Free vascularized fibular graft vs. ilizarov method for post-traumatic tibial bone defect

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of either free vascularised fibular grafts (FVFG) or callus distraction (CD) for the treatment of patients with post-traumatic segmental bone defects of the tibia.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with segmental tibial bone defects after trauma.

Setting
The setting was secondary care. The study was carried out in Kanagawa, Japan.

Dates to which data relate
The effectiveness data related to January 1991 to December 1996. The cost data appear to have related to the same time period. The price year was not stated.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The cost data seem to have been collected retrospectively for the same patient population as that used in the effectiveness analysis.

Study sample
No power calculations to assure a certain power were performed in the planning phase of the study. Nine patients with tibial bone defects after trauma related to motor-vehicle accidents, who underwent either FVFG or CD at the hospital where the study was performed, were selected for the study. One of these patients was excluded because CD was used to reconstruct his bone defect after FVFG had failed. Thus, 8 patients were included in the final study sample, 4 in each of the two groups. The authors did not provide evidence that the study sample was representative of the study population.
Study design
This was a retrospective cohort study that was performed in a single centre. The duration of follow-up ranged from 3 years to 6 years and 8 months (average: 4.8 years) after the original injury.

Analysis of effectiveness
The basis for the clinical study was not stated, but not all of the patients were accounted for in the analysis. Thus, "treatment completers" is the most appropriate classification. The primary health outcomes assessed for both patient groups (FVFG and CD) in the effectiveness analysis were:

- the average duration from trauma onset to surgery;
- the mean duration of external fixation placement time;
- the number of complications, that is, those experiencing pin-site infections (soft-tissue inflammation, soft-tissue infection or bone-infection) and venous congestion of the grafted fibula;
- the healing time to union;
- the number of patients experiencing non-unions or re-fractures at the original docking site;
- the mean total functional scores; and
- the functional results obtained.

The functional scores ranged from 0 to 100, where a score of 100 was the most desirable outcome. The scores considered pain, activities of daily living, motion at the ankle and knee, residual deformity, degenerative joint changes and malalignment, muscle strength and sensation. The functional results could be either excellent (score range: 90 - 100), good (score range: 80 - 89), fair (score range: 70 - 79) or poor (score range: less than 70). There were no statistically significant differences between the FVFG and CD patients in terms of gender, age and number of prior operations. All the patients were men. The average age was 40 years (standard error of the mean, SEM, +/- 12.7 years) in the FVFG group versus 20 years (SEM +/- 2.3 years) in the CD group. There was an average of 3.8 (SEM +/- 1.3) prior operations in the FVFG group versus 4.3 (SEM +/- 1.7) in the CD group. FVFG patients, however, had a significantly larger defect size (average 7.3, SEM +/- 0.4) than CD patients (average 4.5, SEM +/- 0.7), (p=0.02).

Effectiveness results
The average duration from trauma onset to surgery was 17.8 months (range: 4 - 41) in the FVFG group, and 11.5 months (range: 3 - 19) in the CD group.

The mean duration of external fixation placement time was 176.0 days (SEM +/- 31.2) for FVFG patients versus 261.5 days (SEM +/- 66.1) for CD patients, (p>0.05).

Four patients (2 in each group) experienced pin-site infections. All of the pin-site infections were soft-tissue infections. One FVFG patient, but no CD patients, experienced venous congestion of the grafted fibula.

None of the FVFG patients experienced non-unions, whereas two CD patients did.

None of the FVFG patients experienced a re-fracture at the original docking site, whereas one CD patient did.

The healing time to union was 20.0 days (SEM +/- 8.0) days for the FVFG patients versus 36.5 days (SEM +/- 4.0) for the CD patients, (p>0.05).

The mean total functional score was 69.5 (SEM +/- 7.7) for the FVFG patients versus 88.8 (SEM +/- 6.3) for the CD patients, (p>0.05).
In terms of the functional results, none of the FVFG patients showed excellent results, whereas two CD patients did. Two patients (one in each group) showed good results and two patients (one in each group) showed fair results. Two FVFG patients, but no CD patients, showed poor results.

Clinical conclusions
Although the external fixation placement time and the healing time to union were slightly shorter for FVFG patients, the functional outcomes seemed to be slightly better for CD patients than for FVFG patients. However, these differences were not statistically significant.

Measure of benefits used in the economic analysis
No summary measure of benefit was used in the economic analysis. The study was therefore categorised as a cost-consequences analysis.

Direct costs
The resource quantities and the costs were not reported separately. The direct costs included in the study were those of the hospital. These were surgical and medical fees, and hospital bills including nursing care and antibiotics. Hospital charges were used to estimate the costs. The study reported the total costs per group. Discounting was not performed, although it may have been necessary since the patients were followed up for more than 2 years. The price year was not stated.

Statistical analysis of costs
The mean costs and SEM were reported. Unpaired t-tests were performed to compare the costs of both alternatives.

Indirect Costs
No indirect costs were reported.

Currency
Japanese yen (Y) and US dollars ($). The authors did not report the conversion rate used, but it appears to have been $1 = Y 108.

Sensitivity analysis
No sensitivity analyses were performed.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total costs per group (+/- SEM) were Y7,398,536 +/- 2,230,583 ($68,505 +/- 20,653) for the FVFG group versus Y11,798,153 +/- 2,786,218 ($109,242 +/- 25,826) for the CD group, (p>0.05).

Synthesis of costs and benefits
Not applicable due to the cost-consequences approach undertaken.

Authors' conclusions
No clear differences between the two treatment groups could be determined. However, many more cases would be needed to establish statistically significant differences between both methods.

**CRD COMMENTARY - Selection of comparators**
None of the interventions (FVFG or CD) was specifically stated to be the comparator. These interventions were chosen because they represented current practice in the authors' setting, and there was controversy surrounding which one should be used. You should decide whether these interventions are widely performed in your own setting.

**Validity of estimate of measure of effectiveness**
This was a retrospective cohort study. It might not have been appropriate for the study question since it might have introduced selection bias. Moreover, although differences between the baseline characteristics of the groups were not statistically significant, the authors stated that there may have been bias due to differences in defect size, age distribution and the small number of patients in each group. The small sample size made it difficult to detect statistically significant differences in the outcomes between the two groups. The method used to select the patients was unclear. Further, the authors did not report evidence that the study sample was representative of the study population. This may be an important factor given that all the patients were men. Appropriate statistical analyses to take account of potential biases and confounding factors were not performed. Consequently, the reliability of the results is uncertain.

**Validity of estimate of measure of benefit**
The authors did not report a summary measure of health benefit. The study was therefore categorised as a cost-consequences analysis.

**Validity of estimate of costs**
The reporting on the costs was very brief. Charges, which do not reflect the true opportunity costs of the interventions, were reported instead of the costs. The authors reported that the costs of external fixation were not considered for any of the groups, but they did not state that they were the same for both groups. Consequently, not all the costs relevant to the economic analysis were included in the study. The resource quantities and the costs were not reported separately. The costs were not discounted even though the follow-up period was longer than 2 years. The price year was not stated. These limitations introduce uncertainty into the reliability of the results and hinder reflation exercises in other settings.

**Other issues**
The authors compared some of their results with those from other studies, but the issue of the generalisability of the results was not addressed. The study enrolled patients with segmental bone defects and this was reflected in the results.

**Implications of the study**
Although no significant differences were found between the interventions in terms of the effectiveness and costs, there were several caveats that introduced uncertainty into the reliability of the results.

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None stated.

**Bibliographic details**

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Other publications of related interest


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