■ WRIST & HAND

Cost-effectiveness of early surgical fixation versus cast immobilization for adults with a scaphoid waist fracture: five-year follow-up of the Scaphoid Waist Internal Fixation for Fractures Trial

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Aims
The conclusion of the one-year analysis of the Scaphoid Waist Internal Fixation for Fractures Trial (SWIFFT) was that initial cast immobilization with surgical fixation for nonunion was the optimal treatment for patients with a fracture of the waist of the scaphoid. However, there remained significant uncertainty about the medium-term outcomes and how these could influence the patient's health-related quality of life (HRQoL), care requirements, and costs. The aim of this study was to explore how additional data from the five-year follow-up influenced the cost-effectiveness of the treatment of these fractures.

Methods
The analysis presents the patient-reported HRQoL, measured with the EuroQol five-dimension three-level health questionnaire, and the use of healthcare resources at five years after randomization, and considers which factors influenced the results. The original analytical model, in which the implications of the different forms of treatment throughout the patient's life were estimated, was also updated.

Results
Five years after randomization, most patients in both groups returned to the HRQoL level which is consistent with age-adjusted norms and did not require further healthcare. In contrast, those who continued to have clinically relevant adverse events at five years reported significantly worse HRQoL scores and greater care needs. It was also confirmed in the updated model that initial cast immobilization was the most cost-effective strategy, with a mean cost to the health system of £1,606 less per eligible patient compared with those who initially underwent surgery, an annual saving of £7.5 million.

Conclusion
Most patients had no long-term impact from the injury regardless of the form of treatment. However, the few who had clinically defined adverse events at five years had poor HRQoL and greater care needs. The limited difference in these clinical outcomes between the two groups informed the findings of the decision model that, over the patient's lifetime, the small quality-adjusted life year gains for those who underwent surgery initially were not sufficient to justify the higher costs. These findings confirm that initial immobilization in a cast with fixation for nonunion is the optimal form of treatment for these patients.

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Introduction
The one-year analysis of the Scaphoid Waist Internal Fixation for Fractures Trial (SWIFFT) resolved many questions in the short term regarding the optimal treatment of a bicortical fracture of the waist of the scaphoid with ≤ 2 mm

Table I. Updated estimates of the parameters for the extrapolated model.

Parameter	Old value	New value	Notes
Requiring surgery after initial casting, n (%)	20/214 (9.3)	22/214 (10.3)	An additional two patients were found to have had surgery for nonunion (n = 19), three others having nonunion without surgery, with six dropped for treatment crossover
Requiring repeat surgery, n (%)	8/188 (4.2)	9/188 (4.8)	Eight patients had additional surgery (consistent with one-year results), one other patient had long-term nonunion with only primary surgery, with 31 patients dropped for treatment crossover
Proportion of patints for whom surgery was indicated, n (%)	110/116 (94.8)	143/153 (93.5)	Added the proportion of those who received secondary surgery of all of those who may have required it, for both the fixation (8/9) and the casting group (25/28), to the original model estimate
Proportion of second-line surgery resulting in nonunion, n (%)	1/17 (5.9)	4/36 (11.1)	Added trial data on second-line surgery resulting in nonunion (3/19) to the original model values (which were drawn from the literature)
Quality of life decrease for SNAC wrist (grade 4)	-0.275 (-0.069 to -0.481)	-0.133 (-0.043 to -0.223)	Replacing the original estimated decrease for SNAC which used old estimates derived from a different clinical setting, with the values reported in Dias et al[13]
Probability of developing severe OA after union with initial casting, n (%)	12/218 (5.6)*	17/339 (5.1)	Adding the five-year trial data on rate of severe OA (5/121) to original model estimate
Probability of developing severe OA after union with early surgery, n (%)		21/364 (5.8)	Adding the five-year trial data on rate of severe OA (9/146) to original model estimate
Cost of severe OA, £/yr	38	76	Doubling of the cost of severe OA per year in the model to fit with the five-year estimates of cost. The original estimate was based on limited clinical judgement of the needs of patients with OA in general

*In the original model, there was deemed insufficient data to distinguish between postunion severe OA by initial treatment and, as such, the probabilities were estimated as equivalent.[3]
OA, osteoarthritis; SNAC, scaphoid nonunion advanced collapse.

displacement in adults.[1,2] This confirmed that the Patient-Rated Wrist Evaluation (PRWE) score and the rate of union of the fracture were similar between the two groups.[2] The economic evaluation found little difference in the patient-reported health-related quality of life (HRQoL), but a much larger cost associated with initial fixation at the one-year follow-up.[3]

However, an important aim of the treatment of these fractures is to minimize the long-term adverse consequences of the injury or its treatment.[4] These consequences, including osteoarthritis (OA) and scaphoid nonunion advanced collapse (SNAC), are minimized by achieving union and limiting the complications of surgery, such as the penetration of a screw. Such complications have a long-term impact on the HRQoL of the patients, as well as cost implications for the healthcare system relating to their management and resolution.[5]

As part of the one-year analysis, a decision analytic model was constructed to extrapolate these findings to the lifetime HRQoL of the patients and costs to the healthcare system, details of which are available elsewhere and in the Supplementary Material.[1] While this model supported the findings of the one-year clinical[2] and cost-effectiveness analyses,[3] it demonstrated that there was much uncertainty in key parameters, which could change the conclusion about which treatment was more cost-effective in terms of the lifetime health of the patient and costs. This emphasized the value of collecting five-year follow-up data as part of the trial to reduce this uncertainty.

The aim of this study was to explore the effect of the additional five-year follow-up data, and published literature, on the cost-effectiveness of the two forms of treatment. This was to be done first by an analysis of the data, the HRQoL of the patients, and the cost implications when they were reviewed five years after randomization. This analysis was to determine if the similarity of the HRQoL scores but greater costs in the fixation group at one-year follow-up were still evident at this later timepoint. Second, the decision analytic model was updated using the five-year data and associated relevant literature published since the original analysis.

Methods

The initial analysis explored the HRQoL impact and cost of the two forms of treatment, finding that patients in the fixation group had a better mean HRQoL one year after intervention, at a value of 0.016 measured using the EuroQol five-dimension three-level questionnaire (EQ-5D-3L).[6] However, this improvement was not statistically significant (p = 0.379) and was associated with higher costs due to the surgery, by a mean of £1,295 (95% CI 1,084 to 1,504)). Combining these factors resulted in a cost per additional quality-adjusted life year (QALY) gained of £81,962/QALY, well in excess of what is conventionally considered to be a reasonable threshold for cost-effectiveness.[7]

The long-term decision analysis combined the results from the one-year economic evaluation with the existing evidence about the probable rates of adverse events relating to the fracture including OA and SNAC, estimating the impacts of the HRQoL and costs for the rest of the patient's life. Two additional treatment scenarios were created for the model. These estimated the implications of cast immobilization with no surgical intervention for nonunion, and the implications if no

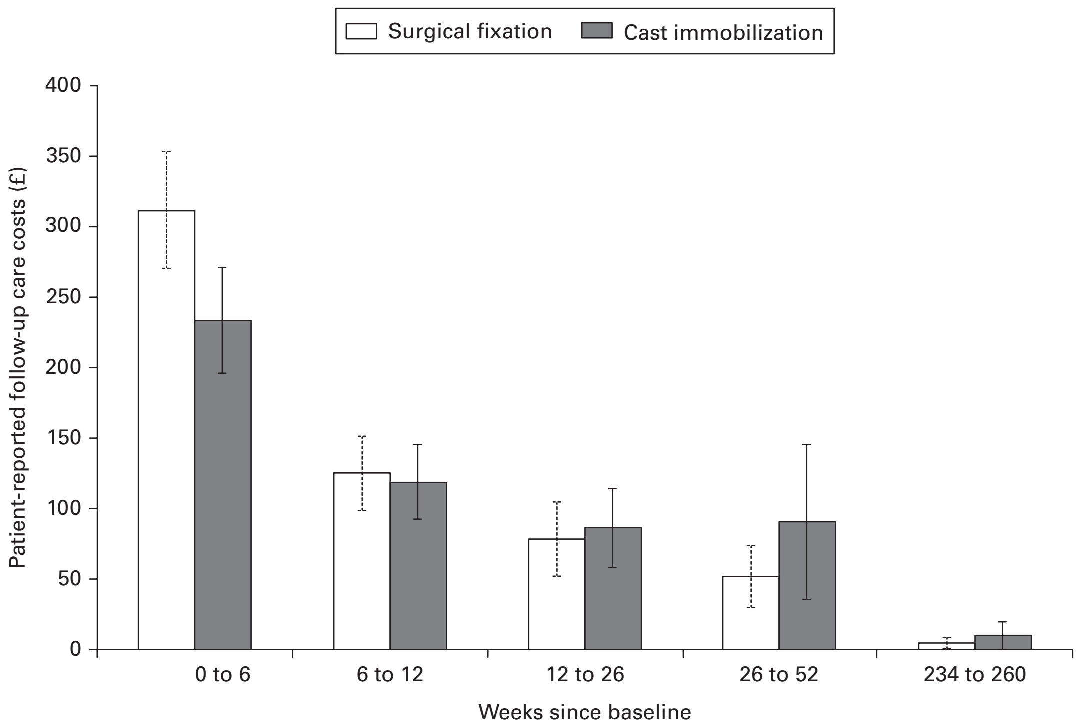

Fig. 1

Costs of patient-reported NHS interactions by follow-up, with 95% CIs.

treatment was available (neither surgery nor casting). Details of how these scenarios were created have been reported.[1] As found in the original decision model in the no-treatment strategy, no short-term treatment costs are incurred but patients are assumed never to achieve union of the fracture with an associated rate of developing SNAC.[3]

Consistent with the initial findings, the model concluded that while early fixation was expected to result in slightly increased mean lifetime QALYs (0.05 QALYs) they were not sufficient to justify the high costs of providing surgery to all patients (at a mean of £1,482), generating an incremental cost-effectiveness ratio (ICER) of £29,660/QALY, above the pre-determined cost-effectiveness threshold of £20,000/QALY. The model was constructed as recommended by the National Institute for Health and Care Excellence (NICE) methods guide.[7]

Importantly, the analytical model had two areas of significant uncertainty, both determined by the limited data at the time of analysis which combined to indicate a 39% chance that the conclusion of the base-case was incorrect. First, the rates of nonunion were used as the primary bridge from the one-year data to the extrapolated model, with those who failed to achieve union being at a higher risk of developing adverse events in the long-term. The one-year analysis identified that, at final follow-up, five patients had a nonunion and others were deemed to have a ‘slight’ (n = 8) or ‘partial’ (n = 13) nonunion.[2] Of the five with a nonunion, one was in the surgery group and four in the cast group. It was not known what the clinical pathway would be for these patients, with the model assuming that all five would undergo fixation. Importantly, a scenario analysis which assumed the opposite, that none would undergo surgery, influenced the outcome of the analysis, with early fixation becoming the more cost-effective option.

Second, the rate of development and implications of OA and SNAC because of the fracture or its treatment was estimated from the literature,[8] rather than the SWIFFT trial, as the lack of follow-up beyond one year restricted the potential to extrapolate into the long term. While the rate of OA and SNAC was subject to uncertainty analysis, through probabilistic and scenario sensitivity analysis, the age of the informative study, from 1990, among other factors, represented a significant limitation in the analysis.

These elements of uncertainty regarding key parameters of the long-term cost-effectiveness of the treatment of these fractures supported the additional period of follow-up and further analysis and the long-term model reported in this study.

Statistical analysis. The analysis of the five-year data has two elements: a summary of the health economic data collected at five years and an update of the extrapolated model in light of additional evidence, both conducted from the perspective of the NHS in line with NICE guidance.[7] The analysis was conducted in keeping with best methodological practice, including the CHEERS checklist[9] and the Economic Evaluation in Clinical Trials of Glick et al.[10]

Consistent with the one-year analysis, the cost of continued patient care in the two groups of the trial was estimated using the patient-reported NHS iterations which were related to the original injury, with unit costs of each interaction applied using published sources.[11] At the five-year follow-up, patients were

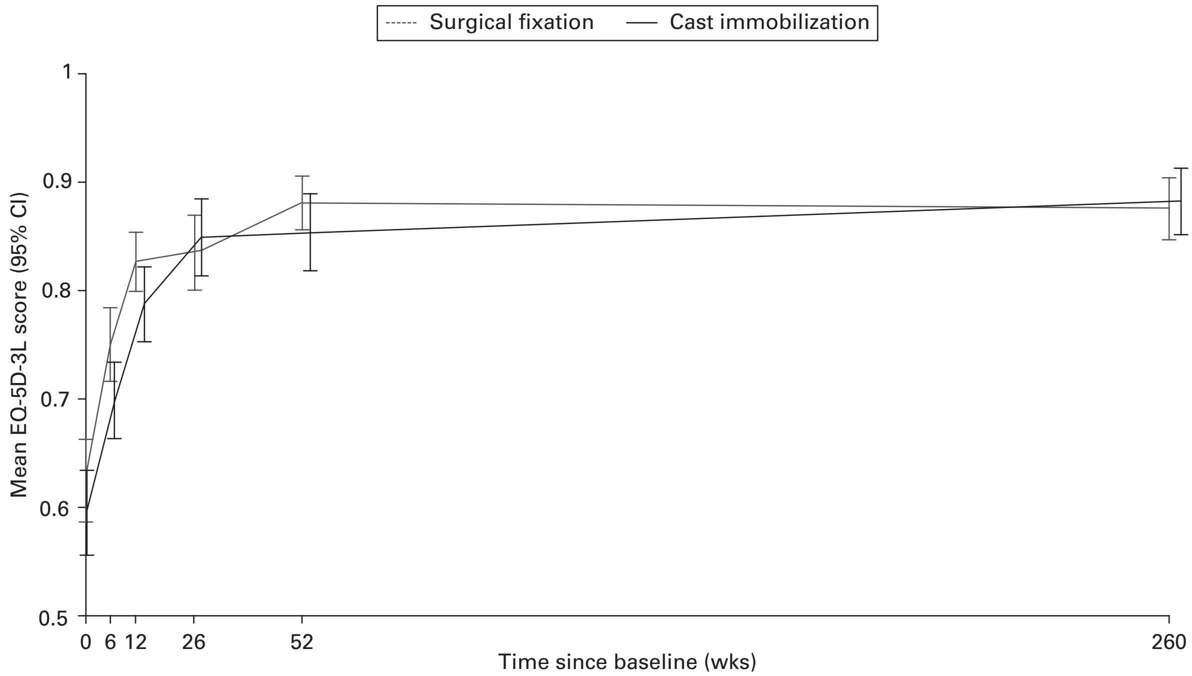

Fig. 2

EuroQol five-dimension three-level health questionnaire score at all follow-up points.

Table II. Cross-tabulation of the status of union at five years with EuroQol five-dimension three-level questionnaire (EQ-5D-3L) and costs.

Variable	Patients, n	Mean score (range; SD)	p-value*
EQ-5D-3L			0.006
Nonunion	7	0.723 (-0.181 to 1; 0.419)	
Union	252	0.891 (0.082 to 1; 0.164)	
Costs, £			< 0.001
Nonunion	7	123 (0 to 719; 268)	
Union	254	3 (0 to 377; 27)	

*Independent-samples *t*-test.

Table III. Cross-tabulation of osteoarthritis (OA) status at five years with EuroQol five-dimension three-level questionnaire (EQ-5D-3L) and costs.

Variable	Patients, n	Mean (range; SD)	p-value*
EQ-5D-3L			0.039
No OA	125	0.901 (0.082 to 1; 0.163)	
OA	134	0.868 (-0.181 to 1; 0.188)	
Costs, £			0.054
No OA	125	1 (0 to 118; 11)	
OA	136	11 (0 to 719; 71)	

*Independent-samples *t*-test.

asked to report related and unrelated interactions with the NHS during the previous six months.

As with the previous analysis, in order to estimate the HRQoL of patients, the patient-reported EQ-5D-3L questionnaire was used and scored using UK tariffs.[12]

In both the HRQoL and cost analyses a complete case, intention-to-treat approach was taken. It was not possible to do a formal analysis for the five years as neither the use of resources nor HRQoL data were collected between the one- and five-year follow-up points, with the intervening period being too long to use methods involving recollection. Therefore, the aim of these analyses was to consider how the patients' HRQoL and the costs compared with population norms and explore the role of diagnosed events, specifically nonunion, OA, and SNAC, in influencing patients' responses. In order to facilitate this, cross-tabulation results are reported for the HRQoL and costs conditional on these three diagnoses, with simple summary statistics, including p-values, drawn from an independent-samples *t*-test, being presented.

The second part of this analysis is an update of the original extrapolated model using a range of the evidence reported at five years and wider evidence from the literature published since the initial analysis, details of which are available elsewhere and in the Supplementary Material.[1] Five elements of the model were updated: the probability of nonunion given initial treatment (i.e. fixation or cast immobilization), the probability of patients receiving surgery for nonunion, the success of surgery to treat nonunion, the rate of the development of OA after union, the cost of OA, and the decrease in quality of life associated with the development of SNAC wrist.

With the exception of the decreased quality of life associated with the development of SNAC, which used the findings of a retrospective analysis of 278 scaphoid nonunions published since the one-year analysis,[13] the updated estimates were drawn from the SWIFFT trial. The original and the updated estimates are reported in Table I, including a brief note of the original source and informative evidence for the update.

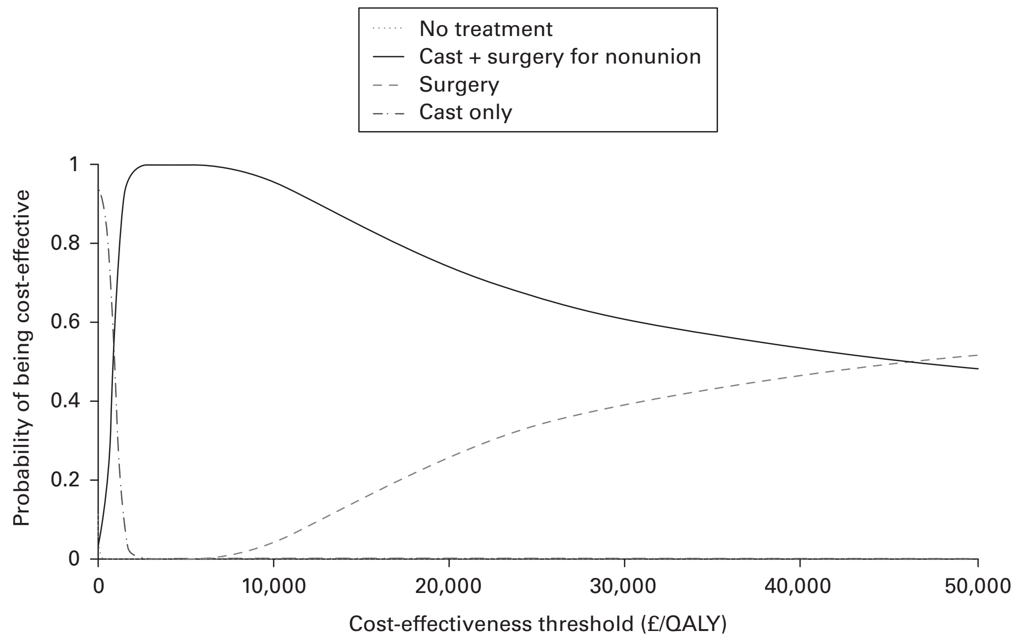

Fig. 3

Cost-effectiveness acceptability curve. QALY, quality-adjusted life year.

Table IV. Cross-tabulation of scaphoid nonunion advanced collapse (SNAC) status at five years with EuroQol five-dimension three-level questionnaire (EQ-5D-3L) and costs.

Variable	Patients, n	Mean score (range; SD)	p-value*
EQ-5D-3L			0.010
No SNAC	199	0.898 (0.082 to 1; 0.166)	
SNAC	44	0.828 (-0.181 to 1; 0.211)	
Costs, £			< 0.001
No SNAC	200	31 (0 to 719; 122)	
SNAC	45	11 (0 to 719; 71)	

*Independent-samples *t*-test.

Results

At five years, patients were asked to report their interactions with the NHS during the previous six months for anything related to the injury or its treatment. These were combined with the costs as previously reported.[1] Figure 1 shows these results for the 336 patients (77% of the original cohort) who completed the questionnaire (174 (79%) in the fixation group and 162 (74%) in the cast group). These costs are reported alongside the previously published costs for the four other follow-up times, showing that in the last six months of the five-year follow-up period the mean costs were very low compared with the previous follow-up period: £4 in the fixation and £9 in the cast group. These low mean costs are mostly made up of patients who reported no involvements with the NHS related to their wrist (n = 325 (97%)) with a few patients reporting a large number of interactions due to complications, ranging from £37 to £719, with the greatest due to the patient reporting numerous overnight stays.

A total of 341 patients (78% of the original cohort) completed the EQ-5D-3L questionnaire (175 (80%) in the fixation group and 165 (75%) in the cast group). Mean QoL scores at five years were0.877 (90% CI 0.849 to 0.905) in the fixation group and 0.884 (95% CI 0.853 to 0.915) in the cast group (a difference of -0.007 compared with 0.016 at one year). These results are shown in Figure 2 with the original one-year scores. Similar to the costs at five years, most patients reported EQ-5D-3L scores consistent with those that would be expected in the general population,[14] but with a few reporting low scores, specifically 14 patients with scores of < 0.5 (seven in each group).

A series of cross-tabulation analyses were conducted contrasting the scores of patients who had nonunion, OA, or SNAC at five years. The following definitions of each are used, and additional details of these values are provided in an accompanying clinical paper.[15] Nonunion was defined using the clinical consensus of union versus nonunion in five-year imaging, in which all 'almost full' and 'slight' unions were defined as union. OA and SNAC were defined using the clinical consensus of OA and SNAC versus no OA or SNAC in the imaging at five years.

Table II shows a summary of the EQ-5D-3L scores and costs at five years with the status of union, showing a lower mean EQ-5D-3L score and higher costs in the patients with a nonunion, as would be expected.

Table III shows a summary of the EQ-5D-3L scores and costs stratified by binary OA status, showing, as with the nonunion status, those patients who had OA also had a lower EQ-5D-3L and a higher level of NHS interaction and costs, as would be expected. Notably, in terms of costs, 124 of the 125 patients who had no detectable OA reported no interaction with the NHS in the last six months related to their injury, with the remaining one reporting the use of resources costing £118.

Table V. Original and updated decision model results, discounted deterministic.

Treatment	Cost, £	QALYs	ICER (£/QALY) vs		NHB* at threshold of:	
			Lowest cost (cast only)	Next less-effective non-dominated	£20,000/QALY	£30,000/QALY
Original model1						
Cast only	836	18.72	N/A	N/A	18.68	18.70
Cast + surgery for nonunion	921	19.07	243	243	19.02	19.04
No treatment	1,749	14.75	Dominated	Dominated	14.67	14.70
Surgery	2,404	19.12	3,952	29,660	19.00	19.04
Updated model						
Cast only	802	18.86	N/A	N/A	18.82	18.83
Cast + surgery for nonunion	984	19.07	855	855	19.02	19.04
No treatment	1,679	16.49	Dominated	Dominated	16.41	16.43
Surgery	2,590	19.11	7,259	47,425	18.98	19.02

*NHB = QALYs – cost/opportunity cost threshold.
ICER, incremental cost-effectiveness ratio; N/A, not applicable; NHB, net health benefit; QALY, quality-adjusted life year.

Fig. 4

Cost-effectiveness scatterplot of three active treatment options. QALYs, quality-adjusted life-years.

Table IV shows the the EQ-5D-3L scores and costs stratified by binary SNAC status. As with union and OA, SNAC was associated with a lower EQ-5D-3L and costs.

Using the updated values shown in Table I, the decision model was rerun to estimate the impact of the additional evidence on the findings of the analysis as shown in Table V compared with the original results.

The primary finding from the updated model was that there were only small changes to the mean costs and QALYs associated with each form of treatment, with the exception of the no-treatment arm, which was influenced by the reduced quality-of-life burden of SNAC in the model. As with the original analysis, early surgery for all patients resulted in the largest QALY gain but also at the greatest cost, with the additional cost not justifying the relatively small gain in QALYs compared with cast plus surgery for nonunions (and ICER of £47,425/QALY). The updated analysis resulted in more certainty regarding cast plus surgery being the cost-effective option, with 74% of iterations of the probabilistic sensitivity analysis finding it to be the cost-effective treatment. This is seen in the cost-effectiveness acceptability curve (Figure 3) which shows the probability of cost-effectiveness of competing options for different values of the threshold for cost-effectiveness used. Figure 4 provides the cost-effectiveness scatterplot for the three treatment options showing the mean total costs and QALYs for the full set of the probabilistic sensitivity analysis. Surgical fixation is clearly and consistently the most expensive option in all analyses, but only slightly more effective on average (Table V).

Discussion

The cost-effectiveness analysis which was conducted after one year of follow-up in the SWIFFT trial concluded that initial immobilization in a cast with fixation for nonunion was the optimal form of treatment, but that there was considerable uncertainty.[1] The uncertainty was primarily due to a gap in the evidence regarding the relationship between short-term clinical outcomes, such as nonunion and the choice of the initial treatment, and to the development of complications such as nonunion and OA in the mid term.

Through both the five-year patient-reported outcomes and the updated decision analytical model, the analysis described in this study addressed this uncertainty in two ways. First, we have shown that, at five years after randomization, most patients in both groups returned to the HRQoL level, which is consistent with age-adjusted norms for the population and did not require any further care from the NHS related to the original injury. In contrast, those who continued to have a clinically relevant adverse event at five years reported significantly worse HRQoL scores and increased care and costs. These differences highlight the importance of extrapolating the medium-term clinical outcomes over the long term, as done through the decision model. Second, by updating the model on the rate of clinically significant events, and some additional literature, this analysis has substantially reduced the uncertainty which was present in the original results, reducing the probability of the conclusion of the cost-effectiveness of initial treatment in a cast and surgery for nonunion being incorrect from 39% to 26%.

An important finding from the decision model was the cost-saving implications for the NHS. The casting plus surgery arm was estimated to cost £1,606 less per eligible patient than if surgery was the initial treatment, discounted over their lifetime. Almost all of this cost saving is the result of a lower level of initial surgery, which has a high cost (mean of £1,632). Given the estimated incidence of 4,650 fractures of the waist of the scaphoid per annum in the UK,[1] this analysis suggested that the use of cast immobilization with surgery for nonunion could be £7.47 million cheaper for each patient in the cohort compared with the provision of initial surgery.

The main strength of this analysis was its use of and development of the five-year SWIFFT trial data. A key strength of the trial was that it was the largest study dealing with this issue which has been undertaken, and its pragmatic multicentre randomized controlled design, which provided robust, gold-standard evidence reflecting practice in the NHS. The model also allowed us to consider the longer-term implications of the SWIFFT findings with further information about the level of HRQoL and costs as well as their determining factors. In addition, it has substantially reduced the uncertainty of the overall conclusion that initial immobilization in a cast with fixation for nonunion is the cost-effective option.

The main weakness of the five-year patient-reported analysis relates to the existence of missing data. While the level of missing data is small considering the length of time since the initial randomization, 22% of EQ-5D-3L questionnaires and 23% of the use of resources were missing, which may have affected the findings. Despite the reduction in the level of uncertainty compared with that found at one-year follow-up, there remains a 26% chance that it is incorrect, mostly because of the need to use relatively old and small studies on the long-term development and implications of adverse events such as the development of OA and SNAC in these patients. The analysis does, however, indicate that the patients' HRQoL implications of this conclusion being incorrect would be small, with a limited difference between the two forms of treatment over the patient's lifetime. While further similar studies would be unlikely to resolve much of this remaining uncertainty and would not be worthwhile from a health economics perspective, additional research into the development, treatment, and implications of adverse events in these patients would be advisable.

As additional clinical evidence becomes available, further extensions to this decision analytical approach may extend our understanding of the cost-effectiveness of the forms of treatment and timelines which are available clinically. For example, studies such as that of Martin et al[16] could be used to inform an extension of this model to consider the optimal time of mobilization following union of a fracture, and the associated frequency of assessments, from a cost-effectiveness perspective.

This analysis of the patients in the SWIFFT trial five years after randomization, and updated decision model, found that the HRQoL of patients had returned to approximate 'norms' for this age group, and that most patients in both treatment groups no longer required care as a result of the injury. It did, however, identify that the few patients who had clinically defined adverse events at five years (nonunion, OA, and SNAC) also had significantly worse HRQoL and higher care needs. The limited difference between the clinical outcomes of the two forms of treatment which were investigated in the trial informed the findings of the decision model that, over the patient's lifetime, the small QALY gains for those who received initial surgery were not sufficient to justify the higher costs.[15] Therefore, the analysis concludes that initial immobilization in a cast with fixation for nonunion is the optimal form of treatment.

Take home message

- Almost all patients had no long-term detrimental impact on their quality of life, nor any healthcare needs, regardless of treatment; however, those with long-term clinical adverse events did.
- The high upfront cost of surgery is not worth the small lifetime health gains it is estimated to entail.

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Supplementary material

Tables showing unit costs used in the short-term element of the analysis and model parameters in the long-term element of the analysis.

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Data sharing:
The datasets generated and analyzed in the current study are not publicly available due to data protection regulations. Access to data is limited to the researchers who have obtained permission for data processing. Further inquiries can be made to the corresponding author.

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