



# Functional recovery in patients with nonunion treated with the Ilizarov technique

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**T**here are few reports on function after limb salvage surgery using the Ilizarov technique, and none that document the pattern of recovery or predict when maximum function returns. This prospective, longitudinal study documents the baseline functional abilities of 40 consecutive patients with nonunion of a fracture in the lower limb. Patients were studied for at least two and a half years following the completion of surgery. Function was measured by timed tests of functional performance and by the Toronto Extremity Salvage Score self-reported patient questionnaire.

Recovery was slowest in the early stages after removal of the frame and greatest between six months and one year. Statistically significant improvement continued up to, but not beyond two years. This observation has important implications for the length of follow-up incorporated into the rehabilitation programmes for patients, predictions of patient status in regard to compensation and for the design of future studies to evaluate functional outcome.

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Distraction osteogenesis is an effective technique in the treatment of high-energy fractures, segmental defects and nonunion.<sup>1,2</sup> The last of these remains a major problem. Despite success in eradicating infection and obtaining bony union, many patients continue to have limited function.<sup>1,3</sup>

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Some have reported inferior long-term outcome and reduced quality of life for patients treated by limb salvage compared with amputation, but others have reported satisfactory results.<sup>4,6</sup>

The use of the Ilizarov technique in the treatment of nonunion, osteomyelitis and malunion is well documented and gives good results.<sup>2</sup> Difficulties remain, however, with reports of stiffness of the joints and reduced muscle strength.<sup>7-10</sup> Relatively little attention has been given to the functional outcome of limb salvage surgery using the Ilizarov technique. Most studies have been retrospective and comprise reports of patient satisfaction or the surgeon's assessment of outcome, without using objective measurements. The need to assess both function and quality of life is increasingly recognised as essential in clinical research.<sup>11</sup> Furthermore, there is a need for the patients to assess their satisfaction with the long-term outcome of orthopaedic procedures, in order both to improve the data collected and to fulfil responsibilities under clinical governance.<sup>12,13</sup> Few studies exist that address these important aspects<sup>5,6,14</sup> and only two have been conducted on patients treated by the Ilizarov technique.<sup>1,15</sup> Even fewer studies have reported function after surgery measured prospectively and objectively, or have identified factors that limit mobility. There has been no report on the expected time for recovery to occur, although a prediction as to when a patient has reached his/her maximum recovery is often required when estimating the workload for rehabilitation services, planning further surgery, and assessing prognosis in medicolegal cases.<sup>16</sup>

The aim of our study was to document the functional capability and the pattern of recovery in a cohort of patients treated by the Ilizarov technique for nonunion of fractures of the lower limb. We measured function using timed performance and a subjective outcome questionnaire. Comparison was made between pre-operative scores and those at a minimum of two and a half years after removal of the frame.

## Patients and Methods

Forty consecutive patients undergoing corrective surgery for nonunion of a fracture of the lower limb using the Ilizarov technique were studied prospectively for a minimum of three years after the application of the frame. No patient was excluded from the study, for which ethical committee

**Table I.** Details of the 40 patients with nonunion who were treated using the Ilizarov technique

	Mean	Range	Standard deviation
Age (years)	33	16 to 56	10.02
Amount lengthened/gap (cm)	3.9	0 to 8.6	2.01
Amount lengthened as % of limb segment	9.5	4.1 to 21	4.25
Lengthening index (days of lengthening/amount lengthened)	22.4	5.7 to 80	13.51
Fixation index (days in fixator/amount lengthened)	70.7	23.2 to 340	61.5
Total length of time in external fixator (days)	220	40 to 701	142

**Table II.** Recovery of function after leg lengthening surgery comparing time intervals and using paired Student's *t*-tests

	Mean recovery ratios (95% CI)			
	Pre-op to 6 months	6 months to 1 year	1 to 2 years	2 to 2.5 years
TESS score (%)	1.15 (1.07 to 1.23)*	1.18 (1.12 to 1.24)†	1.08 (1.06 to 1.10)†	1.01 (0.99 to 1.00)
Walking speed (m/s)	1.18 (1.12 to 1.24)*	1.08 (1.06 to 1.10)†	1.01 (0.99 to 1.00)†	1.07 (1.01 to 1.13)
Sit-to-stand (number in 60 s)	1.05 (1.01 to 1.09)	1.10 (1.08 to 1.13)†	1.02 (1.01 to 1.03)*	1.00 (0.99 to 1.01)
Stair climbing (number in 60 s)	1.08 (0.99 to 1.17)	1.08 (1.05 to 1.11)†	1.02 (1.01 to 1.02)†	0.95 (0.88 to 1.02)

\**p* < 0.05†*p* < 0.001

approval had been obtained. All patients had been referred for further management after at least one previous surgical procedure. A diagnosis of nonunion was made clinically and radiologically on the basis of failure of union within six months and no progress towards healing on sequential radiographs. Infection was identified on the basis of a discharging sinus, growth from operative specimens or an acute inflammatory response on histological examination.<sup>17</sup> The treatment protocol involved the excision of non-viable bone and soft tissue, where indicated, and the removal of any fixation device. Stabilisation was achieved using an Ilizarov fixator with distraction osteogenic techniques to reconstruct the segmental defect.

There were 32 men and eight women, 31 with an ununited tibial and nine an ununited femoral fracture. The mean time from injury to the Ilizarov procedure was two years and 11 months (5 to 134) and the patients had undergone a mean of 3.2 previous operations (1 to 9). Two did not require segmental excision; one was treated by compression alone and one with correction of deformity. Less than half of the patients (18) had active infection at the time of surgery.

Details of the patients and a summary of treatment are presented in Table I. The results for change in function with time are summarised in Table II.

Simple, timed performance tests of walking speed, sit-to-stand and stair climbing were selected as representing basic activities easily accomplished in the clinic setting.<sup>18-20</sup> An additional score, the Toronto Extremity Salvage Score (TESS), was selected as it identifies physical disability, based on the patients' description of function.<sup>21</sup> It is applicable to a heterogeneous population, being sensitive to change across a range of levels of disability. It also meets the recommended goal for patient-rated questionnaires, being completed within 15 minutes.<sup>22</sup>

Functional capability was measured on the day before surgery, and at six, 12, 24 and 30 months after the external

fixator had been removed from the leg. The same person (KLB) made all the measurements. Patients received regular physiotherapy based upon a standard protocol.<sup>8</sup>

The time taken to walk a 20 m course was measured using a previously reported, repeatable and valid technique.<sup>18</sup> Patients stood with both feet on the start line and were asked to walk as quickly as they could around a cone positioned 9.5 m away and to return to the start line; this position of the cone allowed for a 0.5 m turn around the cone. The tests were conducted in a gymnasium with a non-slip floor and the time was recorded using a digital hand-held stopwatch. They were then asked to climb a staircase with seven steps up and six steps down, each of 19 cm depth, repeatedly and in the manner in which they felt comfortable and that they would normally use. The staircase required them to turn at the top before descending. The number of stairs which they ascended and descended in 60 s was recorded. The third test required unassisted standing from a seat 49 cm from the ground and with the feet placed flat on the floor in front of them. Patients were asked to keep their arms folded in front of them so as not to use their hands to push down on the chair or their thighs. On the command 'go' they were asked to stand upright to a position with their knees fully extended, and then sit back down immediately. They were asked to do this repeatedly as fast as possible and the number of times that each subject rose and returned to the starting position in 60 s was recorded. Previous studies have reported that these three actions correlate well with each other.<sup>18,23</sup>

The lower limb version of the TESS was chosen because it has been extensively validated in patients with sarcoma undergoing salvage procedures. Our group had similar characteristics to a sarcoma group in terms of age, part of body affected and magnitude of surgery.<sup>21</sup> Patients were asked to answer 30 questions on a five-point modified Likert scale, ranging from 'not at all difficult' to 'impossible to do'. If the

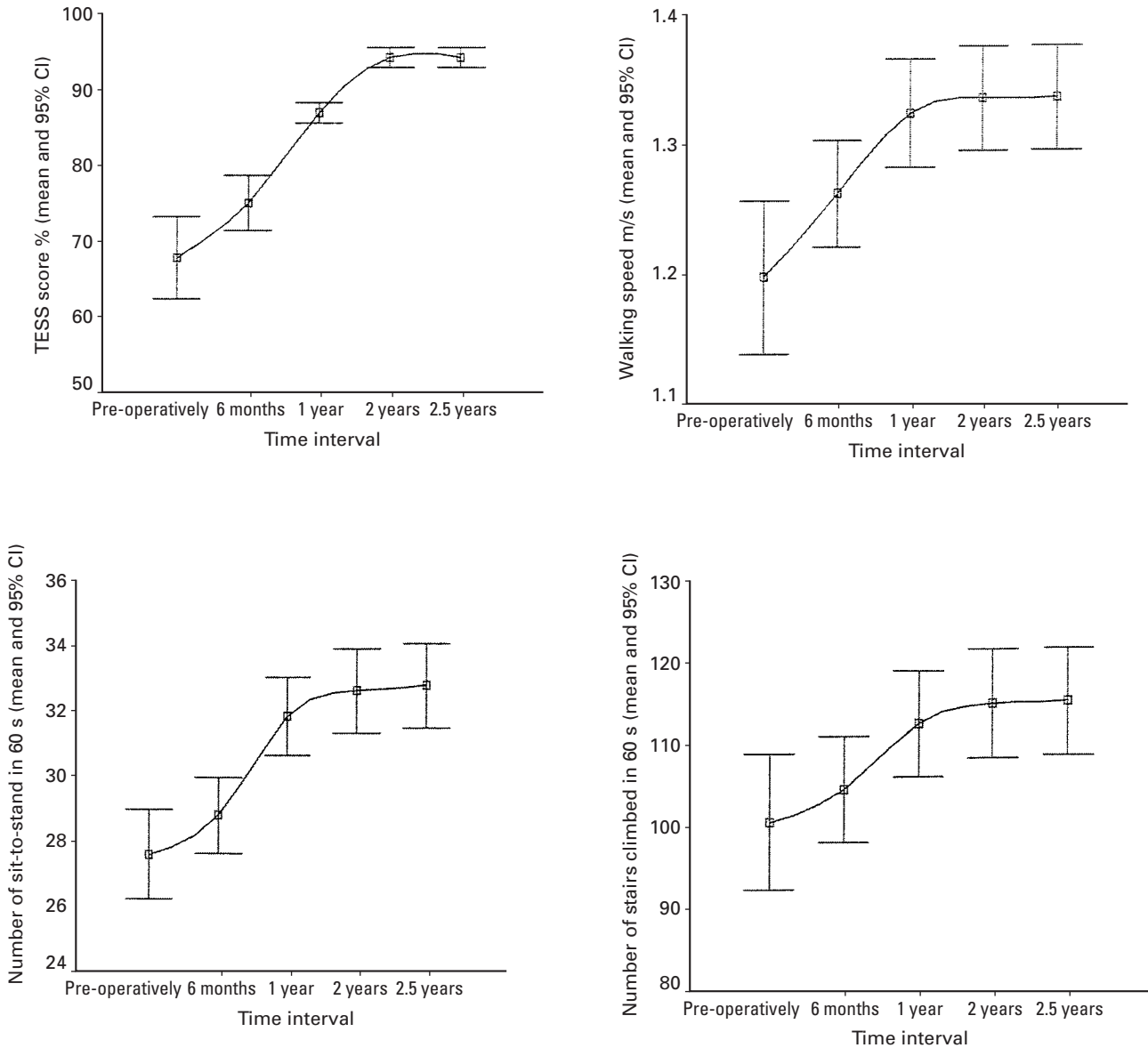


Fig. 1

Recovery of function after leg lengthening surgery using the Ilizarov technique.

activity is not part of the patients normal activities it is marked 'not applicable'. The score is an aggregation of the items and possible scores range from 0 to 100. The scoring of the questionnaire accommodates for inapplicable questions.

**Data analysis.** Data were analysed using the statistical package SPSS version 10 (SPSS, Chicago, Illinois). All patients completed the timed tests and attended all five of the clinical review sessions. The time points were taken at a standardised interval from the date on which the external fixator was removed. The recovery of function between six months and one year and between one and two years was recorded. The rates of recovery (mean and 95% confidence

interval) were calculated as a ratio (TESS score at 6 months/ TESS score at baseline) for the time periods zero to six months, six to 12 months, one to two years and two years to final review. The time course of recovery was displaced as a graph. Paired Student's *t*-tests were carried out on the absolute scores within each interval of recovery in order to compare the significance between scores at the different intervals. To investigate if there were any significant differences in the pattern of recovery for those patients with femoral or tibial nonunion, we undertook further analysis using analysis of variance for repeated measurements and the site of the nonunion as an independent variable. The alpha level for the analysis was set at  $p < 0.05$ .

## Results

There was no significant improvement in any of the performance tests between the pre-operative assessment and that undertaken six months after the frame was removed. Thereafter, the improvements were greater and statistically significant. Compared with pre-operative measurements, the patients at one year had increased their walking speed by 0.15 m/s, could complete 4.4 more sit-to-stand repetitions, climb 12 more stairs and had improved their TESS score by 19% points (Fig. 1). Such differences have been reported to be clinically significant.<sup>21</sup> The improvements continued between one and two years with small, further increases. After two years no significant improvements were observed. There was no significant difference in the recovery of function between those patients with a femoral or a tibial nonunion.

For all functional outcomes, significant improvements in performance were seen between six months and one year, and between one and two years ( $p < 0.001$ ). Recovery was slowest in the early stages after removal of the frame. During the first six months after its removal, most patients regained their pre-operative score, but did not improve on it. At 30 months, there was minimal further improvement on the two-year score. This improvement was neither statistically nor clinically significant (Fig. 1).

## Discussion

This study assessed function using four different tests; all showed a similar pattern of recovery. At six months after removal of the frame, the functional scores showed no significant improvement from the pre-operative score. With regard to the objective measurements, the improvements made between one and two years after removal of the frame were statistically significant, but would not normally be considered to be clinically significant. The patients' self-reported TESS score improved by 7.3% points between one and two years, a change that is both clinically and statistically significant.<sup>21</sup> None of the outcome measurements showed a significant improvement between two years and two and a half years. Thus, it would seem reasonable to assume that clinically significant improvements in function are unlikely to be detected after two years, and that recovery had plateaued by two years.

McKee et al<sup>15</sup> studied a cohort of patients for two years, measuring function with two questionnaires, the Nottingham Health Profiles and the SF-36. They reported that most patients were still improving at 24 months after removal of the frame. By contrast, in this series of patients followed for six months longer, improvement in function was shown to have stabilised at two years, and the small improvements made after this were neither statistically or clinically significant. These findings demonstrating a surprisingly lengthy time taken for recovery to occur are important. Many studies that are conducted prospectively have a shorter follow-

up than the two and a half years after removal of the frame used in our study.<sup>15,24</sup> The significant improvement demonstrated between one and two years has important implications for the study design of length of follow-up incorporated into any future research project.

It is recognised that for an outcome measurement to be responsive, the scores should be evenly distributed around the middle score, and there should be no floor or ceiling effects, where patients have declined or improved beyond the measured range.<sup>25</sup> The data were examined for such effects. At baseline, all of the TESS scores were significantly higher than zero. At the final review the mean score was near to the ceiling of 100 (mean 93.8) but only one patient scored the maximum. In this population, TESS meets the recommendation that floor and ceiling scores should occur in less than 15% of subjects.<sup>22</sup> It is not surprising that, from a group of patients, all of whom have been diagnosed with nonunion, few scored the maximum (100), as this requires that the subject is able to carry out all functional activities, including participation in sport. Likewise, although there was good recovery of walking speed, at 30 months the speeds were markedly slower than reference values reported for healthy normals of the same age.<sup>19</sup>

Patients undergoing distraction osteogenesis, have commonly suffered high-energy trauma or severe complications requiring surgical reconstruction. They often have complex personal injury claims or are involved in difficult medical negligence cases. For these patients it is particularly important to have information regarding return to function, so that they can plan socially and financially during the prolonged period of rehabilitation. It is also of vital importance in judging the prognosis for function at different stages after trauma in personal injury claims.

There was a similar pattern of recovery for all of the physical tests, although the recovery of walking showed a more linear increase in speed during the first year of recovery, whereas the other recovery curves were more 's' shaped. The close relationship between the performance of the different tests has been observed by other authors.<sup>18,23</sup> Overall, the sit-to-stand test is recommended if a single physical measure is required, as it is sensitive to change and easy to complete in the clinical environment. The TESS questionnaire is also recommended, as it gives data derived directly and adds depth to the measurement of functional ability.

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