

Health status after Ilizarov reconstruction of post-traumatic lower-limb deformity

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Previous studies of the Ilizarov procedure have concentrated on musculoskeletal assessments rather than the opinions of patients. In a prospective trial of 25 consecutive patients, we evaluated the effect of Ilizarov reconstruction of post-traumatic deformity on general health status using the SF36 and Nottingham Health Profile (NHP).

The patients had very low preoperative scores, which remained low during treatment and correction, but increased postoperatively. The mean overall SF36 score improved from 36 ± 3 to 58 ± 7 ($p = 0.031$) and the NHP score from 39 ± 11 to 67 ± 10 ($p = 0.002$). The improvements in scores were not limited to the physical components and were equal or better than the improvements reported for other orthopaedic procedures, including total joint arthroplasty.

Ilizarov-type reconstruction of deformity of the lower limb not only restores bony configuration, but also produces a large improvement in the general health status of patients.

J Bone Joint Surg [Br] 1998;80-B:360-4.

Received 22 July 1997; Accepted after revision 30 September 1997

The Ilizarov procedure is well established in the treatment of many complex musculoskeletal disorders including non-union, osteomyelitis, angular deformities and limb-length discrepancies.¹⁻¹³ There is a high rate of complications which include pin-track infection, stiffness of adjacent joints and severe pain; these may have a detrimental effect on the outcome.^{3,4,11,14} Previous evaluations of outcome after reconstruction have concentrated exclusively on musculoskeletal measures rather than the overall functional

result or general health status.¹ Some general outcome data are available for children.^{4,15,16}

The use of modern, patient-orientated health-status questionnaires, such as the SF36 and the Nottingham Health Profile (NHP), has recently been described.¹⁷⁻²⁴ These are designed to describe the patient's assessment of success after medical intervention. They also allow for comparison between interventions over a wide variety of fields, and have confirmed the effectiveness of many orthopaedic procedures.^{20,21,25,26}

We describe the results of a prospective trial to examine the effect of Ilizarov reconstruction on the general health status of adult patients.

Patients and Methods

We studied 25 patients who had had an Ilizarov reconstruction performed by a single surgeon (MDM). They had either had failed previous conventional surgery, had been infected, had complex deformities or had serious comorbid conditions or soft-tissue deficiency.²⁷⁻²⁹ Most with post-traumatic deformity of the lower limb treated at our institution had had conventional surgery. We excluded patients who had had correction of congenital deformities, or bilateral limb lengthening for short stature and those who were unable to complete the forms because of previous head injury, psychopathology or lack of command of English.

In addition to standard clinical and radiological measurement and assessment of work status and the use of analgesics, all patients in the trial completed two patient-orientated general health-status questionnaires, the SF36 and the NHP, before surgery (preop), during correction (in-frame), and at 3, 6, 12 and 24 months postoperatively (postop). The SF36 measures eight health attributes: physical function, limitations in activities because of physical health problems and emotional problems, bodily pain, general health perceptions, vitality, social function and mental health.^{23,24} The NHP is a two-part, health-status questionnaire which is used to indicate physical, emotional and social health problems.^{17,18} Both scales have been extensively tested for reliability and validity.

Of the 25 patients, two subsequently had amputations and one was lost to follow-up; these were excluded from the study. The remaining 22 patients were followed to the

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0301-620X/98/28192 \$2.00

Table I. Mean (\pm SEM) preoperative in-frame and postoperative SF36 scores in 22 patients

SF36 category	Preop	In-frame	Postop	Change (\pm)	p value
Physical function	38 \pm 6	29 \pm 6	46 \pm 7	(+) 8 \pm 11	0.277
Social function	33 \pm 5	50 \pm 8	67 \pm 7	(+) 34 \pm 9	0.016*
Role-physical	32 \pm 6	15 \pm 7 [†]	34 \pm 9	(+) 2 \pm 6	0.196
Role-emotional	39 \pm 5	42 \pm 9	75 \pm 9	(+) 36 \pm 13	0.039*
Mental health	36 \pm 4	49 \pm 6	69 \pm 5	(+) 33 \pm 8	0.001*
Bodily pain	37 \pm 3	39 \pm 6	62 \pm 7	(+) 25 \pm 9	0.011*
General health	35 \pm 6	41 \pm 9	57 \pm 8	(+) 22 \pm 10	0.032*
Vitality	37 \pm 4	43 \pm 5	46 \pm 7	(+) 9 \pm 7	0.540
Overall	36 \pm 3	39 \pm 9	58 \pm 7	(+) 22 \pm 15	0.031*

* p < 0.05

[†] less than preoperative value (p = 0.04)

definitive outcome. There were 12 men and 10 women with a mean age of 39.8 years (18 to 72). The mean time from injury to the Ilizarov procedure was 28.7 months (6 to 120). Of these 22, 20 had had a mean of 4.3 prior operative procedures (2 to 14) before application of the Ilizarov device. There were 12 cases of nonunion and 10 of malunion; 11 of these patients were actively infected. Fifteen patients had a leg-length discrepancy or bony defect (mean 6.2 cm, range 3 to 15 cm) and 13 had angular or rotation deformities (mean 31°, range 5 to 48°). Twelve patients had tibial frames, nine had femoral frames and one had a combined tibial and femoral frame. The mean time in the frame was 9.8 months (3 to 18). The mean follow-up after removal of the frame was 18.8 months (12 to 24) and the mean follow-up after application of the frame was 28.6 months (21.8 to 36.8).

Comparison of the means of the preop, in-frame, and postop values was performed using a paired, two-tailed Student's *t*-test and correlation using the Pearson correlation coefficient. A value of p < 0.05 was considered to be statistically significant.

Results

Clinical assessment. ASAMI criteria¹ dictate that an excellent result is union (with no additional bone graft), no infection, deformity of less than 7° and leg-length discrepancy of 2.5 cm or less. A good result is union with any two of the other three criteria, a fair result is union with one of the other three criteria, and a poor result is nonunion or refracture, or union with none of the other three criteria. According to ASAMI criteria there were nine excellent, eight good, three fair and two poor results. The two poor results were both in patients who suffered recurrence of deformity or refracture after removal of the frames. Both required further surgery and had a good or excellent final result.

There were 32 complications in 18 patients. These included pin-track infection (18), adjacent joint stiffness (knee/ankle/hip, 7), severe pain requiring admission for pain control (3), refracture (1), and recurrence of deformity (1). Two patients had amputations. One was a 42-year-old intravenous drug abuser who had successfully completed Ilizarov treatment for chronically infected nonunion of the

distal tibia. Infection was eradicated and the tibia united, but he then sustained an open fracture of the distal tibia which was treated by a below-knee amputation. The second patient was a 79-year-old insulin-dependent diabetic with a chronically infected distal tibial nonunion, peripheral vascular disease and hypertension. She had a below-knee amputation for ischaemic changes in her limb.

Return to work. Before injury, 15 patients had jobs, three were students and four were retired or unemployed. After their initial treatment and before their Ilizarov reconstruction, only two patients had been able to return to modified employment. The retired or unemployed patients had been unable to return to their recreational pursuits, and all patients had had difficulty with the activities of daily living (see below). Two of the three students had ceased their studies. After their Ilizarov reconstructions 13 of the 15 who had had jobs were able to return to employment (four at modified work), all three students returned to their studies and one of the unemployed patients was able to return to work. Sixteen patients were able to return to recreational pursuits, although generally at a reduced level. Nineteen had improvement in their ability to perform activities of daily living.

Analgesic use. Before their Ilizarov reconstruction, 20 patients took narcotic analgesics on a daily basis, and two on an occasional basis. Six had been diagnosed as 'substance abusers' or as addicted to analgesics. After the Ilizarov reconstruction, only three patients took narcotic analgesics on a daily basis, two on an occasional basis, and none was considered to be addicted.

SF36. The severity of the disability of these patients was illustrated by very low preoperative SF36 scores. The preoperative SF36 scores showed significant decreases compared with population controls in all categories (Table I). A mean preoperative score of 36 \pm 3 compares poorly with that of patients with depressive disorders, congestive heart failure or severe arthritis.^{20,23,24} While patients were undergoing correction of their deformity (in-frame), scores remained generally low, and only one category showed a significant change. This was the 'role function-physical' category of the SF36 which showed a significant decrease, as may be expected given the cumbersome nature of the Ilizarov device. Dramatic improvements were seen in postoperative scores which included the categories for pain,

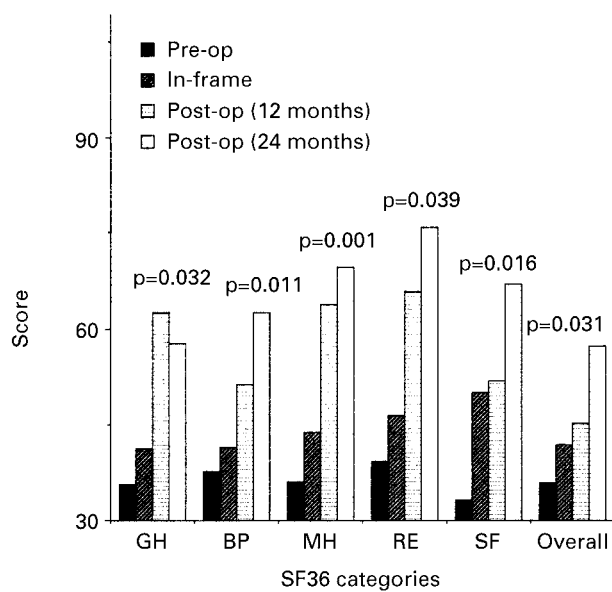


Fig. 1

SF36 scores for the six categories which showed improvement relative to preoperative values. P values compare preoperative with final postoperative values (GH = general health perceptions; BP = bodily pain; MH = mental health; RE = role function-emotional; and SF = social functioning (for preop, in-frame, postop 12 months n = 22; for postop 24 months n = 17)).

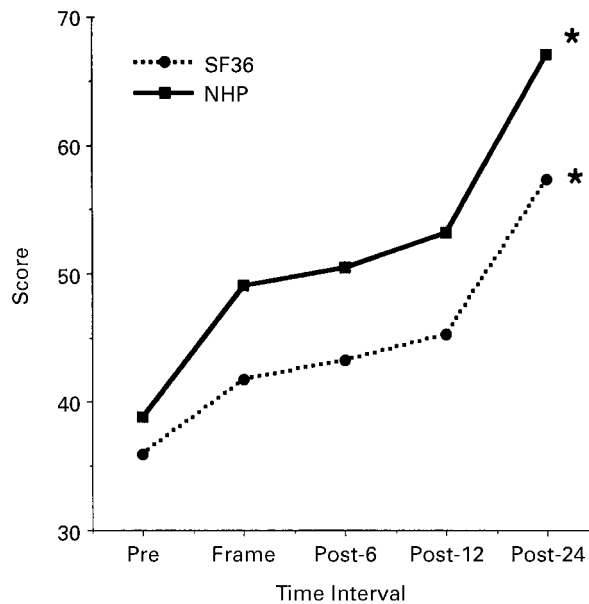


Fig. 2

Time course of functional outcome, comparing overall means of the SF36 and NHP (*indicates significant improvement relative to preoperative values (p = 0.031 SF36, p = 0.002 NHP; for preop, in-frame, postop 12 months n = 22; for postop 24 months n = 17)).

Table II. Mean (\pm SEM) preoperative, in-frame and postoperative NHP scores in 22 patients

NHP category	Preop	In-frame	Postop	Change (\pm)	p value
Physical mobility	34 \pm 3	49 \pm 8	65 \pm 6	(+) 31 \pm 7	0.031*
Pain	33 \pm 7	40 \pm 9	61 \pm 11	(+) 28 \pm 8	0.055
Sleep	31 \pm 6	39 \pm 9	69 \pm 10	(+) 38 \pm 8	0.005*
Social isolation	48 \pm 8	57 \pm 10	70 \pm 7	(+) 22 \pm 10	0.059
Energy level	33 \pm 9	40 \pm 9	60 \pm 5	(+) 37 \pm 9	0.082
Emotional reaction	40 \pm 13	59 \pm 11	77 \pm 14	(+) 37 \pm 15	0.094
Average	39 \pm 11	49 \pm 12	67 \pm 10	(+) 28 \pm 11	0.002*

* p < 0.05

social function, role function-emotional, general health perceptions, mental health and 'overall' (Fig. 1), but there was no significant improvement in the so-called 'physical' function categories of physical function, role function – physical and vitality (Fig. 2). The size of the improvement of the overall scores, from 36 \pm 3 to 58 \pm 7, compares favourably with that of other orthopaedic interventions measured in a similar way.^{20,25,30} The time course of functional outcome would suggest that improvement was still occurring 24 months after removal of the frame (Fig. 2).

Nottingham Health Profile. The preoperative scores on the NHP correlated well with the preoperative SF36 scores ($r = 0.77$, $p = 0.003$), and were very low in all categories. Again, the presence of a post-traumatic deformity of the lower limb had an effect not only on 'physical' components of the NHP, but also on the mental or emotional portions, including sleep (Table II). Patients' scores remained low while undergoing correction and there were no significant changes in any category. The decrease in the role function-

physical category of the SF36 was not reflected in the roughly corresponding physical mobility portion of the NHP while patients were in Ilizarov frames. Postoperative scores showed significant increases in most categories (Fig. 3), with an overall improvement in the mean or overall score from 39 \pm 11 to 67 \pm 10. Again, these improvements compare well with those for other medical interventions.^{25,26} Only two categories, although better, failed to show statistically improved scores. The time course of the improvement in functional outcome paralleled the SF36 scores, suggesting that patients may well continue to improve with longer follow-up (Fig. 2).

Subgroup analysis. We analysed various subgroups to determine if any had significantly different improvements in functional outcome. Using the change in overall or mean SF36 or NHP scores from preoperatively to postoperatively, we detected no significant difference between tibial and femoral correction ($p = 0.21$), nonunion *v* malunion correction ($p = 0.34$), or correction with lengthening *v* with-

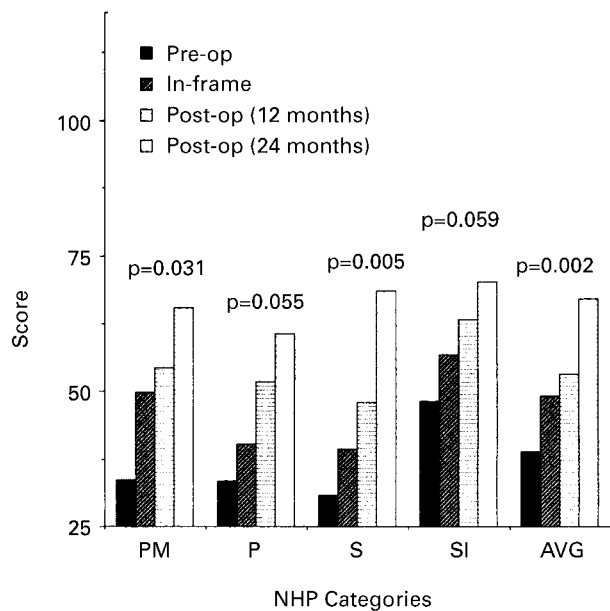


Fig. 3

NHP scores for four categories which showed improvement relative to preoperative values. P values compare preoperative with final postoperative values (PM = physical mobility, SI = social isolation, S = sleep, and P = pain. For preop, in-frame, postop 12 months $n = 22$; for postop 24 months $n = 17$.)

out lengthening ($p = 0.12$). There was a trend for actively infected patients to show greater improvement (due primarily to lower initial values) when compared with non-infected patients, but this was not quite statistically significant ($p = 0.08$). Patients who had a good or excellent outcome ($n = 17$), as measured by conventional scores, had a greater magnitude of increase in SF36 and NHP scores compared with those patients who had a fair or poor outcome ($n = 5$; $p = 0.04$). There was no significant correlation between outcome (improvement in average SF36, NHP scores) and length of time in the frame ($p = 0.31$), number of previous operative procedures ($p = 0.22$) or age ($p = 0.18$).

Discussion

One of the significant findings of our study was the severe effect on the general health status of a complex post-traumatic deformity of the lower limb. Preoperative evaluation showed that not only were the physical scores affected but also mental health, pain and overall health perceptions were dramatically reduced compared with those in control populations. The debilitating psychological, physical and socio-economic effect of an infected tibial nonunion has previously been examined by other authors using other methods and our study confirms their findings.³¹ The use of modern health-status outcome assessments such as the SF36 or NHP shows that these individuals compare poorly with patients with well-recognized debilitating conditions such as end-stage congestive

heart failure or ischaemic heart disease or those having cancer chemotherapy or renal dialysis.^{23,24} The impact of these orthopaedic conditions on the quality of life of the patient should not be underestimated.

One of the disadvantages of previous studies measuring SF36 scores after the correction of post-traumatic problems is the lack of any preoperative data.^{26,30} In our patients the postoperative scores still show significant deficiencies compared with normal controls, and without the preoperative data the advantage of reconstruction could be questioned. There were no significant decreases in overall health status during the correction of their deformity (the in-frame period), except for the role function-physical as measured by the SF36. A number of factors may be involved. The already very low preoperative patient scores may have made it difficult to show significant decreases. In addition, many patients seemed to have a higher level of discomfort in the frame, but were pleased that definitive treatment had been started. The correction of deformity and eradication of infection therefore provided positive reinforcement.

The results and complication rates which we have demonstrated are similar to previously reported series.^{1-8,11,12} We feel that our findings in general health status are applicable to most patients undergoing reconstruction. The size of the increase in general health scores seen in our patients compares favourably with the outcome of such interventions as total joint replacement and spinal surgery.^{20,22,26}

When introducing a new measurement tool, it is important to ascertain that it actually measures what it is supposed to measure (validity), and that it will be consistent in its measurements in different settings or at different times (reliability). Both the SF36 and the NHP have been tested extensively and found to be reliable and valid in assessing the general health status of large samples of respondents with a variety of medical conditions, including musculoskeletal disorders.^{17,18,20-25} A potential disadvantage is that although individual components of these questionnaires, such as pain and physical function, may correlate well with disease or joint specific outcome, the overall scores often fail to change significantly after treatment, indicating a lack of 'sensitivity' in their ability to evaluate a given intervention.^{20,26,30} These questionnaires are also culture- and language-specific and the appropriate version needs to be used for a given population to avoid spurious results. Our study is Canadian, and given our unique juxtaposition between British and American cultures we used the American version of the SF36 and the British version of the NHP.

The most dramatic improvements were in pain, sleep, emotional and mental health categories. Early during follow-up, most benefit was seen in areas such as pain and sleep. Compared with the time from the original injury, it takes appreciably longer for improvements in muscle strength and endurance, dexterity and joint movement to be reflected in improved function scores. As can be seen from

Figure 3, most patients were still improving at 24 months after removal of the frame. Despite successful treatment and dramatic improvement in their outcome, however, they were not restored to normal health status.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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