ORIGINAL ARTICLE

Prospective, multi-center study of the effectiveness of orthodontic/orthognathic surgery care in the United Kingdom

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Introduction: The aim of this study was to evaluate the effectiveness of orthodontic/orthognathic surgical care provided in the North West region of England. It was an observational, prospective cohort study at 13 maxillofacial clinics in the United Kingdom. **Methods:** The 131 patients comprised 47 males (35.9%) and 84 females (64.1%), with an average age of 22.6 years. They received orthodontic/orthognathic treatment according to the normal protocols of the operators. They were then followed until all orthodontic treatment was completed. Final skeletal pattern, final peer assessment rating score, number of attendances, and duration of treatment were recorded. **Results:** At the end of the 5-year study, 94 patients had completed treatment, and 71 had complete data. Data analysis showed that, overall, the treatments provided were effective in terms of skeletal and dental occlusal outcomes; the final mean peer assessment rating score was 10.58. However, treatment duration was longer than commonly expected, with a mean length of 32.8 months (SD,11.3). The outcome of treatment was influenced by only pretreatment skeletal discrepancy. **Conclusions:** This prospective investigation showed that orthodontic/orthognathic surgical care was effective. The outcome of treatment was influenced only by the severity of the pretreatment skeletal discrepancy. (Am J Orthod Dentofacial Orthop 2009;135:709-14)

This article is a report on a prospective cohort study of the effectiveness of orthognathic surgery provided in the North West region of England, United Kingdom.

Orthognathic surgery, combined with orthodontic treatment, is commonly used to correct a malocclusion with a substantial skeletal component. When we reviewed the literature on this type of treatment, it appeared that most research was carried out by using retrospective methods, which are, by their very nature, biased. We then undertook a systematic review, confining our search strategy to prospective investigations (Appendix). This yielded 30 articles over the last 10 years. When we critically evaluated these studies, we found that they were characterized by small sample sizes with no calculation of the power of the study[1]; unclear inclusion or exclusion criteria[2]; low response rates to questionnaires, with no details of the characteristics of the nonresponders[3]; inclusion of patients who had not completed their treatment[4]; and collection of pretreatment data 1 to 3 months before surgery, after presurgical orthodontic treatment.[5]

We identified several randomized, controlled trials. These studies were, however, concerned with outcomes such as the effectiveness of differing methods of fixation,[6] antibiotic regimens,[7,8] psychological preparation of the patient for surgery,[9,10] and oral function.[11] Thus, they did not address the effectiveness of this treatment modality.

We found no prospective investigations on the morphologic outcome and the process of orthognathic/orthodontic treatment. As a result, we decided to carry out a multi-center, prospective cohort study into the process and outcome of orthognathic treatment.

This study was designed to answer the following questions.

1. Is orthodontic/orthognathic surgical treatment effective in correcting skeletal and dental morphology?
2. What is the process of this treatment?
3. Are there any predictors of the effectiveness of orthodontic/orthognathic surgical treatment?

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MATERIAL AND METHODS

Thirteen orthodontic/oral-maxillofacial departments in the United Kingdom took part in the study. These were selected because they had high surgical caseloads, and the orthodontists and maxillofacial surgeons were willing to participate. Before the start of the investigation, we held a "study day" at which the orthodontists and surgeons from each department were instructed in the study methodology and the specific requirements for data collection.

When patients came for a consultation and the clinician determined that that they would benefit from orthognathic surgery for skeletal discrepancy, they were asked to participate in the study. The inclusion criteria were as follows: (1) age, 16 years or above; (2) willing to participate; (3) treatment not for posttraumatic reconstruction or correction of a congenital birth defect; and (4) sufficiently severe skeletal malocclusion, necessitating both orthognathic surgery and orthodontic treatment.

At this point, the objectives and the methodology of the study were explained and the patient's consent sought. When a patient agreed to take part in the study, the following data and records were collected: (1) age and sex, (2) zip code (to identify the patient's social deprivation with the Townsend index[12]), (3) plaster study models of the teeth, and (4) lateral cephalogram and panoramic radiographs.

The patients were treated to the usual protocols of the orthodontists and maxillofacial surgeons. We did not standardize the treatment procedures or the orthodontic appliances, because we intended to evaluate the real-world effectiveness of treatment.

Data were collected before the start of treatment, once the patient decided to undergo orthodontic/orthognathic surgical care, and after all treatment, when the orthodontic appliances were removed.

The following measurements were derived from the data.

1. Cephalometric analyses of radiographs. The radiographs were digitized, and all measurements were corrected for magnification, by using a known measurement scale on each radiograph. A limited cephalometric analysis, of predetermined key measurements, was used to avoid type I errors due to multiple testing. We calculated ANB angle, maxillary and mandibular unit length difference, and overjet as outcome measures. We chose these variables because they were the ones that we aimed to change.
2. Process data. The duration of the various phases of treatment, the number of attendances, the type of surgical procedure, and any complications were recorded from the patients' records.
3. A calibrated examiner (E.T.) scored the study casts using the peer assessment rating (PAR) index to measure dento-occlusal changes.[13]

A sample of 30 sets of study casts and radiographs was remeasured. The intraclass correlation coefficient was 0.9 for the PAR index data. The intraclass correlation coefficient for the cephalometric data ranged from 0.85 to 0.9, and root means squared ranged from 0.4 to 1.0 mm for linear and 1.0° to 1.2° for angular measurementsw. These were acceptable levels of error.

Statistical analysis

The data were analyzed with SPSS software (version 16.0, SPSS, Chicago, Ill). Standard descriptive and exploratory statistics were generated. We used multivariate statistics to attempt to identify predictors of treatment outcome. This was done by using sequential regressions on the main outcome measures of final ANB angle, final overjet, final unit difference between the maxilla and the mandible, final PAR score, and total treatment duration, with the following independent variables: pretreatment value of the outcome measures, pretreatment maxillary/mandibular plane angles, number of attendances required to complete treatment, and pretreatment incisal relationship as defined by the British Standards Classification.

RESULTS

The patients received care from 24 orthodontists and 20 maxillofacial surgeons. Enrollment started on October 9, 1998, and was completed on March 3, 2000, for a total of 131 patients. There were 47 males (35.9%) and 84 females (64.1%), with an average age of 22.6 years (range, 16.3-51.2 years). They could be further divided into 16 Class I (9.2%), 61 Class II (47.3%), and 53 Class III (40.5%) malocclusions. All Class I patients had an anterior open bite.

All patients had orthodontic appliances fitted, but 37 (28%) did not complete their treatment and did not have orthognathic surgery. Ninety-four completed treatment; of these, 71 (76%) had complete study model and cephalometric data after treatment.

The surgery performed included 24% of the patients having a mandibular osteotomy only, 10% having a maxillary osteotomy only, and 66% having a bimaxillary procedure. Data on attendances and duration of treatment are shown in Tables I and II.

The pretreatment and posttreatment study models were scored with the PAR index by a calibrated examiner. The relevant PAR scores are included in Table III.

Table I. Duration of treatment

Treatment segment	Mean time in months (SD)
First attendance to end of treatment	45.2 (12.5)
Appliance fitting to end of treatment	32.8 (11.3)
Presurgical orthodontics	25.2 (8.5)
Surgery to completion	6.8 (4.9)

Table II. Number of attendances required for treatment

Treatment segment	Number of attendances (SD)
Presurgery	14.6 (5.7)
Postsurgery	6.7 (2.6)
Total attendances	21.3 (6.4)

The values from the cephalometric analyses of the radiographs are represented for each pretreatment incisal classification and are shown in Tables IV through VI.

The data showed that the treatment was successful in reducing overjet and correcting the skeletal discrepancy for most patients.

The regression analyses for the outcome variables of final skeletal pattern (ANB angle and unit difference) are shown in Tables VII and VIII. These showed that, for posttreatment ANB, the only significant predictors were pretreatment ANB and maxillary/mandibular plane angle. Similarly, for the posttreatment unit difference, the only predictor was pretreatment unit difference. Interestingly, the type of skeletal pattern and the incisal relationship with respect to Class II or Class III had no effect in these models.

When we ran the regressions on final overjet, PAR score, and total duration of treatment, we could not achieve a good fit; there were no statistically significant predictors.

Thirty-seven patients (28%) who entered the study did not complete their planned treatment or were happy with the results of the presurgical orthodontic treatment, and 94 (72%) had the planned surgery.

The data showed that the mean age of the patients who did not complete orthodontic treatment was 19.1 years (SD, 4.0), whereas those who completed all treatment had a mean age of 23.1 years (SD, 8.9) ($P = 0.001$, *t* test). There were no differences in socioeconomic status between the groups.

DISCUSSION

An important finding of this investigation was that the progress of treatment was much slower than is traditionally believed. Patients are still frequently told that orthognathic treatment will be completed within 2 years; this erroneous information is often given when they are considering treatment. Our results show that this information is overly optimistic.

Table III. PAR scores for the patients in the study

Stage	Mean (95% CI)
Pretreatment	40.48 (38.5, 42.4)
Posttreatment	10.58 (8.7, 12.4)
PAR score reduction	72% (67, 78)

Table IV. Cephalometric measurements for Class I patients

	Start of treatment n = 16		End of treatment n = 9	
Measurement	Mean	SD	Mean	SD
SNA (°)	79.7	2.5	80.3	2.6
SNB (°)	75.0	4.0	76.5	3.1
ANB (°)	4.6	3.0	3.8	2.1
Unit difference (mm)	26.8	8.1	26.2	2.81
Overjet (mm)	2.9	0.67	2.7	1.4

When the process of treatment is examined more closely, it appears that the patients were given adequate time to consider the implications of this complex treatment. Nevertheless, presurgical orthodontic treatment appears to be quite prolonged, with a mean treatment time of 25 months (rather than the often estimated time of 18 months). Further delays to treatment appear to be the wait between the end of orthodontic treatment and the orthognathic surgery.

It is difficult to explain these differences unless we consider that there is a natural inclination for clinicians to overestimate their efficiency at providing treatment. Our literature review found few studies that reported on the duration of orthodontic/orthognathic treatment. A Medline search found only 2 investigations specifically concerned with this question.[14,15] In both studies, the investigators retrospectively reviewed the charts of patients who had undergone orthodontic/orthognathic treatment. In the study in Norway, they concluded that the average time to complete treatment was 21.9 months, with median treatment times of 15.4 and 5.9 months for presurgical and postsurgical orthodontic treatment, respectively.[14] These treatment times were considerably shorter than we found in our investigation. Possible reasons for this difference could be that our study did not suffer from selection bias, because all patients were included regardless of treatment outcome. Other differences could have been due to the setting of the studies. The system of care in Norway might have been more effective, but this is only conjecture.

Table V. Cephalometric measurements for Class II patients

	Start of treatment n = 61		End of treatment m = 32	
Measurement	*Mean*	*SD*	*Mean*	*SD*
SNA (°)	80.2	3.5	81.5	4.2
SNB (°)	74.2	3.7	77.2	4.3
ANB (°)	5.9	2.5	4.3	3.1
Unit difference (mm)	24.6	5.8	27.2	5.9
Overjet (mm)	8.7	2.8	2.5	1.4

Table VI. Cephalometric measurements for Class III patients

	Start of treatment n = 53		End of treatment n = 37	
Measurement	*Mean*	*SD*	*Mean*	*SD*
SNA (°)	79.9	4.0	82.6	4.6
SNB (°)	82.5	4.9	80.4	4.5
ANB (°)	−2.6	3.5	2.1	2.4
Unit difference (mm)	35.6	6.3	31.6	5.0
Overjet (mm)	−2.6	2.7	1.9	1.4

Table VII. Results for sequential linear regression (dependent variable: final ANB)

		Coefficients				95% CI for Beta	
Variable	R^2 *change*	*Beta*	*SE*	*t*	*Significance*	*Lower bound*	*Upper bound*
Constant		1.34	3.55	.37	0.70	−5.77	8.46
Pretreatment ANB	.30	.33	.08	3.80	0.00	.16	.51
Maxillomandibular plane (°)	.08	.08	.03	2.48	0.01	.01	.14
Attendance	.00	–.46	1.01	–.45	0.64	−2.50	1.56
Class II skeletal pattern	.01	–.08	.91	–.09	0.92	−1.91	1.75
Class III skeletal pattern		1.08	1.15	.93	0.35	−1.22	3.38
R = 0.63							
R^2 = 0.40							
Adjusted R^2 = 0.35							

Table VIII. Results for sequential linear regression (dependent variable: final unit difference)

		Coefficients				95% CI for Beta	
Variable	R^2 *change*	*Beta*	*SE*	*t*	*Significance*	*Lower bound*	*Upper bound*
Constant		6.33	5.41	1.17	0.24	−4.49	17.15
Pretreatment unit difference	.59	.53	.06	7.98	0.00	.39	.66
Pretreatment maxillomandibular plane (°)	.00	.00	.04	.16	0.87	–.08	.10
Attendances	.01	2.21	1.48	1.49	0.14	–.75	5.19
Class II skeletal pattern	.01	1.16	1.33	.87	0.38	−1.50	3.83
Class III skeletal pattern		–.89	1.49	–.59	0.55	−3.88	2.09
R = 0.79							
R^2 = 0.63							
Adjusted R^2 = 0.59							

In the other investigation, based in the United Kingdom, the authors reported median treatment times of 17 months. However, this study could have suffered from considerable selection bias, since the authors reported on only 65 patients who had received treatment over a 5-year period; these providers' caseloads must have been higher than this figure.

Comparison of the skeletal and dental changes in our investigation with other studies is difficult because most studies used retrospective data that is likely to be influenced by selection bias. In addition, some investigators used many different cephalometric analyses on small samples of subjects. Nevertheless, it appears that the initial skeletal and dental discrepancies and the changes from treatment are similar to those from other investigations.[16-18]

When we consider these data, we can conclude that, if 1 goal of treatment is to normalize the skeletal pattern with respect to the anteroposterior relationship of the mandible to the maxilla, the treatment can be considered moderately effective; 44% of the patients had a posttreatment unit difference that was within 1 SD of the normal population mean that would be expected to include 66% of the population. Also, most patients in this investigation had significant pretreatment cephalometric discrepancies. Importantly, no other prospective investigation has produced similar data.

Although there was some variation in the skeletal effects of treatment, this was not the case for dentoalveolar change. Most patients, after treatment, had an overjet that could be considered normal. This was reflected in the PAR scores, which reinforced that the treatment was effective. Only 2 other investigations of orthognathic surgery have analyzed PAR scores.[19,20] Interestingly, the results for the final PAR score were, on average, 4 points lower than in this investigation; this could be considered clinically significant. When the study by Baker et al[19] was carefully evaluated, however, it appeared that 8 subjectts were not included in their sample of 50 because of unfavorable treatment outcomes. The other investigation was a retrospective study in the United States that was a long-term follow-up of 33 of a possible 135 patients; as a result, there was selection bias, and the study might not be comparable.[20]

Our PAR index results were interesting because they suggested that, although the standard of the occlusal result was high, it was not as high as that reported in other investigations evaluating orthodontic treatment.[21] We should, however, be cautious in making this observation, because there were differences in the studies, and it could be suggested that, because orthognathic treatment is often complex for the most severe malocclusons, as evidenced by the high pretreatment scores, a high standard of occlusal result might not always be achievable.

When we examined the factors that influenced the outcome of the skeletal correction, we found that the pretreatment skeletal discrepancy had an effect. In many ways, this was expected, because the greater the initial skeletal discrepancy, the more complex the surgery. It was also important to find that there was no effect of the type of pretreatment discrepancy (in terms of Class I, Class II, or Class III) on the posttreatment skeletal pattern. This suggests that, in the short term, there are no real differences between the success of surgery for Class I, Class II, or Class III patients.

An important factor that must always be assessed when studying the effectiveness of any treatment is the proportion of patients who do not complete treatment. In this investigation, our noncompletion rate was 28%; although this could be considered high, it is not as high as for other types of orthodontic treatment. For example, a recent investigation into the effectiveness of Twin-block treatment reported a dropout rate of 34%.[22] Again, no prospective investigations into orthognathic surgery have reported this variable, so it is impossible to make comparisons.

Investigation of the factors that influenced patient dropout provided useful information; the only factor that had an effect was the patient's age. It can be suggested that more mature patients had a greater understanding of the complexities and the burden of treatment than the younger ones, and, as a result, they tended to persevere until the end of treatment.

It was disappointing that, despite considerable efforts, data were not collected or lost for some patients in the study. We intended that this investigation would have an intention-to-treat methodology, in which data would be collected from all patients, even if they did not complete treatment. However, this led to ethical problems in taking radiographs that would not be in the patients' best interest. As a result, our final analysis lacks data on the 37% of patients who did not complete treatment. This data loss was further compounded because final cephalometric data were not collected for 16 patients because of protocol violations. We therefore collected data on 83% of the patients who completed treatment. There are no recommendations on the acceptable level of data loss for prospective cohort studies. As a consequence, when our results are interpreted, it is important to consider this data loss.

CONCLUSIONS

1. Orthodontic/orthognathic surgical treatment is effective in successfully correcting the dental and skeletal relationships of patients.
2. The process of treatment is not as efficient as reported elsewhere. This might be due to the nature of previous investigations.
3. The effectiveness of the treatment was influenced by the severity of the pretreatment skeletal discrepancy.

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APPENDIX

The first step of this investigation was an electronic search by using the Medline and Embase databases. We used the following search terms.

For Medline, ((Jaw near abnormalit*) or Prognathism or (Facial near disproportion)); Part Two (Surgery) AND (Orthognathic or (Oral near surg*) or (mandibular near advancement) or (osteotom* and le fort) or (osteotom* and (sagittal near1 split))); or Part three (Exclusions) NOT ((third near 1 molar) or Periodont* or Implant* or Lesion* or Tumor* or Neoplasm * or (drug near therap*) or an? esthesia or nutrition*).

For Embase, Part One (((Jaw near malformation) or (Jaw near abnormalit*) or Prognathia or (Facial near asymmetry)); Part Two (Surgery) AND (Orthognathic or Maxillofacial in DE or (Oral near surg*) or (mandib* near advancement) or (mandib* near reconstruction) or (osteotom* and (le fort or maxil*)) or (osteotom* and (sagittal near split))); or Part three (Exclusions) NOT ((molar near (third or tooth)) or (wisdom near tooth) or Periodont* or Implant* or Lesion* or Tumor* or Neoplasm* or (drug near therap*) or an? esthesia or nutrition*).

The searches were limited to include only articles in English from 1990 on. We then used these studies to develop the following criteria for a hand search of articles concerned with the effectiveness of orthognathic surgery procedures on skeletal pattern (including relapse), soft-tissue pattern, psychosocial factors, temporomandibular symptoms, nerve function, and other miscellaneous outcomes such as occlusal index scores, electromyography, and so on. We excluded articles about the effectiveness of computerized prediction.

A hand search was carried out of issues of *American Journal of Orthodontics and Dentofacial Orthopedics, European Journal of Orthodontics, British Journal of Orthodontics, Journal of Oral Maxillofacial Surgery, International Journal of Oral Maxillofacial Surgery, British Journal of Oral Maxillofacial Surgery, Journal of Cranio-Maxillofacial Surgery,* and *International Journal of Adult Orthodontics and Orthognathic Surgery* from 1990 to 2006.