Do the Benefits of Rigid Internal Fixation of Mandible Fractures Justify the Added Costs? Results From a Randomized Controlled Trial

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Purpose: Owing to its putative advantages over conventional maxillomandibular fixation (MMF), open-reduction and rigid internal fixation (ORIF) is used frequently to treat mandible fractures, particularly in noncompliant patients. The resource-intensive nature of ORIF, the large variation in its use, and the lack of systematic studies substantiating ORIF attributed benefits compel a randomized controlled investigation comparing ORIF to MMF treatment. The objective of this study was to determine whether ORIF provides better clinical and functional outcomes than MMF in noncomplying type of patients with a similar range of mandible fracture severity.

Patients and Methods: From a total of 336 patients who sought treatment for mandible fractures, 142 patients with moderately severe mandible fractures were assigned randomly to receive MMF or ORIF and followed prospectively for 12 months. A variety of clinician and patient-reported measures were used to assess outcomes at the 1, 6, and 12 months follow-up visits. These measures included clinician-reported number of surgical complications, patient-reported number of complaints, as well as cumulative costs of treatment. Pain intensity was measured on a 10-point scale and the 12-item General Oral Health Assessment Index was used to assess the patients' oral health-related quality of life. Because the protocol allowed clinical judgment to overrule the randomly assigned treatment, outcomes were compared on an "intent-to-treat" basis as well as in terms of actual treatment received.

Results: The sociodemographic and clinical characteristics of the injury did not differ among the 2 groups. On an intent-to-treat basis, the difference in complication rates was not significant but favored MMF; 8.1% of patients developed complications with MMF versus 12.5% with ORIF. Differences in the rate of patient complaints were not significant on an intent-to-treat basis, but a significant between-group difference ($P = .012$) favoring MMF was noted on an as-treated basis at the 1 month recall, with 40% of ORIF patients reporting greater than 1 complaint versus 18.8% of MMF patients. No significant differences were detected between the 2 treatment groups at any time point

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with respect to oral health-related quality of life reflected by the General Oral Health Assessment Index scores. In-patient days and total costs did not differ significantly on an intent-to-treat basis, but on an as-treated basis, patients treated with MMF had fewer in-patient days on average (1.64 vs 5.50 for ORIF) and lower average costs of treatment ($7,206 vs $26,089 for ORIF). In the intent-to-treat analyses, patients receiving MMF treatment had significantly lower (P = .05) pain scores at the 12-month recall (mean = 0.58, SE = 0.30) compared with patients assigned to ORIF (mean = 1.78, SE = 0.52).

Conclusion: Our study did not show a clear overall benefit of the resource-intensive ORIF over conventional MMF treatment in the management of moderately severe mandible fractures in at-risk patients; our data instead suggest some cost as well as oral health quality-of-life advantages for the use of MMF in this patient population.

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After initial ebbs and flows in enthusiasm, open-reduction and rigid internal fixation with plating systems (ORIF) are now integral to the management of mandible fractures. The popularity of ORIF derives from its putative advantages—early return to function, better patient acceptance, and outcomes that are less influenced by patient compliance.[1] Although the use of ORIF increases initial treatment costs, it is used frequently on the premise that ORIF is actually cheaper than maxillomandibular fixation (MMF) in the long run because it decreases overall resource use by lowering the risk of complications and rehospitalizations resulting from patient noncompliance.

The conceptual appeal of ORIF notwithstanding, there have been few formal studies and virtually no prospective studies comparing outcomes to conventional treatment with MMF. Reported results from several surgical studies focusing on economic analyses of the competing treatment strategies have been inconsistent. Investigators including Hoffman et al,[2] Thaller et al,[3] and Dodson and Pfeffle,[4] have argued that ORIF may be the more cost-effective approach for treating mandible fractures if the costs of treating potential complications are considered. In contrast, El-Degwi and Mathog[5] and Schmidt et al[6] suggest that the use of MMF offers considerable cost-savings over ORIF. The conflicting assessments reflect the methodologic problems intrinsic to the studies hitherto; retrospective chart reviews, small patient numbers, a broad spectrum of injury severity, and short-term follow-up. Furthermore, framing the nature of the benefits of ORIF purely in monetary terms (cost-benefit analyses) excludes any consideration of its purported health effects (cost-effectiveness analysis) such as reduced pain and discomfort, outcomes that are of more direct interest to the patient.

The opportunity costs associated with ORIF of orofacial injuries are of particular interest to trauma centers, which are experiencing a growing disconnect between health care reimbursements and the actual costs of providing care.[7] Persons who engage in high-risk behaviors that lead to facial injury often lack adequate insurance coverage,[8] and providing trauma care requires a significant financial commitment from hospitals participating in an organized trauma system. Because resource limitations are the ultimate constraint underlying all health care decisions, it is important that clinician choices between ORIF and MMF for similar mandible fractures be informed by the trade-offs in terms of clinical benefits and costs.

To evaluate whether the incremental benefits attributed to ORIF justify the associated added costs, we conducted a prospective, controlled study comparing ORIF and MMF outcomes in at-risk patients with similar mandible fracture severity. We hypothesized that the net benefits of the initially expensive ORIF approach for treating mandible fractures render it cost-effective in the long term.

Patients and Methods

SITE AND STUDY COHORT

The study was conducted at the King/Drew Medical Center in Los Angeles, a prototypic, Level-1 Trauma Center serving a large low-income urban neighborhood. Consecutive adult patients presenting to the Oral and Maxillofacial Surgery (OMS) Service with a mandible fracture between August 1996 and May 2001 were considered for the enrollment in the study. Patients were ineligible if they were younger than age 18, had gunshot injuries, were pregnant, evidenced an altered mental status attributable to head injuries, or stated an inability or unwillingness to return for follow-up care.

STUDY PROTOCOL

The study protocol was approved independently by the Human Subjects Protection Committees of the King/Drew Medical Center and the University of California, Los Angeles. For eligible and consenting patients, the surgical residents completed standard

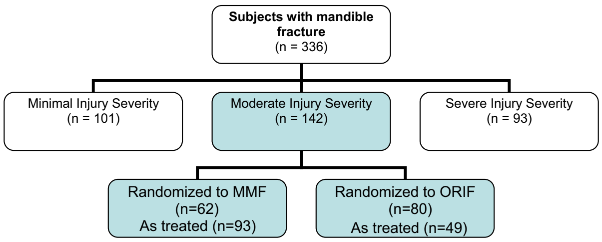

FIGURE 1. Summary of randomization.

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questionnaires describing the history and physical characteristics of the injury. After surgical treatment, the residents also recorded specific details of the treatment provided and documented any complications manifest at regular or emergent follow-up visits. Concomitantly, trained research staff conducted baseline psychosocial interviews around the time of hospital admission. Follow-up assessments were carried out by residents and the interviewers at recall visits scheduled roughly at 10 days, 1 month, 6 months, and 12 months postdischarge. Patient data collected at baseline included sociodemographic information and the etiology of the injury. The physical characteristics of the mandible fractures were derived through a combination of clinical exam and radiographs and the fracture severity summarized using an injury severity score described previously.[9] The 4-item CAGE test was used to assess alcohol abuse.[10]

RANDOMIZATION

As summarized by Figure 1, enrolled patients were assigned to 1 of 3 groups based on the severity of injury reflected by the degree of interfragmentary displacements on the diagnostic radiographs. Based on the study protocol, patients with minimal interfragmentary displacements (0-2 mm) were treated primarily by closed reduction with MMF whereas patients with severe interfragmentary displacements (≥5 mm) were treated mostly by open reduction and rigid internal fixation with bone plates. The subset of patients with moderate fracture displacements (2-5 mm) formed our study cohort. Patients in this group were assigned to receive either MMF (4-5 weeks) or ORIF (postoperative return to function) on the basis of their hospital identification number, allowing treatment assignment to proceed without delay, with the haphazard distribution of the digits in the hospital identifier serving as a randomizing device. Both groups of patients were treated by a team of oral and maxillofacial surgery residents and attending surgeons. To accommodate contextual factors not reflected by interfragmentary displacement, the clinical judgment of the attending surgeon was allowed to overrule the randomly assigned treatment.

OUTCOME MEASURES

We used a combination of hospital as well as patient perspectives to frame the added value of ORIF. Information on resource use was collected at the time of hospital admission, after the primary surgery or treatment of complications, and at the various follow-up visits. The direct costs of providing care included the daily costs associated with hospitalization, charges for operating room resources (hardware, personnel, room time), specialty fees (surgical, anesthesiology), and use of outpatient resources (fracture clinic time, radiographs, medications) related to the initial and follow-up care of the orofacial injury. Clinician-reported outcomes included the nature and frequency of ensuing complications including infections, loose hardware, restriction of mouth opening, malocclusion, and motor and sensory deficits. Additionally, we collected patient appraisals of and satisfaction with their current levels of functioning. At each follow-up visit, a summary "Patient Complaints" variable was constructed by summing self-report indicators of swelling, orofacial pain, bad taste, limitation of mouth opening, painful teeth, irritation by the wires used to immobilize the teeth/jaws, foreign body sensation, and perception of a bad bite (malocclusion). Pain intensity was assessed on a 10-point scale, with 0 representing no pain and 10 representing the worst pain possible. Additionally, we used the 12-item General Oral Health Assessment Index (GOHAI) questionnaire to measure oral health-related quality of life, which, in addition to an overall score, provides subscale measures for various domains of oral health-related quality of life, namely physical function, physical limitations, orofacial pain, general oral health perceptions, social functioning, and esthetic concerns. The GOHAI score ranges from 12 to 60, with a higher score indicating a better reported oral health status.[11]

CASE-MIX ADJUSTMENT

Studies comparing outcomes between surgical interventions are subject to confounding biases if one group has patients with greater injury severity.[12] To allow for detailed case-mix measures that would account for both the number and severity of individual mandible fractures, we developed a system for systematically cataloging injury attributes and used it to develop a summary measure of injury severity. Briefly, we used key anatomic and morphologic features of the mandibular fracture to develop the FLOSID (Fracture type, Location, Occlusion, Soft tissue involvement, Infection, and interfragmentary Displacement) taxonomy for characterizing injury. Each of the 6 dimensions were assigned a weight based on clinical judgment and then combined into a composite measure of injury severity, the Mandible Injury Severity

Table 1. BASELINE CHARACTERISTICS OF PATIENTS BY TREATMENT GROUP

Variable	Treatment Group (%)* ORIF Group (n = 49)	Treatment Group (%)* MMF Group (n = 93)
Gender, male	87.8	86
Race		
African-American	85.7	72.0
Hispanic	8.2	22.6
Other	6.1	5.4
Marital Status		
Single	87.7	83.9
Married/living together	12.2	16.1
Education		
Not completed high school	42.9	34.4
High school graduate	44.9	59.9
Beyond high school	12.2	6.5
Employment status		
Unemployed	75.5	73.1
Nature of injury		
Assaultive	81.6	82.8
Accidental	18.4	18.1
Use alcohol regularly	22.4	25.8
CAGE >1	30.6	31.2
Use street drugs regularly	14.3	25.8

*All variables expressed in percentages, except where noted. All group differences are nonsignificant ($P > .05$) except for patient age.

CAGE, alcohol abuse.

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Score, which has been described previously and validated.[9]

STATISTICAL ANALYSIS

Statistical analyses were carried out using commercial software packages (SPSS, version 14.0; SPSS, Inc, Chicago, IL, and SAS, version 9.2; SAS, Cary, NC). To account for the overriding of patient treatment assignments due to surgical judgment, analyses were conducted on both an intent-to-treat basis as well as a treatment-received basis.[13] In the intent-to-treat analysis, patients who ended up being managed by a treatment method other than that originally assigned (n = 49) were included in the statistical analyses in accordance with their originally assigned treatment group; ie, their outcomes were attributed to the group to which they were randomized initially and not to the group in which they were actually treated. Additionally, we used mixture-model methods developed in the statistical literature for estimating the so-called "complier average causal effect,"[14] where the application to the present context does not refer to patient noncompliance but rather to allowing surgical judgment to overrule the randomization so that the treatment received differs from the treatment assigned. This approach, necessitated by ethical concerns with a randomized protocol in a surgical context, allowed for randomized assignment to be carried out in a majority of cases and guarded against potential biases that can arise from simple conditioning on the treatment received.

Summary statistics were calculated within treatment and assignment groups to characterize distributions of demographic and clinical variables recorded at baseline. To assess the possibility of bias resulting from unequal distribution of injury severity between treatment groups, sample means were compared using an independent sample t test, and histograms were produced to visually compare severity score distributions.

Differences in rates of complications and patient complaints between treatment groups were compared using χ^2 tests of independence and Fisher exact tests. Total associated treatment costs were calculated by aggregating hospital charges including inpatient days, operating room time, surgical fees and anesthe-

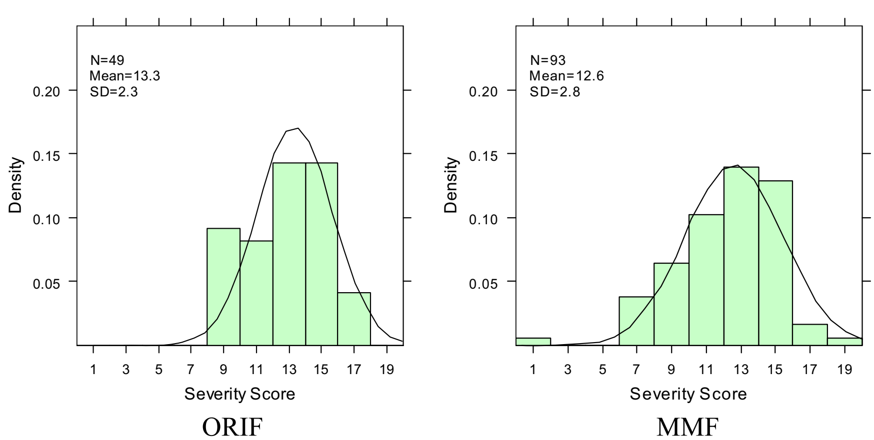

FIGURE 2. Summary injury severity scores for both cohorts.

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Table 2. COST OUTCOMES BY TREATMENT GROUP

	Treatment Group	No.	Mean	SE	Significance (2-tailed)
Inpatient days					
Intent-to-treat	MMF Only	61	2.69	0.476	
	ORIF	78	3.19	0.414	0.425
As treated	MMF Only	91	1.64	0.206	
	ORIF	48	5.50	0.682	<0.001
Total costs					
Intent-to-treat	MMF Only	62	$11,924	1,983	
	ORIF	80	$15,116	1,792	0.236
As treated	MMF only	93	$7,206	807	
	ORIF	49	$26,089	2,805	<0.0001

Abbreviations: MMF, maxillomandibular fixation, ORIF, open-reduction and rigid internal fixation; SE, standard error.

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sia fees, and compared between groups using independent sample *t* tests. Visual plots were constructed to identify outcome trends over time in the 2 treatment groups. Plots of mean pain over time and mean GOHAI scores over time were constructed with separate lines for each treatment group, with error bars representing ± 1 SE of the mean at each follow-up period. Patient-reported pain and individual GOHAI scores were compared between groups at 1 month, 6 months, and 12 months using independent sample *t* tests, repeated measures analysis of variance, and linear mixed-effect regression models. Comparisons between groups on the continuous outcomes of cost, pain, and GOHAI also were conducted using analysis of covariance models to adjust for injury severity and for factors that differed between groups. Injury severity as well as patient gender, race, employment status, age, association of major trauma, and presence of mandibular nerve deficits at admission were all controlled in analysis of covariance models.

Results

PATIENT CHARACTERISTICS AND CLINICAL FEATURES OF INJURY AT BASELINE EVALUATION

Of 336 orofacial injury patients who were recruited for longitudinal assessments, a subsample of 142 patients with moderate fracture displacements was available for randomization. Either due to the clinical judgment of the attending surgeon or contextual constraints (eg, unavailability of operating room, weekend admit), 40 of 80 patients originally assigned to receive treatment with ORIF were treated solely with closed reduction using MMF. On the other hand, 9 of the patients randomized to the MMF group ended up receiving ORIF. Baseline sociodemographic characteristics for the patients are shown in Table 1. In general, the subjects were predominantly single, unemployed, minority males with high school education or less. Observed patient characteristics were balanced across treatment arms with the exception of age; the mean age of the patients in the ORIF cohort was 38 years (range, 19-58 years) and for the MMF cohort was 32 years (range, 18-50 years). Patients in both groups had a similar spectrum of injury severity as summarized by the Mandible Injury Severity Score ($t = -1.7$, $P = .098$) (Fig 2).

COST OUTCOMES

Distinctions between treatments on the basis of cost outcomes were blurred in the intent-to-treat analysis, but when compared on an as-treated basis, the use of ORIF was significantly more resource-intensive than MMF, both in terms of inpatient days and total costs (Table 2). On an as-treated basis, patients receiving ORIF spent an average of 5.5 days in the hospital,

Table 3. COMPLICATIONS BY TREATMENT GROUP

	Treatment Group	No.	Complications (n)	(%)	Significance (2-tailed)
Intent-to-treat	MMF	62	5	8.1	
	ORIF	80	10	12.5	0.394
As treated	MMF	93	7	7.5	
	ORIF	49	8	16.3	0.105

Abbreviations: MMF, maxillomandibular fixation, ORIF, open-reduction and rigid internal fixation.

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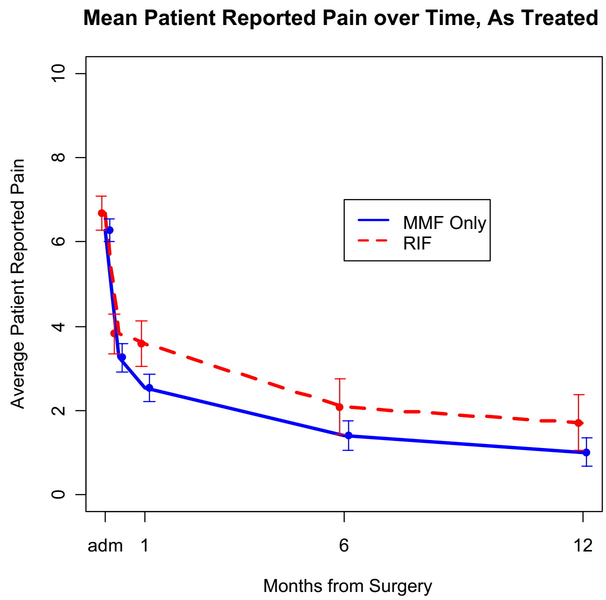

FIGURE 3. Temporal changes in mean pain scores assessed at admission, 10 days, 1-, 6-, and 12-month follow-up for ORIF (*dashed line*) and MMF (*solid line*) treatment. Error bars = ±1 SE.

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whereas patients in the MMF group spent an average of 1.64 days, and the costs of providing care with ORIF were substantially higher than the costs of MMF (\$26,089 vs \$7,206, $P < .0001$).

HEALTH OUTCOMES

Based on clinician reports, 8 (16.3%) patients in the ORIF group and 7 (7.5%) patients in the MMF group suffered a complication (Table 3). Most complications were handled with no obvious sequelae for the patient, but 4 patients needed a reoperation. Soft tissue infections comprised the bulk of the complications reported and in most instances, were treated successfully on an ambulatory basis using local wound care and systemic antibiotics. In the ORIF group, 2 patients developed implant-related infections, 1 at 6 months and 1 at 12 months postsurgery, leading to subsequent removal of the fixation hardware. Additionally, 2 patients in the MMF group developed a fracture nonunion and had to undergo surgical revision with bone grafting and ORIF. Patients treated with ORIF were more likely to evidence an IAN nerve deficit postoperatively than patients treated with MMF (66.7% vs 25.0% respectively, $P < .0001$).

Figure 3 shows the time course of mean scores for patient self-reported pain at hospital admission evaluation and at 1-, 6-, and 12-month follow-ups. Surgically-treated patients started with slightly higher pain scores, were more symptomatic at the 1-month follow-up, and continued to be more symptomatic than the MMF-treated patients at each subsequent follow-up. Patients in both groups reported a decrease in average pain over the follow-up period. Although point estimates of average pain scores were slightly higher in the ORIF treatment group at the 1-, 6-, and 12-months follow-ups, the 2 treatment groups did not significantly differ at any follow-up time. A repeated measures analysis of variance supported this conclusion; a finding further substantiated by the piecewise linear repeated measures regression model that failed to indicate a significant difference in the pain trends over time between the treatment groups. The conclusion of no significant difference also was seen in the mixture-model analysis that allowed the treatment assigned to differ from treatment received.

Patient complaints were significantly more common in the ORIF treatment group at the 1-month follow-up ($P = .012$). However, the 2 treatment groups did not differ in number of complaints at 6 or 12 months post-treatment (Table 4). Patients' perceptions of their oral health and functional status, as reflected by the GOHAI scores, improved over the year in both groups. Temporal changes in mean GOHAI scores through the assessment period are shown in Figure 4. Although ORIF-treated patients had slightly lower GOHAI scores at the time of hospital discharge and at the 1-month follow-up visit, the scores were similar to the MMF group at the 12-month follow-up assessment (Table 5). A repeated measures analysis of variance indicated no significant differences between treatment groups at any time point, and a linear trend repeated measures regression model failed to suggest

Table 4. PATIENT COMPLAINTS BY TREATMENT GROUP

	Treatment Group	1 Month Post-Treatment No.	1 Month With >1 Complaint (%)	1 Month Significance (2-tailed)	6 Months Post-Treatment No.	6 Months With >1 Complaint (%)	6 Months Significance (2-tailed)	12 Months Post-Treatment No.	12 Months With >1 Complaint (%)	12 Months Significance (2-tailed)
Intent-to-treat	MMF	53	20.8		32	6.3		35	0.00	
	ORIF	67	29.9	0.258	43	9.3	1.0	43	9.3	0.123
As treated	MMF	80	18.8		50	8.0		51	3.9	
	ORIF	40	40.0	0.012	25	8.0	1.0	27	7.4	0.606

Abbreviations: MMF, maxillomandibular fixation, ORIF, open-reduction and rigid internal fixation.

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FIGURE 4. Temporal changes in mean GOHAI scores assessed at 10 days, 1-, 6-, and 12-month follow-up for ORIF (*dashed line*) and MMF (*solid line*) treatment. Error bars = ±1 SE.

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a difference between treatment groups in the GOHAI trend over time. Similarly, the mixture-model analysis did not show any significant difference in GOHAI scores between the groups.

For a more expensive treatment to compare favorably to conventional treatment in terms of cost-effectiveness, a necessary condition is that the more expensive treatment shows a distinct health-outcome advantage. However, as Table 5 makes manifest, the average GOHAI score was higher in the MMF group at 1 month and 12 months postsurgery. Only at the 6-month follow-up was the average GOHAI score in the ORIF group 1.88 points higher than the MMF group on an as-treated basis. When the costs of providing ORIF care are factored in, improving the 6-month GOHAI score by 1 unit results in an additional cost of $9,705.

Qualitatively, a slightly larger proportion of the MMF cohort at the 6-month follow-up expressed trouble chewing firm foods or eating without discomfort (Table 6). Patients in the MMF group reported lower average levels of pain at 6 and 12 months postsurgery, with the difference at 12 months reaching statistical significance in the absence of case-mix adjustment (Table 7). After adjustment for case mix, the least-squares means were still lower in the MMF group, but the differences in pain levels expressed by the ORIF and MMF cohorts at the 6- and 12-month assessments were no longer statistically significant (Table 7).

Discussion

Although ORIF incorporates several technical advantages that facilitate the management of complex mandibular fractures, for patients with less severe injuries it is essential to ask: do the purported benefits of ORIF for mandible fractures justify the associated added costs? Beyond a more precise reduction of the fractured bone, the perceived advantages of ORIF organize themselves along two common themes: predictable healing and better patient acceptance. The promise of predictable healing is particularly attractive in the case of noncompliant patients who constitute a significant subset of those sustaining assaultive facial injury and are assumed to be at greater risk for postoperative complications. Frequently implicit in the use of ORIF in these at-risk patients is the assumption that this resource-intensive treatment approach is actually cheaper in the long run because it minimizes the potential costs of treating noncompliance-related morbidity. Relatedly, the early return to function afforded by ORIF is believed to promote the patient's oral health-related quality of life and minimize any masticatory disability resulting from prolonged immobilization of the jaws.[15] However, outside of retrospective chart reviews, there is little scientific evidence to corroborate the experiential advantages of the ORIF approach in terms of important outcomes such as morbidity, quality of life and cost. The prolif-

Table 5. GOHAI SCORES BY TREATMENT GROUP

	Treatment Group	1 Month Post-Treatment No.	Mean (SE)	Significance (2-tailed)	6 Months Post-Treatment No.	Mean (SD)	Significance (2-tailed)	12 Months Post-Treatment No.	Mean (SD)	Significance (2-tailed)
Intent-to-treat	MMF	53	34.15 (1.36)		32	42.81 (2.09)		37	51.14 (1.33)	
	ORIF	69	32.19 (1.17)	0.274	43	43.05 (1.63)	0.929	46	47.52 (1.74)	0.103
As treated	MMF	82	33.57 (1.10)		50	42.32 (1.53)		53	49.21 (1.53)	
	ORIF	40	31.95 (1.49)	0.392	25	44.20 (2.37)	0.495	30	49.00 (1.68)	0.931

Abbreviations: GOHAI, General Oral Health Assessment Index; MMF, maxillomandibular fixation, ORIF, open-reduction and rigid internal fixation; SD, standard deviation; SE, standard error.

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Table 6. RESPONSES TO SELECT ORAL HEALTH-RELATED QUALITY-OF-LIFE QUESTIONS AT 6-MONTH FOLLOW-UP

During the Past Week, How Often:	MMF Only (%) (n = 50)	ORIF (%) (n = 25)
Did you limit the kinds or amounts of foods you eat because of problems with your teeth or jaw?		
Always/Often	20	24
Sometimes/Seldom/Never	80	76
Did you have trouble biting or chewing any kinds of foods, such as firm meats or apples?		
Always/Often	30	16
Sometimes/Seldom/Never	70	84
Were you able to eat anything you wanted without feeling discomfort?		
Always/Often	40	36
Sometimes/Seldom/Never	60	64
Did you use medication to relieve pain or discomfort around your mouth?		
Always/Often	20	20
Sometimes/Seldom/Never	80	80

Abbreviations: MMF, maxillomandibular fixation, ORIF, open-reduction and rigid internal fixation.

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eration of bone plating systems does not automatically imply that ORIF is superior to conventional MMF; if anything, the clinician variation in recommending ORIF for the same mandibular fractures manifests uncertainty about the proper role of the technology.[16]

Using a prospective, randomized control design involving patients with comparable injury severity, we determined that ORIF is not a cost-effective alternate for treating moderately displaced mandible fractures. Viewed through the lens of both hospital and patient, ORIF did not produce compelling advantages over conventional MMF and actually showed a number of disadvantages. Although charges for treatment rendered are institution-specific and not directly comparable, our study results confirm the findings of other investigators[6,7] that the costs of ORIF care are nearly 3-fold higher than conventional MMF. The opportunity costs of surgical intervention include increased anesthesia and operating room time, use of expensive equipment and hardware, increased hospital days and greater demands on personnel. We found that the use of ORIF over MMF for similar mandible fractures has significantly higher costs per patient (mean difference = US $18,883). Given the constraints of trauma care reimbursements,[17] such a financial outlay would severely strain the resources of publicly funded trauma centers if a large number of

Table 7. COMPARISON OF OUTCOME MEASURES: UNADJUSTED AND ADJUSTED FOR CASE-MIX

Outcome	Intent to Treat (Mean SE)		As Treated (Mean SE)	
	Unadjusted	Adjusted*	Unadjusted	Adjusted*
Total cost (n = 142)				
MMF	$11,924 (1,983)	$17,770 (3,954)	$7,206 (807)	$11,655 (3,294)
ORIF	$15,115 (1,792)	$23,454 (3,782)	$26,089 (2,805)	$30,760 (3,303)
Difference†	$3,191 (2,673)	$5,684 (2,752)‡	$18,882 (2,919)§	$19,105 (2,512)§
Pain at 6 months (n = 73)				
MMF	1.22 (0.39)	0.74 (1.3)	1.39 (0.35)	0.42 (1.4)
ORIF	1.93 (0.48)	1.65 (1.3)	2.08 (0.67)	1.67 (1.3)
Difference	0.71 (0.62)	0.91 (0.70)	0.70 (0.76)	1.245 (0.785)
Pain at 12 months (n = 77)				
MMF	0.58 (0.30)	1.05 (1.3)	1.00 (0.34)	1.08 (1.4)
ORIF	1.78 (0.52)	2.40 (1.2)	1.71 (0.67)	2.10 (1.2)
Difference	1.2 (0.60)‡	1.35 (0.66)‡	0.71 (0.76)	1.02 (0.788)

Abbreviations: MMF, maxillomandibular fixation, ORIF, open-reduction and rigid internal fixation; SE, standard error.

*Adjusted for gender, race, employment status, major trauma, nerve deficit, age, and injury severity.

†Significance for differences in total costs was assessed on a $\log^{10}$ scale to satisfy assumptions for statistical tests. Actual values and differences are expressed in real terms for interpretability.

‡Significant at $\alpha = 0.05$.

§Significant at $\alpha = 0.001$.

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patients with mandible fractures were treated surgically.

A central advantage attributed to ORIF surgery is the lower risk of complications, particularly in patients perceived to be unwilling to comply with the 4 to 6 weeks of maxillomandibular fixation or with postsurgery instructions. In one of the few structured attempts to evaluate the cost-effectiveness of ORIF in treating mandibular fractures, Dodson and Pfeffle[4] reported that the high average costs (US $11,637/case) of treating any ensuing complications might render ORIF more cost-effective than non-rigid fixation. Their study was based on a retrospective chart review of a convenience sample of 34 patients treated for mandible fractures. In contrast, our prospective study, which randomly assigned 142 patients with a similar spectrum of injury into 2 treatment groups, produced complication rates that were not significantly different between the 2 groups of patients either on an "intent-to-treat" basis or an "as-treated" basis. In fact, the complication rates associated with MMF treatment were actually lower than ORIF treatment. Our findings echo that of Ehrenfeld et al[18] and reinforce the evolving concept of biologic internal fixation that emphasizes minimal damage to the soft tissue envelope over the precise reduction and absolute stability required by compression fixation.[19] Interestingly, patients who received ORIF had higher postoperative rates of inferior alveolar nerve deficits. This finding may be attributable to the additional manipulation of the mandible segments that is frequently required for applying bone plates. Given that many of our subjects had characteristics suggestive of poor compliance,[20] our study results contradict common notions about higher complication rates with the use of MMF treatment in noncompliant patients.

With regard to patient comfort and acceptance, we compared the 2 treatment methods using patient reports of pain, perception of treatment side effects, and a standardized measure of oral health-related quality of life. Surgically treated patients reported slightly higher pain scores at all assessment time points including the 1-month follow-up. Similarly, patient complaints were significantly more common in the ORIF group at the 1-month follow-up. This finding contradicts a central premise of ORIF therapy; namely that it affords enhanced patient comfort. The discordant finding of increased pain and discomfort with ORIF presumably reflects the added burden of the surgical exposure required to expose and reduce the fractures with the bone plates. The discomfort of the healing surgical access site seemed to be more perceived as more intrusive than the irritation of mandibular immobilization. No significant difference was detected at any time point between the 2 groups with respect to the GOHAI score used to manifest the patients' oral health-related quality of life. Therefore, any benefit from the early return of function provided by ORIF seems to be either small in magnitude or masked by other factors. Even considering the incremental quality-of-life benefit afforded by ORIF at the 6-month follow-up, it seems difficult to justify the added cost of $18,882 for the dubious advantage of less than 2 points on the GOHAI.

Our study has several important strengths. These include a prospective, randomized controlled design, repeated assessments using standardized questionnaires, and a statistical plan that included both intention-to-treat analysis and a strategy to allow treatment assignment to be overruled based on clinician judgment. Other unique features include the extended duration of the follow-up, the FLOSID taxonomy[9] to systematically collect fracture information, the Mandible Injury Severity Score to quantitatively summarize injury severity and control for baseline differences between the groups, and the use of both cost as well as quality-of-life domains to compare treatment outcomes. A large proportion of our study cohort consisted of patients at risk for poor compliance, offering a test of ORIF in a setting where it might be expected to outperform MMF. Limitations of our study include loss of some patients to follow-up at all time points, the fact that participating clinicians overruled the randomized treatment assignment in a substantial number of cases, and the fact that we did not attempt to monetize costs and benefits from a societal perspective. Still, given the available data, we would be reluctant to routinely recommend ORIF for patients with moderately displaced mandibular fractures unless there was a compelling clinical or patient-related need.

In summary, our study shows that the gains for the patient in having ORIF of a moderately displaced mandibular fracture are negligible and difficult to justify given the substantive added costs. Contrary to common trepidation, our results corroborate that MMF is a reliable, safe, and cost-effective method of treating mandible fractures in patients perceived to be poor compliers. What is not yet determined is which fracture patterns or subset of patients would benefit from ORIF. There is not doubt that ORIF has value as a treatment option in certain circumstances, especially in the management of complex injuries. However, the individualized determination is best made after careful assessment of the clinical variables and informed by data from controlled studies instead of anecdotes of improved outcomes.

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