptoms of dyspnoea during the last month? Have you had discomfort or pain in the chest during the last month?

The questionnaires were modified from (5) and validated regarding dyspnoea (6, 7) as well as chest pain (8). Modifications involved translation and addition of some questions.

Validations have been made in previous population studies evaluating clinical signs (7) and left ventricular wall motion abnormalities (9) in cardiac dyspnoea, as well as prognosis in patients with chest pain (uncomplicated angina pectoris; complicated angina pectoris; myocardial infarction) (8).

Health-related Quality of Life questionnaires

The patients completed 3 self-administered questionnaires for the assessment of health-related QoL: the Physical Activity Score (PAS), the Nottingham Health Profile (NHP) and the Psychological General Well-Being (PGWB) index. These questionnaires have been carefully validated and tested for its reliability (10–13).

The PAS represents 1 dimension of an angina-specific questionnaire (14), the Angina Pectoris Quality of Life questionnaire, which contains 6 questions for the self-estimation of physical abilities and limitations. Each response is graded from 1 to 6 and the mean value for all 6 questions is calculated. The higher the value, the greater the degree of disability.

The NHP is divided into 2 parts. Part I, which is used in this study, consists of 38 statements which convey limitations of activity or aspects of distress in 6 dimensions: physical mobility, pain, sleep, energy, social isolation and emotional reactions. Patients are required to indicate by a yes/no answer which of the problems they are experiencing at the time they complete the questionnaire. A score ranging from 0 to 100 can be calculated for each dimension (15). The higher the score, the worse the health-related QoL. Reference values from a healthy population are available (16).

The PGWB index contains 22 questions, dealing with 6 dimensions of well-being: anxiety, depressed mood, vitality, general health, self-control and well-being (11). The response format is graded from 1 to 6

Table II. *Clinical characteristics at operation in responders* and non-responders among different age groups (%)*

	Age 32–59 years Responders Yes/No $n = 287/309$	Age 60–67 years Responders Yes/No $n = 331/267$	Age 68–86 years Responders Yes/No $n = 258/267$	p for interaction with age†
Female sex	14/13	16/22	17/29	0.05
NYHA class				
1	3/3	1/3	<1/3	
2	15/18	11/13	9/9	
3	65/54	62/51	68/50	
4	17/24	25/33	22/39	
Previous MI	59/64	52/63	55/64	
Angina pectoris	97/97	99/97	>99/97	
Congestive HF	8/9	10/10	14/23	
Hypertension	36/29	38/41	32/39	0.02
Diabetes mellitus	9/12	12/13	9/9	
Renal dysfunction	4/5	18/24	47/57	
Cerebrovascular disease	3/4	8/7	12/12	
Claudication	7/8	13/12	10/14	
Obesity	18/13	10/14	8/8	
Current smoker	20/24	8/12	4/4	
Previous PTCA	6/11	3/6	2/4	
3-vessel disease	57/52	68/64	75/74	
EF <0.40	8/9	6/6	7/10	

NYHA, New York Heart Association; MI, myocardial infarction; HF, heart failure; PTCA, percutaneous transluminal coronary angioplasty; EF, ejection fraction.
*Responders are defined as patients answering the questionnaire both prior to and at 5 years after operation
†Given if below 0.05.

Table III. *Physical activity prior to and at 5 years after operation*

	Pre-op				5 years post-op			
Age (years)	<60 %	60–67 %	>67 %		<60 %	60–67 %	>67 %	
Physical activity not limited	5	3	4		36	43	35	
Physical activity slightly limited	23	24	19		39	32	33	
Physical activity severely limited	45	41	36		19	20	22	
Unable to perform physical activity	28	33	42		7	6	10	
	0.0006*				—**			
					<0.0001†	<0.0001‡	<0.0001§	
Physical activity limited due to:				*p*				*p*
Tiredness	11	10	13	—*	16	14	21**	
					—†	—‡	0.004§	
Palpitations	2	2	1	—	3	3	4	—
					—	—	—	
Dyspnoea	25	27	22	—	34	35	41	
					0.009	0.008	<0.0001	
Chest pain	77	78	77	—	25	20	18	—
					<0.0001	<0.0001	<0.0001	

* *p* for correlation with actual age.
** *p* for correlation with actual age, adjusted for preoperative value.
† *p* for change from preop - patients aged 28–59 years.
‡ *p* for change from preop - patients aged 60–67 years.
§ *p* for change from preop - patients aged 68–86 years.
— indicates *p*-value above 0.05.

(total score range 22–132), with the highest value corresponding to superior well-being. Reference values derived in an unselected population are available (14).

Selection of questionnaires

The symptomatic response to myocardial ischaemia in angina pectoris is chest discomfort, induced by physical or mental stress, thereby limiting physical performance. However, angina pectoris has also other detrimental impacts, such as increased anxiety and limitations of leisure activity, working capacity and social and sexual function (17).

The PAS represents 1 dimension of a disease-specific questionnaire for the estimation of physical capacity in angina pectoris (13). The NHP and the PGWB index are categorized as generic questionnaires. The NHP is most useful in patients with chronic diseases and/or with pronounced symptoms (18). The NHP has previously been used to evaluate the effect of CABG (19, 20). The PGWB index is suitable for addressing the impact of symptoms on well-being and is applicable in healthy as well as patient populations. The purpose of this choice of questionnaires was to capture the whole range of outcomes, from symptomatic limitations of physical abilities due to angina pectoris to overall well-being and health-related QoL. These questionnaires were chosen rather than other estimates, observed to have a lesser ability to reflect subjective results after CABG, such as NYHA classification, and return to work.

Statistics

In Table I the Mann-Whitney U test was used for age and functional class and Fisher's exact test for dichotomous variables. Logistic regression was used to test interaction in Table II. Otherwise, Spearman's rank statistic were used to test correlation with age. Actual age was used in all *p*-value calculations. Patients were divided into the 3 age groups for illustrative purposes. Adjustments for preoperative values in Tables III–VI were made by using Spearman's partial rank statistic. For changes over time within groups Wilcoxon's signed rank test and the sign test were used, for ordered/continuous variables and dichotomous variables, respectively.

Except for Tables I and II, only patients answering the questionnaire both prior to and at 5 years after CABG were included in the analysis.

All *p*-values are 2-sided and considered significant if below 0.05 in Tables I and II and if below 0.01 otherwise. In Tables I and II *p*-values are noted if below 0.05, and in the remaining tables if below 0.01.

RESULTS

Symptoms and physical activity

Physical activity (Table III). There was an association between limitation of physical activity and age prior to, but not 5 years after, CABG. In all three age groups the degree of limitation of physical activity decreased 5 years after CABG compared with prior to the operation.

Among patients in the oldest age group more of them had their physical activity limited due to tiredness 5 years after CABG than prior to surgery, but this difference was not significant in the two youngest groups. The proportion of patients who had their physical activity limited due to dyspnoea increased after the operation in all three age groups, whereas the proportion who had their physical activity limited due to chest pain decreased markedly in all three age groups.

Symptoms of dyspnoea (Table IV)

Prior to surgery there was an association between age and dyspnoea in 5 of 7 specific situations (more dyspnoea in the elderly), whereas such an association was found only in 1 of 7 situations 5 years after surgery. The proportion of patients who were free from dyspnoea 5 years after the operation increased markedly compared with prior to surgery in all 3 age groups.

Correspondingly the proportion of patients with symptoms of

Table IV. *Symptoms of dyspnoea prior to and at 5 years after operation*

	Pre-op				5 years post-op			
Age (years)	<60 %	60–67 %	>67 %	*p*	<60 %	60–67 %	>67 %	*p*
No dyspnoea	14	15	10	—*	42 <0.0001†	40 <0.0001‡	37 <0.0001§	—**
When walking uphill or quickly on the level	83	82	87	—	55 <0.0001	55 <0.0001	58 <0.0001	—
When walking with people of own age on the level in their speed	65	65	72	—	33 <0.0001	35 <0.0001	38 <0.0001	—
Have to stop to catch breath when walking on the level in own speed	26	35	45	<0.0001	10 <0.0001	12 <0.0001	20 <0.0001	
When dressing or washing	14	23	27	0.0001	9 0.009	9 <0.0001	10 <0.0001	—
At rest, when sitting down, or at night	8	12	15	0.003	3 0.007	3 <0.0001	4 <0.0001	—
Have to sit down and rest when returning from a walk	58	61	69	0.001	27 <0.0001	33 <0.0001	42 <0.0001	0.002
Wake up at night due to dyspnoea	10	17	22	<0.0001	6 —	6 <0.0001	8 <0.0001	—

* *p* for correlation with actual age.
** *p* for correlation with actual age, adjusted for preoperative value.
† *p* for change from preop - patients aged 28–59 years.
‡ *p* for change from preop - patients aged 60–67 years.
§ *p* for change from preop - patients aged 68–86 years.
— indicates *p*-value above 0.05.

dyspnoea at specific occasions decreased in all age groups 5 years after surgery, with the exception of patients aged <60 years with regard to waking up at night due to dyspnoea.

Number of attacks of chest pain (Table V)

The frequency of attacks of chest pain was not related to age neither prior to surgery nor 5 years later. The number of attacks of chest pain decreased significantly in all 3 age groups.

Chest pain on various occasions (Table VI)

Prior to CABG the occurrence of chest pain was related to age (more common in elderly subjects) on the following occasions: when walking in own speed, when dressing or washing, at night and when out in windy or cold weather.

Five years after surgery chest pain was not positively associated with age in any situation. On the other hand, chest pain was observed to be negatively associated with age 5 years after surgery when under stress and after dinner.

In all situations chest pain was markedly and significantly reduced 5 years after CABG compared with prior to surgery in all 3 age groups.

Physical activity score (Fig. 1). Both prior to and 5 years after CABG there was a significant correlation between age and PAS indicating less physical activity in elderly subjects. There

Table V. *Number of attacks with chest pain per week prior to and at 5 years after operation*

	Pre-op			5 years post-op		
Age (years)	<60 %	60–67 %	>67 %	<60 %	60–67 %	>67 %
Number of attacks						
None	6	2	3	50	56	57
Less than once a week	10	8	6	20	20	17
1–2 per week	14	15	11	12	9	11
3–6 per week	15	21	20	9	5	2
Once or twice daily	32	29	32	6	6	8
Several daily	24	25	28	4	4	4
	0.03*			—**		
				<0.0001†	<0.0001‡	<0.0001§

* *p* for correlation with actual age.
** *p* for correlation with actual age, adjusted for preoperative value.
† *p* for change from preop - patients aged 28–59 years.
‡ *p* for change from preop - patients aged 60–67 years.
§ *p* for change from preop - patients aged 68–86 years.
— *p*-value above 0.05.

Table VI. *Chest pain at various occasions prior to and at 5 years after operation*

	Pre-op				5 years post-op			
Age (years)	<60 %	60–67 %	>67 %	*p*	<60 %	60–67 %	>67 %	*p*
When walking uphill or quickly on the level	91	93	97	*	43	38	42	—**
					<0.0001†	<0.0001‡	<0.0001§	
When walking with people of own age on the level in their speed	75	75	85	0.004	25	25	25	—
					<0.0001	<0.0001	<0.0001	
When walking on the level in own speed	27	35	44	<0.0001	5	7	9	—
					<0.0001	<0.0001	<0.0001	
When dressing or washing	18	25	34	<0.0001	4	7	4	—
					<0.0001	<0.0001	<0.0001	
At rest, when sitting down	13	18	17	—	4	3	5	—
					0.0008	<0.0001	0.0001	
At night	23	31	39	<0.0001	7	8	9	—
					<0.0001	<0.0001	<0.0001	
When under stress	89	82	85	—	48	37	35	0.002
					<0.0001	<0.0001	<0.0001	
After dinner	32	37	37	—	16	9	6	0.002
					<0.0001	<0.0001	<0.0001	
When out in windy or cold weather	78	86	89	0.0007	43	41	42	—
					<0.0001	<0.0001	<0.0001	

*p for correlation with actual age.
** p for correlation with actual age, adjusted for preoperative value.
† p for change from preop - patients aged 28–59 years.
‡ p for change from preop - patients aged 60–67 years.
§ p for change from preop - patients aged 68–86 years.
— indicates p-value above 0.05.

was also an association between improvement and age, the improvement being more marked in younger patients than in elderly patients, although a significant improvement was observed in all 3 age groups.

Nottingham Health Profile

Subcomponents (Fig. 2). Prior to surgery there was a positive association between age and the pain and mobility subcomponents, indicating more symptoms in the elderly. On the other hand, there was a negative association between age and emotions prior to surgery (more problems in younger patients).

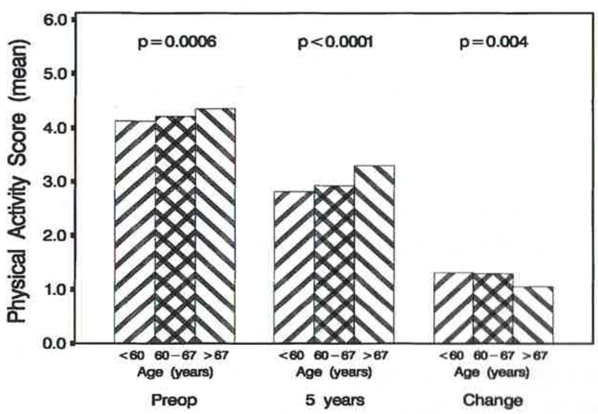

Fig. 1. Mean of physical activity score prior to and at 5 years after operation in relation to age.

Five years after the operation there was a positive association between age and the following subcomponents: energy, pain and mobility. Improvement was significantly more marked in younger patients in the emotions and energy subcomponents.

In terms of sleep there was no improvement in the oldest age group and in terms of social isolation there was no improvement in any of the age groups. Significant improvements were found in all other subcomponents in all 3 age groups.

Psychological General Well-Being Index

Total score (Fig. 3). Prior to CABG there was a significant correlation between age and PGWB with less well being seen in younger patients. Such a correlation was not found 5 years after CABG. The improvement was significant in all 3 age groups, but there was only a trend towards an association between low age and improvement.

Subcomponents. Prior to surgery there was a positive association between anxiety and age and between well-being and age. Five years after surgery there was still a positive association between age and anxiety. In all subcomponents there was an improvement in all 3 age groups 5 years after CABG compared with prior to surgery. Improvement was similar regardless of age with exception for well-being, where improvement was more marked in younger patients.

Relation to other study groups

Compared with a normal population, patients showed a lower health-related QoL prior to CABG, but a similar QoL 5 years

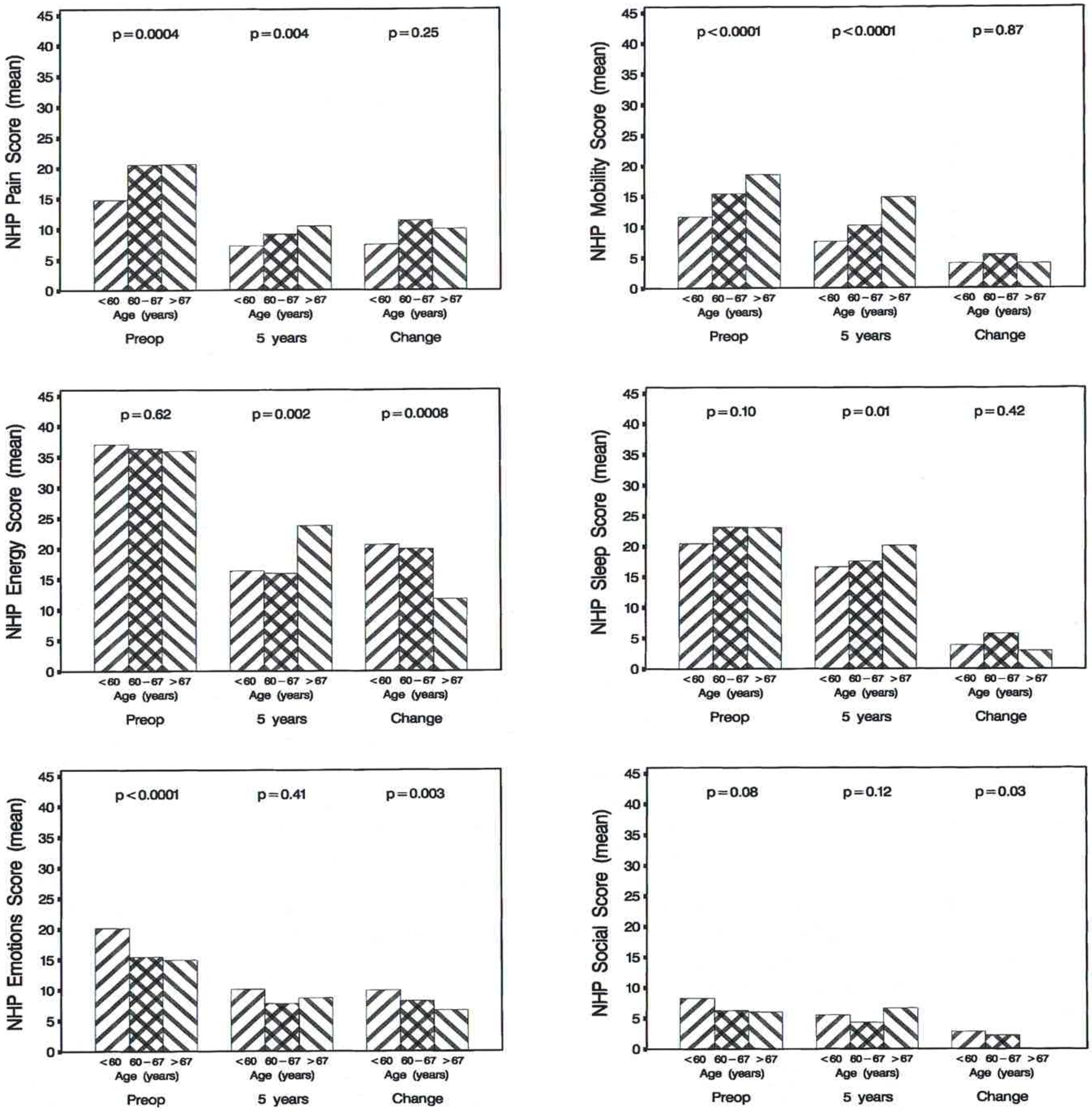

Fig. 2. Mean of NHP subcomponent score prior to and at 5 years after operation in relation to age. Upper right = mobility; upper left = pain; medium right = sleep; medium left = energy; lower right = social; lower left = emotions. NHP = Nottingham Health Profile.

after CABG when measured with PGWB total score (14). When compared with another patient population, it was found that patients with heartburn had a better health-related QoL than patients waiting for CABG (14).

When evaluating various subcomponents of NHP, patients appeared to have a worse health-related QoL prior to CABG than a normal population, whereas 5 years after CABG health-related QoL was similar to a normal population (12). However health-related QoL according to NHP subcomponents was better among patients both prior to and after CABG as compared with patients suffering from arthrosis and arthritis (12, 21).

DISCUSSION

This study evaluates the impact of CABG on improvement in various aspects of QoL during 5 years after the operation in relation to age. Although we found somewhat less improvement in QoL among elderly patients when evaluating health-related

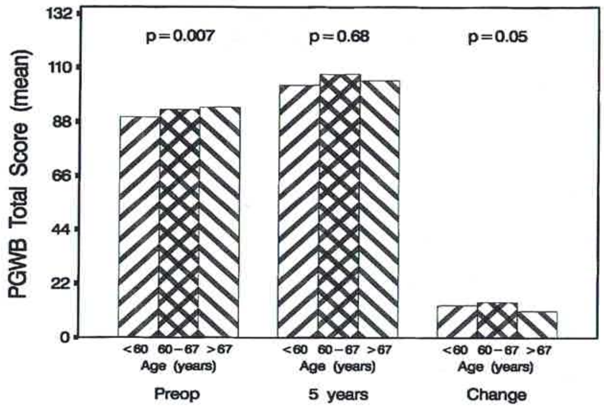

Fig. 3. Mean of Psychological General Well-Being (PGWB) total score prior to and at 5 years after operation in relation to age.

QoL questionnaires, their relief of symptoms and improvement in physical activity was similar to that among younger patients.

Previous studies have found favourable and in some cases equal results in an ageing population as in a younger population in terms of health-related QoL after CABG (22–26).

It has previously been shown that CABG in older patients is more expensive than in younger patients due to more complications and longer hospitalizations (27). It is therefore important to consider age aspects on outcome, not only in terms of survival, but also in terms of symptoms and various aspects of health-related QoL.

Unlike younger patients, among elderly patients the main goal of surgery is not necessarily to prolong life, but to eliminate angina and improve health-related QoL.

We did not study return to work in this investigation. Other studies have found that chest pain is the main variable negatively influencing return to work, but also that increasing age is a negative factor (28). It is therefore important that we see a marked and similar improvement in physical activity, relief of chest pain and relief of dyspnoea regardless of age. This observation indicates that we can expect a similar relief of symptoms related to myocardial ischaemia also in the elderly.

Despite the fact that younger patients had more pain at dinner and under stress even 5 years after surgery, we observed that younger patients improved more in terms of physical activity than older patients. This indicates that chest pain at rest might not prevent patients from improving their physical capacity after CABG.

In accordance with other studies (29), we have previously shown that the alteration of health-related QoL after CABG is an early phenomenon after surgery (30). When evaluating well-being in terms of various measurements of health-related QoL, our long-term results presented in this report appear slightly different from the improvement in symptoms which was unrelated to age. Thus, at least with regard to PAS, improvement tended to be less marked in the elderly. A similar tendency was observed with regard to both NHP and PGWB. Although we found a tendency towards less improvement in health-related QoL among elderly patients, there was still an impressive effect. This is in accordance with previous findings in octogenarians (31).

There was a discrepancy with regard to the association between age and physical respective psychological symptoms; a positive association with the former and a negative association with the latter. This finding is in agreement with what has been found among patients with other manifestations of ischaemic heart disease (32).

Prior to surgery we found a negative correlation between age and emotions and a positive correlation between age and anxiety. We have no explanation to this finding other than that emotion and anxiety measure different aspects of health-related QoL.

A possible explanation for the slight discrepancy in age correlation with symptoms and other aspects of health-related QoL is that various measurements of health-related QoL take into account not only symptoms of ischaemic heart disease, but other symptoms as well. It is possible that rehabilitation programs can improve long-term health-related QoL and this might favourably affect the older age groups. Thus, it has been shown that 5-year restriction in physical mobility on the NHP was lower among patients undergoing a rehabilitation program after CABG (33).

Limitations

1. We were unable to administer reminders and this might have reduced the response rate to our questionnaire. The low response rate prior to CABG was primarily due to administrative reasons or the fact that emergency surgery was performed, precluding the possibility to make an assessment at short notice. The symptomatic results of CABG in the patients who did not respond to the questionnaires is unknown. Those patients appeared to suffer from more severe coronary artery disease than the responders. Therefore, our results may not be applicable in a totally non-selected population undergoing CABG.
2. The patients were approached with the first questionnaire at the time of coronary angiography, where not only angina pectoris, but also the personal distress of mental preparation for cardiac surgery may have affected health-related QoL scores. However, favourable expectations of the surgical procedure might also have influenced the results.
3. No objective data on long term myocardial function and myocardial ischaemia was available. However, it is important to stress that the major objective of CABG is to relieve symptoms.
4. There was a lack of information regarding lipid management during follow-up.
5. There was no information on the number of patients who underwent rehabilitation programmes.
6. Since there are a total of over 200 tests performed in this study, the increased probability of false significances should be considered. A Bonferroni correction (which is

too conservative to be quite appropriate in this case) would require an uncorrected p-value of below 0.0003 for significance at the 0.05 level.

Implications

Our results suggest that the relief of symptoms and improvement in physical activity during long-term follow-up after CABG is similar in elderly patients and younger patients. Improvement in other aspects of health-related QoL, which take into account not only symptoms related to myocardial ischaemia, tended to be less marked in elderly patients. Overall age seemed to have a small impact on the improved well being 5 years after coronary surgery. Due to a limited response rate our results may not be applicable to a non-selected population of CABG patients.

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