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Reaming Does Not Affect Functional Outcomes after Open and Closed Tibial Shaft Fractures: The Results of a Randomized Controlled Trial

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REAMING DOES NOT AFFECT FUNCTIONAL OUTCOMES AFTER OPEN AND CLOSED TIBIAL SHAFT FRACTURES: THE RESULTS OF A RANDOMIZED CONTROLLED TRIAL

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Abstract

Objectives—We sought to determine the effect of reaming on 1-year SF-36 and SMFA scores from the Study to Prospectively Evaluate Reamed Intramedullary Nails in patients with Tibial Fractures (SPRINT).

Design—Prospective randomized controlled trial. 1,319 patients were randomized to reamed or unreamed nails. Fractures were categorized as open or closed.

Setting—29 academic and community health centers across the US, Canada, and the Netherlands

Conflicts of Interest: The authors have no relevant conflicts of interest

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Patients/Participants—1,319 skeletally mature patients with closed and open diaphyseal tibia fractures.

Intervention—Reamed versus unreamed tibial nails

Main Outcome Measurements—SF-36 and the SMFA. Outcomes were obtained during the initial hospitalization to reflect preinjury status, and again at the 2-week, 3-month, 6-month, and 1-year follow-up. Repeated measures analyses were performed with $P < 0.05$ considered significant.

Results—There were no differences between the reamed and unreamed groups at 12 months for either the SF-36 Physical Component Score (PCS) (42.9 v 43.4, p = 0.54, 95% Confidence Interval for the difference [CI] −2.1 to 1.1) or the SMFA Dysfunction Index (DI) (18.0 v 17.6, p=0.79. 95% CI −2.2 to 2.9). At one year, functional outcomes were significantly below baseline for the SF-36 PCS, SMFA DI, and SMFA Bothersome Index (p < 0.001). Time and fracture type were significantly associated with functional outcome.

Conclusions—Reaming does not affect functional outcomes following intramedullary nailing for tibial shaft fractures. Patients with open fractures have worse functional outcomes than those with a closed injury. Patients do not reach their baseline function by one year after surgery.

Keywords

Tibia fracture; Intramedullary; Reamed; Unreamed; Functional

INTRODUCTION

Tibia fractures are the most common long-bone fracture in the United States with an estimated annual incidence of nearly 500,000.[1] Intramedullary fixation of diaphyseal tibia fractures has led to a significant reduction in reoperation rates[2–5] compared to plate or external fixation and is now the preferred method of treatment for both open and closed fractures of the tibia shaft.[6–8] Despite the frequency of these injuries, there have been few reports about the functional outcomes following operative management with most reports limited to smaller trials or series which have not used validated health utility measures.[9–18]

The Study to Prospectively evaluate Reamed Intramedullary Nails in Tibial fractures (SPRINT) was a prospective, multi-center randomized controlled trial to evaluate the effect of reaming versus not reaming on intramedullary fixation of open and closed tibial shaft fractures.[19] In addition to surgeon-reported rates of complications and reoperations, patients were asked to complete the validated Medical Outcomes Study 36-item Short-Form General Health Survey (SF-36)[20] and the Short Musculoskeletal Function Assessment (SMFA)[21] to determine baseline function and follow their recovery. We sought to determine how type of injury, time from injury, and surgical technique affected functional outcome.

PATIENTS AND METHODS

From July 2000 to September 2005, 1,319 skeletally mature patients with open and closed tibial-shaft fractures were enrolled from 29 centers in an international randomized control trial studying the effects of reamed versus non-reamed nails on tibial union rates. The trial was approved by human subjects committees at each center and was registered at

Clinicaltrials.gov (identifier: NCT00038129) and approved by each institution's ethics review board.

Eligibility and Randomization

Eligible adults were skeletally mature men and women with a closed or open fracture of the tibia that was amenable to operative fixation with an intramedullary nail. Patients were excluded if they had a pathologic fracture, a fracture that was not amenable to a reamed or unreamed tibial nail, or if they were likely to have problems with follow up. Participating investigators randomized patients by accessing a twenty-four-hour toll-free remote telephone randomization system that ensured concealment. Randomization was stratified by the center and the severity of soft-tissue injury (open, closed, or both open and closed) in randomly permuted blocks of 2 and 4. Patients and clinicians were unaware of block sizes. Patients with a bilateral fracture were assigned the same treatment for both fractures. Patients were allocated to fracture fixation with an intramedullary nail following reaming of the intramedullary canal (the reamed nailing group) or with an intramedullary nail without prior reaming (the unreamed nailing group). Patients were blinded to their method of nailing.

Sample Size

To determine sample size, we initially defined the primary outcome as a reoperation for nonunion or deep infection including bone-grafting, implant exchange or removal, and debridement of bone and soft tissue. After the first interim analysis in January 2003, when 332 patients had been enrolled, the event rate was substantially lower (13%) than anticipated on the basis of our review of previous studies (32%). In response, we proposed, and both the Data Safety and Monitoring Board and the primary funding agency (Canadian Institutes of Health Research) accepted, adopting an expanded primary composite outcome that included dynamization of the fracture (i.e., interlocking screw removal to allow fracture-site compression with weightbearing) in the operating room or in the outpatient clinic; removal of locking screws because of hardware breakage or loosening; autodynamization (spontaneous screw breakage leading to dynamization at the fracture site. The final sample size was based on the expanded definition of reoperation and ensured >80% power for a relative risk of 0.63 for event rates of >13%. To ensure 1200 patients with full follow-up, we enrolled 1339, with 1169 completing at least one functional outcome score (Figure 1). A full description of the study design and analysis of primary outcomes has been previously published elsewhere.[19,22]

The original SPRINT study was not powered to detect differences in functional outcome between reamed and unreamed nailing. However, an a priori analysis shows that 234 patients in each group would be required to detect an arbitrarily chosen 3-point difference in SF-36 scores with a significance level of 5% and power of 80%. The minimum clinically important difference (MCID) in SF-36 scores from 3–20 have been reported for lower extremity primary total joint arthroplasty.[23] As yet no minimal clinically important difference has been reported for tibial shaft fractures.

Under the supervision of study personnel who were blinded to the method of treatment, patients completed self-administered functional outcome questionnaires at discharge from the hospital, and at multiple time points during the one-year followup. Study personnel had been trained to facilitate completion of the questionnaire without influencing patient responses. Preinjury function was assessed at time of hospital discharge, which has previously been shown to have high enough accuracy to allow for the substitution of prospectively collected baseline information.[24]

Study Measures

The SF-36 is a generalized outcome measure of health-related quality of life (HRQL) that can be aggregated in a Physical Component (PCS) and Mental Component Summary score (MCS).[25,26] It is the most frequently used health-status measure in the United States.[27] The test has a range of 0–100 with lower scores indicating poorer function, and is calibrated to have a general population mean of 50 with a standard deviation of 10 for the total score.[20] The SF-36 was administered at the 2-week, 3-month, 6-month, and 12-month follow up.

The SMFA is a 46-item generalized health-status questionnaire with a focus on the effects of musculoskeletal injury or disease.[28] It has two major components: a Dysfunction Index (DI) as well as a Bothersome Index (BI). Both indices are scored from 0–100 with higher scores indicating poorer function. The SMFA has a population mean of 12.7 with a standard deviation of 15.6.[21] The SMFA was administered at the 3-month, 6-month, and 12-month follow up. Both the SMFA and SF-36 are self-reported, well-validated and widely used.

STATISTICAL ANALYSIS

Analyses were limited to only those patients who completed either the SMFA and SF-36 questionnaires at at least one of their 3-, 6-, or 12-month follow up visits. Functional scores were compared using independent samples t-tests and paired t-tests. Rates of the primary SPRINT outcomes were compared using Fisher's exact test. A $p < 0.05$ was considered significant.

A mixed model repeated measures analysis was performed with HRQL at 2-weeks, 3-, 6-, and 12-months as the dependent variables. Treatment (reamed versus unreamed), time from injury, treatment by time interaction, pre-injury HRQL, open versus closed, open versus closed by time interaction, open versus closed by treatment interaction, and clinical center were chosen *a priori* as independent variables.

De-identified data were stored in the SPRINT DataFax Database.[19,22] Computations were performed using SAS software, version 9.2 (SAS Institute, Cary, NC). Statistical significance was defined as a $p < 0.05$ on the basis of a two-sided hypothesis test.

RESULTS

Reamed versus Unreamed at One Year

Seven hundred sixty-eight of 1169 patients (66%) completed at least one of the 4 functional outcomes scores at the 12-month followup. Patient demographic information, injury characteristics, and allocation group for each time point are listed in Table 1. Patient functional outcomes at baseline and at 12 months are listed in Table 2. There were no differences in functional outcomes between reamed and unreamed patients.

At one year, neither the reamed nor unreamed patients had returned to their baseline function. Reamed patients had a final SF-36 PCS that was significantly lower than their preinjury function (42.8 versus 52.4, 95% CI of the difference −10.8 to −8.4, $p < 0.001$), as was their SF-36 MCS (51.8 versus 53.7, 95% CI −3.2 to −0.7, $p = 0.003$). Similarly, in the reamed group, the 12-month SMFA DI was worse than their baseline (18.0 versus 7.3, 95% CI 8.8 to 12.6, $p < 0.001$), as was the SMFA BI (21.5 versus 10.4, 95% CI 8.4 to 14.0, $p < 0.001$). In unreamed nails, the SF-36 PCS was significantly lower than baseline (43.7 versus 52.9, 95% CI −10.5 to −7.9, $p < 0.001$) as was the SF-36 MCS (52.1 versus 54.0, 95% CI −3.1 to −0.6, $p = 0.003$). In the unreamed group, the SMFA DI was significantly poorer than baseline (17.2 versus 8.0, 95% CI 7.2 to 11.3, $p < 0.001$), as was the SMFA BI (19.2 versus 10.8, 95% CI 5.9 to 10.9, $p < 0.001$).

When fractures were stratified by injury type (open versus closed and reamed versus unreamed), patients in all groups remained significantly below their baseline function for the SF-36 PCS, SMFA Dysfunction, and SMFA Bother. Only those who underwent closed unreamed nailing were able to return to their preinjury SF-36 MCS score at one year (see Table, Supplemental Digital Content 1).

Patients with SPRINT Primary Outcome at One Year

A total of 1058 patients completed at least one of the functional outcomes measures at at least one of their 3-, 6-, or 12-month follow up visits and were included in the mixed model repeated measures analysis. In patients with closed fractures, 38 of 377 reamed patients and 57 of 357 unreamed patients experienced the primary outcome (10% versus 16%, $p = 0.021$). In patients with open fractures, 46 of 166 reamed patients and 36 of 158 unreamed patients experienced the primary outcome (28% versus 23%, $p = 0.371$).

Repeated Measures Analysis

On the repeated measures analysis for the entire cohort, significant predictors of the SF-36 PCS were time ($p < 0.001$), open versus closed fracture ($p < 0.001$), open versus closed by time interaction ($p < 0.001$), and treatment by time interaction ($p = 0.04$). For the SF-36 MCS, significant predictors for functional scores were time ($p < 0.001$) and open versus closed ($p = 0.01$). For the SMFA DI, significant predictors of functional scores were time ($p < 0.001$), open versus closed ($p < 0.001$), and treatment by time interaction ($p = 0.03$). For the SMFA BI, significant predictors of function were time ($p < 0.001$) and open versus closed ($p < 0.001$). The main effect of reamed versus unreamed nailing was not a significant predictor in any of the functional subcategories. The 95% CI for the difference of means between functional scores for reamed and unreamed nails contained zero at all time points, indicating no significant treatment effect, with the exception of the 12-month SF-36 PCS for open fractures (38.5 vs 40.5, 95% CI 0.15 to 3.89). Functional scores steadily improved over time for all fractures (Figure 2). Tables in the Appendix (see Supplemental Digital Content 2) provide detailed information on subgroup scores and comparisons over time.

DISCUSSION

Although the SPRINT study found a small reduction in nonunion events with reamed intramedullary nails for closed tibial shaft fractures,[19] we did not find a significant difference between reamed and unreamed nails in functional outcomes at one year. We also found that patients had not reached their baseline functional status by one year after surgery. Functional scores were associated with time since surgery and whether or not the injury was open or closed. While treatment type generally did not have an effect on the unadjusted functional outcomes, in one comparison of the repeated measures analysis we found that patients with unreamed nails in open tibia fractures had a statistically significant 2 point improvement in the SF-36 PCS at 12 months. Similarly, the treatment by time interaction for this subscore was found to be significant with $p = 0.04$. This may be related to the notable but nonsignificant reduction in the composite endpoint of autodynamization, revision surgery, and bone grafting seen in unreamed nails for open tibia fractures in the SPRINT study.[19] Additionally, patients who were included in this study had a small and nonsignificant reduction in the SPRINT primary outcome. However, while this one data point out of many is statistically significant, it is doubtful that it has any clinical impact on the patient, as it has been suggested that the minimum clinically significant difference for the SF-36 is anywhere from 4.9 points to 10.[29,30] As such, it does not appear that reaming has an impact on functional outcomes.

It is interesting to note that those with closed unreamed fractures were able to achieve a nonsignficant difference in their SF-36 MCS at one year, while the other patients still had a statistically significant difference. However, these differences were smaller than what would be considered clinically significant. Based on the repeated measures analysis, a major portion of this recovery is seen within the first 6 months. This suggests that these injuries have a substantial psychological impact and that the first 6 months after treatment is an important part of a patients' mental recovery. Furthermore, it is possible for patients to return to their mental baseline by one year despite having continued physical functional deficits.

In this study, patients with closed fractures who underwent unreamed nailing had a statistically significant increase in the number of primary events (dynamization, autodynamization, removal of interlocking screws for breakage or loosening, bone grafting, exchange nailing) at a rate similar to that reported in the original SPRINT study which was driven primarily by an increase in autodynamizations.[14] While analysis of the primary outcome and its relationship to functional outcome was not the focus of this project, this increase in the primary outcome did not appear to be associated with a significant difference in functional outcomes for these patients.

This is the largest study of its kind to follow both open and closed tibial fractures and builds upon the work of Mackenzie et al[31,32] in the early 1990s using validated health outcomes tools to study patient function and HRQL after lower extremity trauma. Since then there have been multiple reports of functional outcomes following intramedullary fixation of tibia fractures[33,34], however cohorts have often been small and assessments were limited to questions regarding knee pain or activity and employment[35,36]. Court-Brown et al, evaluated the functional recovery of 100 patients with closed tibia fractures who were enrolled in a prospective trial of reamed versus unreamed tibial nails and found that the average time to return to work and jumping activities was approximately 11 weeks, though they did not report the proportion of those who had returned to full activity at one year. Similar to our study, the investigators did not find a significant difference between reamed and unreamed nails.[17] Gaston et al followed 100 patients for one year and found that the average length of time to return to work was 13 weeks, though return to sport was much longer at 45 weeks.[12] Neither study reported validated health outcomes measures.

Our findings support the fact that open tibia fracture have worse outcomes, though studies that report functional outcomes in this group are few, and none have used standardized HRQL measures. Keating et al, compared reamed versus unreamed nailing in 61 open tibia fractures in a prospective randomized controlled trial and found that only 74% had returned to work by 22 months, with even fewer returning to sport. As in our study, there were no clinically significant functional differences seen between reamed and unreamed nails.[13] He also reported the results of 103 open tibia fractures treated with reamed intramedullary nailing and found that even at an average of 26 months, rates of return to previous activities remained low with only 59% returning to their previous occupation and only 49% returning to previous sporting activities.[14]

Our study has a number of strengths, primarily its prospective, randomized, multicenter nature and use of standardized, validated functional outcomes tools. To our knowledge, ours is the largest study to date to report on the standardized functional outcomes following tibia fractures with well over 1,000 patients enrolled. The size of this study and inclusion of both open and closed fractures provided us with large enough subgroups to meaningfully analyze multiple interactions between treatment method and type of injury. Furthermore, the diversity of locations used in this trial and use of multiple surgeons improves the generalizability of our results and their applicability to clinical practice. Our use of well-validated and widely used HRQL measures to assess both global function and the effect musculoskeletal impairment allow us to put the functional impact of tibial shaft fracture in the context of conditions not limited to the musculoskeletal system. This information can be used in the future for analyses of cost-effectiveness and the utility of health care expenditures.

Despite its strengths, our study does have some weaknesses. For example, we did not include any region specific measures of function. However, while measures such as the Western Ontario and McMaster Arthritis Index (WOMAC) or Knee Injury and Osteoarthritis Outcome Score (KOOS) can provide detailed information on lower extremity function, they may miss more global areas of function and do not include a psychological component, both of which can significantly impact patient quality of life. As such, we feel our use of the SMFA appropriately captures the impact of injuries on patient-related function and health quality. Furthermore, the SMFA has been found to correlate well with functional recovery of other injuries to the lower extremity,[37,38] and its widespread use allows us to put functional recovery from tibial fractures in the context of other injuries (Table 3).

Another limitation is our relatively short follow-up. While one year is frequently used to assess fracture healing and surgical complications in the trauma literature, it may be inadequate to fully document functional recovery. It is clear in our cohort that, though patients steadily improved at each follow-up, physical subscores at one year after surgery remained significantly below their reported baseline as well as population norms.[21] Given the trajectory of their subscores, it is likely that they would have continued to improve and hopefully regained their full function with additional time. Lefaivre et al, were able to obtain more than 12-year followup of 56 patients who had suffered closed or open tibia fractures who were treated with intramedullary nailing and found the average SF-36 and SMFA scores to be no different than population norms.[39] However, they were unable to document at what time during followup this return to function had occurred given the retrospective nature of the study. This suggests that patients with tibia fractures will eventually reach age-matched population norms in terms of global function, though recovery may be prolonged.

While it appears that the majority of recovery after tibial shaft fractures has occurred during the first year, the fact that both psychological and physical function scores are still significantly below baseline function is sobering. These results have important implications for patient care in terms of managing both patient and physician expectations of recovery. As health care expenditures and outcomes become scrutinized ever more closely, reliable functional outcomes data will be necessary to critically evaluate treatment efficacy. [21,40] Our results provide a benchmark against which other treatment methods may be compared in the future.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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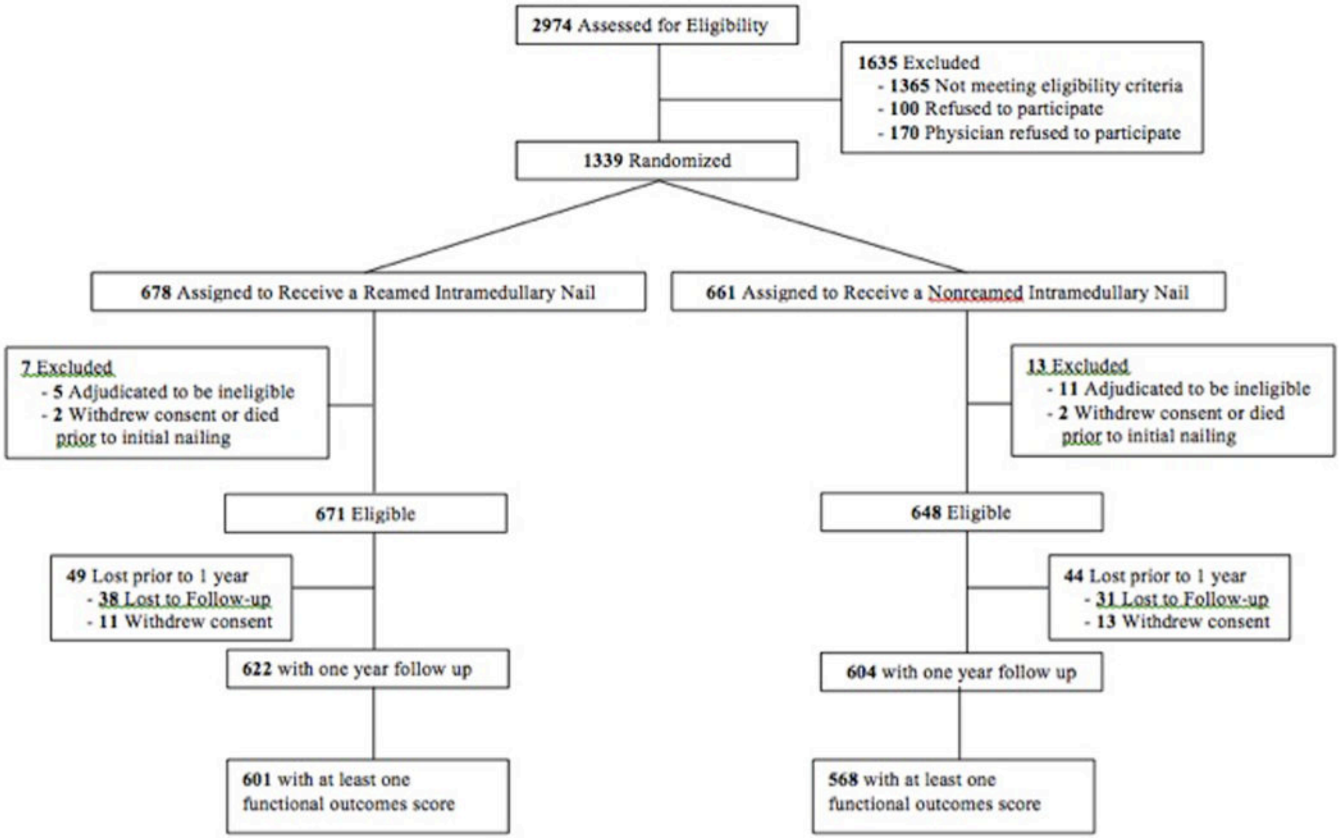

Figure 1.
Flowchart for patient enrollment and randomization.

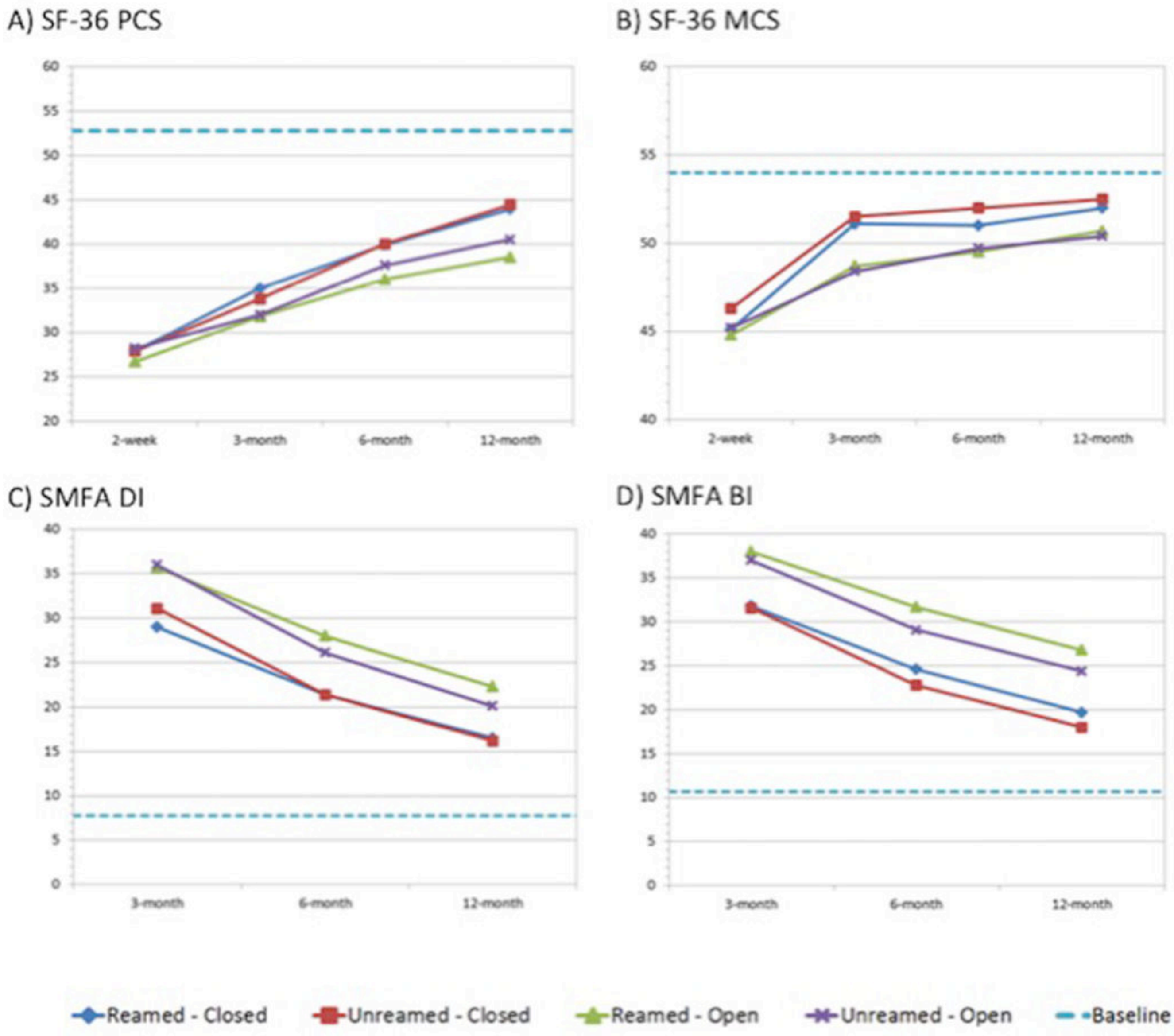

Figure 2.

Reamed and unreamed SF-36 and SMFA scores over time stratified by open versus closed fractures. **A)** SF-36 Physical Component Score. **B)** SF-36 Mental Component Score. **C)** SMFA Dysfunction Index. **D)** SMFA Bothersome Index

TABLE 1

Demographic characteristics of patients at each followup.*

Characteristics	discharge	2 weeks post surgery	3 months	6 months	12 months
n	1169	922	997	852	768
age at discharge, mean (SD)	39.2 (15.5)	38.7 (15.5)	39.2 (15.6)	39.7 (15.7)	40.3 (15.7)
gender, n (%)					
male	872 (74.6)	694 (75.3)	724 (72.6)	622(73.0)	554 (72.1)
female	297 (25.4)	228 (24.7)	273 (27.4)	230 (27.0)	214 (27.9)
reamed open, n(%)	192 (16.4)	137 (14.9)	153 (15.3)	129 (15.1)	119 (15.5)
unreamed open	180 (15.4)	134 (14.5)	146 (14.6)	126 (14.8)	114 (14.8)
reamed closed	409 (35.0)	330 (35.8)	350 (35.1)	305 (35.8)	271 (35.3)
unreamed closed	388 (33.2)	321 (34.8)	348 (34.9)	292 (34.3)	264 (34.4)

* Patients had to have a valid score for at least one of SF-36 PCS, MCS, or SMFA Dysfunction or Bother Index to be included.

TABLE 2

Unadjusted functional outcomes in all tibia patients at baseline and 12 months.

	Reamed	Unreamed	Mean Difference	p-value
Pre-Injury				
SF-36 PCS	52.6 (9.4)	53.1 (8.7)	−0.5 (−1.5, 0.6)	0.38
SF-36 MCS	54.0 (8.6)	53.9 (8.6)	0.1 (−0.9, 1.1)	0.82
SMFA DI	8.0 (13.1)	7.7 (13.3)	0.4 (−1.2,1.9)	0.66
SMFA BI	10.6 (15.2)	10.5 (14.8)	0.2 (−1.8,2.1)	0.87
One -Year				
SF-36 PCS	42.9 (11.1)	43.4 (11.5)	−0.5 (−2.1, 1.1)	0.54
SF-36 MCS	51.8 (12.1)	51.8 (11.8)	0.0 (−1.7, 1.7)	0.98
SMFA DI	18.0 (17.1)	17.6 (17.4)	0.4 (−2.2, 2.9)	0.79
SMFA BI	20.6 (21.8)	19.8 (21.4)	0.8 (−2.4 to 4.0)	0.62

*Values given as mean (standard deviation) and mean difference (95% CI)

TABLE 3

SMFA Dysfunction Score of tibia fractures relative to other injuries reported in the literature.

Diagnosis	Average Dysfunction Score	Treatment	Average Length of Followup	Reference	# of patients
Ankle Fracture	8.1	ORIF	12 months	Egol	198
Syndesmosis Injury	11.4	ORIF	18 months	Weening	39
Closed tibial shaft fracture	15.9	IMN	12 months		535
Tibial Plateau fracture	18.2	ORIF	2.5 years	Su	25
Talar Neck Fracture	19	ORIF	5.2 years	Sanders	69
Tibial Plateau Fracture	19.5	ORIF	20 months	Bhattacharyya	9
Calcaneus	20.4	ORIF	44 months	Herscovici	35
Open tibial shaft fracture	22	IMN	12 months		233
Acetabular Fracture	24	ORIF	55 months	Anglen	26