

OUTCOMES RESEARCH

Surgery and obstructive sleep apnea: Long-term clinical outcomes

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OBJECTIVE: Outcome data on the surgical treatment of obstructive sleep apnea are, in general, based on short-term follow-up (<6-9 months). This examination was undertaken to assess long-term results.

METHODS: Forty patients who underwent soft tissue and skeletal surgery were the subjects of this review. Methods of evaluation included polysomnographic variables (respiratory disturbance index (RDI), low oxyhemoglobin desaturation (LSAT)), body mass index, quality-of-life assessments, roentgenographic analysis, and complications. Statistical analysis used the SAS 6.12 system.

RESULTS: Thirty-six of 40 patients (90%) showed long-term clinical success. The mean preoperative RDI, nasal continuous positive airway pressure RDI, and long-term RDI were 71.2 ± 27.0 , 7.6 ± 5.2 and 7.6 ± 5.1 , respectively. The mean preoperative LSAT, nasal continuous positive airway pressure LSAT, and long-term LSAT were $67.5\% \pm 14.8\%$, $87.1\% \pm 3.2\%$, and $86.3\% \pm 3.9\%$, respectively. The mean follow-up was 50.7 ± 31.9 months. The patients showed a statistically significant long-term weight gain ($P = 0.0002$) compared with their 6-month postoperative level (body mass index 31.4 ± 6.7 vs 32.2 ± 6.3). There was a positive correlation with the amount of skeletal advancement and clinical outcome.

CONCLUSION: Comprehensive evaluation and surgical treatment can result in successful long-term clinical outcome. (Otolaryngol Head Neck Surg 2000;122:415-21.)

In 1982 the treatment concepts of obstructive sleep apnea (OSA) dramatically changed. Sullivan et al¹ reported on the application of nasal continuous positive airway pressure (CPAP). Nasal CPAP produced results similar to those of tracheostomy in reversing excessive daytime somnolence (EDS) and the cardiopulmonary sequelae of OSA.² The short-term success of nasal CPAP gave way to the concern of long-term patient compliance. Waldhorn et al³ in 1990 attempted to allay concerns over long-term compliance by reporting a 76% compliance rate in a group of 96 patients followed up for a mean of 14.5 months. This review, as well as others, had inherent flaws because the compliance rate was based on subjective patient reporting. Kribbs et al⁴ in 1991 completed an objective review of patient compliance by placing covert monitors on the nasal CPAP machines of 85 patients. They concluded that subjective patient reporting is, indeed, flawed. Patients tended to significantly overestimate night-to-night use of nasal CPAP. Most patients (60%) in the study claimed to use nasal CPAP nightly; however, only 16 of 35 patients (46%) met the criteria for regular use, defined by at least 4 hours of CPAP administered at least 70% of the days monitored. Two of 35 patients studied used nasal CPAP for at least 7 hours on more than 70% of the days monitored. They concluded that nasal CPAP falls short of its therapeutic goal.

Surgical treatment of OSA had its own distinct problems. Tracheostomy, described by Kuhlo et al⁵ in 1969, was the first surgical treatment of OSA. Although results approach 100% in eliminating sleep disordered breathing, it is poorly tolerated.⁶ Cited causes of tracheostomy intolerance include wound infection (granulation), stenosis, bleeding, and psychological dependence.

Uvulopalatopharyngoplasty (UPPP) followed tracheostomy in 1979.⁷ Although UPPP was originally described as a treatment for snoring, Fujita et al⁷ modified this soft palate procedure to treat OSA. It has proved to be an excellent method of controlling snoring; however, several retrospective reviews reported improvement in only 50% of patients and complete control of the syndrome in only 30%.^{8,9}

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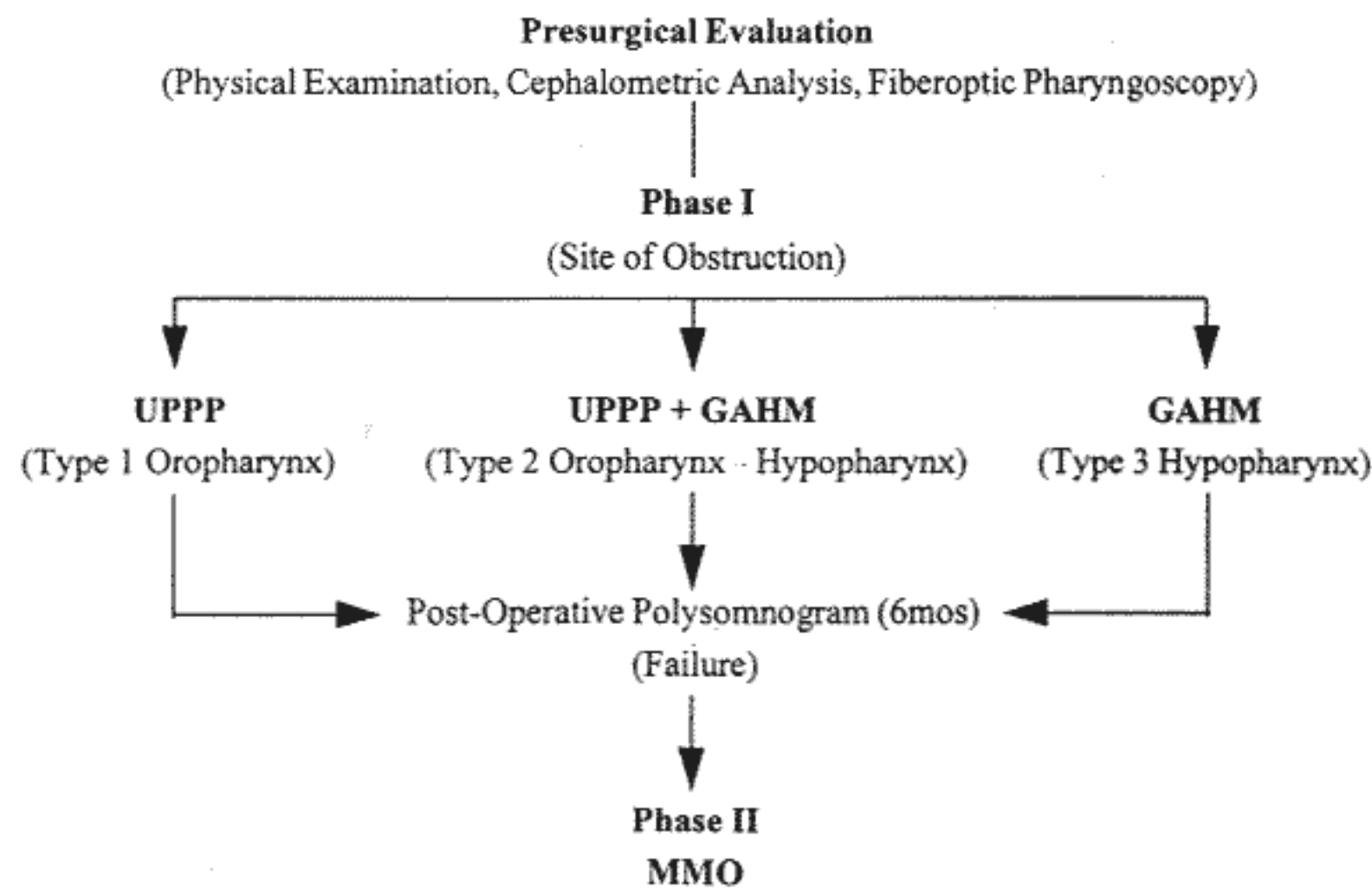


Fig 1. Surgical protocol.

Poor surgical outcomes have led to misunderstanding and confusion about the surgical role in OSA. In 1985, we reviewed a group of UPPP failures and concluded that, although the procedure eliminated the obstruction at the level of the soft palate, persistent obstruction remained at the tongue base.¹⁰ It is now generally accepted that OSA results from diffuse narrowing of the upper airway, which includes the soft palate, lateral pharyngeal wall, and base of the tongue.^{11,12}

On the basis of this concept of diffuse airway narrowing, we designed a surgical protocol with reported clinical outcomes in 1988 (Fig 1).¹³ The surgical protocol includes a presurgical evaluation to isolate areas of obstruction; this evaluation is followed by potentially 2 phases of surgery. The presurgical evaluation includes a physical examination, cephalometric analysis, and fiberoptic laryngoscopy.

Phase I surgical treatment is based on the level of obstruction, as determined in the presurgical evaluation. Surgical treatment can include UPPP for oropharyngeal obstruction and/or genioglossus advancement with hyoid suspension (GAHM) for base-of-tongue obstruction (Fig 2). Successful clinical outcomes of phase I surgery are based on severity and range from approximately 75% in patients with mild-to-moderate OSA to 40% in patients with severe OSA. Outcomes are reported on a 6-month postoperative polysomnogram.

Phase II surgical reconstruction is reserved for phase I failures and consists of maxillary and mandibular advancement osteotomy. Severe OSA presents many difficult challenges; however, surgical success at 6 months is approximately 95%, which is the same as the effectiveness rate of nasal CPAP.^{13,14}

Clinical outcome reviews for both nasal CPAP and

surgery have generally been based on short-term follow-up (<6-9 months). There is very little information on long-term clinical results. Issues of age and weight gain can possibly affect surgical treatment over time. This clinical review was undertaken to assess long-term clinical results of patients with severe OSA in whom phase II surgical reconstruction was successfully completed, as determined by a 6-month follow-up polysomnogram.

METHODS

Patients included in this review were treated between 1985 and 1995. Parameters assessed included quality-of-life issues, polysomnographic and cephalometric data, and surgical complications.

Quality-of-life assessments included review of snoring and EDS as they affected daily routine. The assessments were made by questionnaires and reviewed by the primary author (R.W.R.) in interviews with the patient before and after the surgery. Snoring was assessed by the bed partner and scored as absent, mild (not disturbing bed partner), moderate (disturbing bed partner), or severe (bed partner leaves room). EDS was evaluated by the absence or presence of tiredness affecting daily routine, job performance, or driving; the need for napping; and the need for caffeine drinks. The Epworth Sleepiness Scale, visual analog scale, and Physical and Mental Health Summary (SF-36) were added as a part of the patient evaluation in 1994 and are therefore not part of this review.

The polysomnogram systematically monitored electroencephalogram (C-3/A2/C4/A1), electro-oculogram, chin and leg electromyograms, electrocardiogram (modified V2 lead), airflow, thoracic and abdominal effort, and pulse oximetry. Polysomnographic variables evaluated included the respi-

Table 1. Patient characteristics (40 patients)

Characteristic	Data
Age (y)	45.6 ± 20.7
Sex (F/M)	7/33
BMI (kg/m ²)	31.4 ± 6.7
RDI	71.2 ± 27.0
LSAT (%)	67.5 ± 14.8

ratory disturbance index (RDI) (Apnea + Hypopnea/Total sleep time × 60) and oxyhemoglobin desaturation nadir (LSAT). At each recording the body mass index (BMI) was calculated, and a lateral cephalometric roentgenogram was obtained for analysis (Fig 3). Cephalometric data were obtained before surgery (T₁), 1 to 3 weeks after surgery (T₂), 6 months after surgery (T₃), and long-term after surgery (T₄). All cephalometric roentgenograms were traced by the primary author. Traditional skeletal and soft tissue measurements evaluated maxillary and mandibular advancement, skeletal relapse, and airway changes. Measurements included the following: sella-nasion-point A angle (SNA; 82° ± 2°), sella-nasion-point B angle (SNB; 80° ± 2°), mandibular plane-hyoid (15.4 ± 3 mm), and posterior airway space (PAS; 11 ± 1.8 mm).¹⁰ The margin of error in assessing skeletal relapse was considered 0.5 mm, and changes less than this were considered not significant (NS).²³ Skeletal relapse analysis focused on the mandible because of its relationship to the genioglossus muscle, tongue base, and hypopharyngeal airway. Statistical analysis used the SAS 6.12 system.

Criteria for surgical success required either of the following: improvement in quality-of-life assessments and objective polysomnographic data equivalent to that seen in patients monitored with nasal CPAP; or postoperative RDI less than 20 with at least a 50% reduction during the preoperative study as well as LSAT levels equivalent to those seen in patients with nasal CPAP. Patients greater than 1 year from surgery were considered for this review. Although the investigation is ongoing, 40 patients have completed review and are the subject of this report.

RESULTS

The study included patients surgically treated between 1985 and 1995. The patient characteristics are shown on Table 1. Seven women and 33 men were included in the study; the mean age was 45.6 ± 20.7 years. The preoperative RDI and LSAT were 71.2 ± 27.0 and 67.5% ± 14.8%, respectively. The mean BMI was 31.4 ± 6.7 kg/m². Before entering the surgical protocol, all patients exhibited profound EDS, which may have included poor work performance, difficulty in driving, and the need for naps. Thirty-six patients (90%) were classified as severe snorers, and 4 patients (10%) were moderate

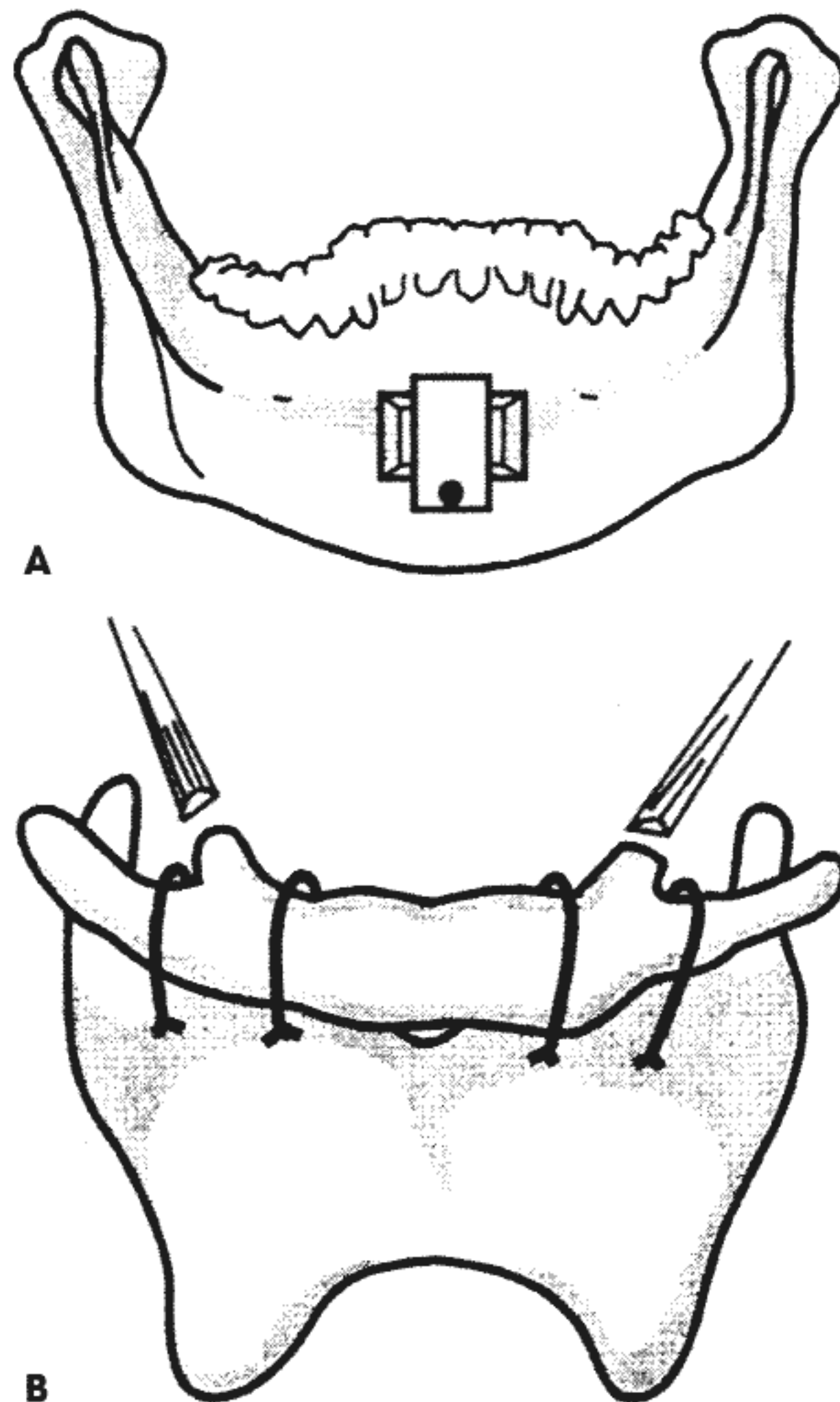


Fig 2. A, Anterior mandibular osteotomy, frontal view. B, Diagram of modified hyoid suspension.

snorers. At the 6-month postoperative evaluation, all patients reported marked improvement or resolution of their EDS. Thirty-two patients (80%) no longer snored, as witnessed by the bed partner, and 8 patients (20%) were classified as mild snorers. The 6-month postoperative RDI and LSAT were 9.3 ± 5.4 and 85.6% ± 4.1%, respectively. The mean BMI was 31.0 ± 6.4 kg/m². The nasal CPAP RDI was 7.6 ± 5.7, and LSAT was 87.1% ± 3.2% (*P* = NS).

The mean long-term follow-up was 50.7 ± 31.9 months (range 12-146 months). Thirty-six patients continued to show successful results (Table 2). The mean RDI was 7.6 ± 5.1, and LSAT was 86.3% ± 3.9%. This group demonstrated a modest but clinically significant weight gain between the 6-month and long-term follow-up periods (BMI 31.4 ± 6.3 vs 32.2 ± 6.4 kg/m² [*P* = 0.002]). All 36 patients reported that their EDS remained in check. The number of nonsnorers decreased

SNA	$82^{\circ} \pm 2$
SNB	$80^{\circ} \pm 2$
PAS	$11\text{mm} \pm 1.8$
PNS-P	$35\text{mm} \pm 3.5$
MP-H	$15\text{mm} \pm 2.8$

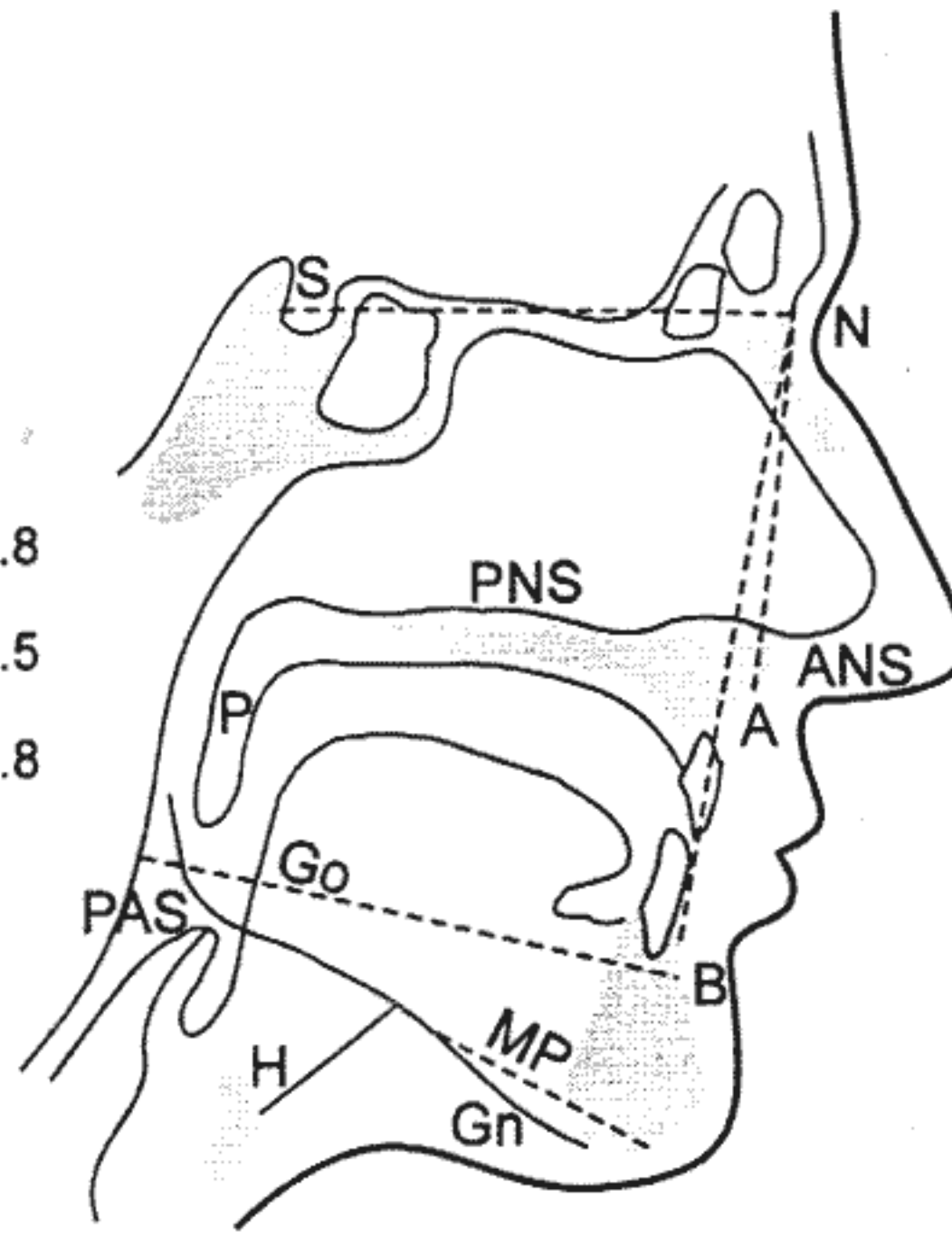


Fig 3. Cephalometric tracing and analysis. *PNS-P*, Posterior nasal spine-palate; *MP-H*, mandibular plane-hyoid.

to 26 (65%), and the number of mild snorers increased to 10 (35%). No bed partner reported moderate or severe snoring. Four patients did not show long-term success (61.0 ± 24.7 months) (Table 3). The 6-month RDI was 10.5 ± 6.7 and increased to 43.0 ± 28.5 . The LSAT decreased from $87.5\% \pm 1.7\%$ to $81.8\% \pm 3.9\%$. All 4 patients had recurrence of their EDS. One patient was a severe snorer, 2 patients were moderate snorers, and 1 patient was a mild snorer.

Cephalometric data analysis showed the group, as a whole, exhibited maxillary and mandibular deficiency with an SNA angle of $78.9^{\circ} \pm 3.7^{\circ}$ and SNB $74.8^{\circ} \pm 5.4^{\circ}$ (Table 4). Ten patients, however, did not demonstrate mandibular deficiency (SNB $> 78^{\circ}$). The mean maxillary, mandibular, and genioglossus advancements for the entire group (40 patients) were 7.1 ± 1.3 mm, 10.8 ± 2.7 mm, and 13.2 ± 1.8 mm. The mean maxillary, mandibular, and genioglossus advancements for the successful group (36 patients) versus the unsuccessful group were 7.25 ± 1.2 versus 5.8 ± 1.5 mm, 10.9 ± 2.5 versus 9.8 ± 2.6 mm, and 13.3 ± 1.8 versus 12.5 ± 1.9 , respectively ($P = \text{NS}$). At the long-term follow-up (T_2 - T_4) mandibular skeletal relapse for the successful group was 7% (0.76 mm). The preoperative PAS (T_2) was 3.7 ± 1.6 mm and increased to 10.1 ± 2.1 mm immediately after surgery (T_4). The long-term PAS was 6.7 ± 1.9 mm. Additional analysis compared mandibular advancement for patients with RDIs from 0 to 10 versus 11 to 20, and a clinically significant difference between these

two subsets was observed ($P = 0.0001$) (Table 5).

Early complications included superficial wound infection (2 patients—5%), traumatic lower incisor injury associated with GAHM (1 patient—2.5%), aspiration caused by hyoid suspension (1 patient—2.5%), and anesthesia of the inferior alveolar nerve (36 patients—90%). Late complications included removal of mandibular hardware (1 patient—2.5%), temporomandibular joint derangement (1 patient—2.5%), and persistent anesthesia of the inferior alveolar nerve (5 patients—12.5%).

DISCUSSION

The surgical technique involved a single-segment Le Fort osteotomy, as described by Bell¹⁵; a bilateral sagittal split osteotomy, with the modified technique described by Epker¹⁶; and the genioglossus and hyoid advancement method of Riley-Powell.^{17,18} This study included patients surgically treated between 1985 and 1995. Fixation techniques in 1985 and 1986 used wire osteosynthesis and 6 to 8 weeks of maxillary mandibular fixation (MMF) with or without skeletal suspension. In 1987 the surgical techniques were modified. Rigid internal fixation (RIF) replaced wire osteosynthesis, and skeletal suspension wires were used with 2 weeks of MMF. All osteotomy sites were grafted with outer table calvarial bone with the technique described by Powell and Riley.¹⁹ RIF was achieved with 4 to 2.0 mm titanium plates in the maxilla and 3 to 2.3 mm superior

Table 2. Long-term success (36 patients)

Parameter	Preoperative	CPAP	Postoperative (6 mo)	Postoperative (long-term)	P value
RDI	69.9 ± 25.9	7.6 ± 5.2	9.3 ± 5.3	7.6 ± 5.1	NS
LSAT (%)	69.8 ± 15.5	87.0 ± 3.2	85.6 ± 4.6	86.3 ± 3.9	NS
BMI (kg/m ²)	31.7 ± 6.6	—	31.4 ± 6.3	32.2 ± 6.4	0.002

Table 3. Long-term failure (4 patients)

Parameter	Preoperative	CPAP	Postoperative (6 mo)	Postoperative (long-term)	P value
RDI	83.2 ± 37.9	13.5 ± 2.1	10.5 ± 6.7	43.0 ± 28.6	0.0001
LSAT (%)	66.5 ± 13.5	86.5 ± 2.1	87.5 ± 1.7	81.7 ± 3.8	—
BMI (kg/m ²)	28.7 ± 7.1	—	28.0 ± 6.7	30.6 ± 9.2	—

Table 4. Preoperative and postoperative cephalometric analyses

	SNA (°)	SNB (°)	PAS (mm)
Preoperative	78.9 ± 3.7	74.8 ± 5.4	3.7 ± 1.6
Postoperative	84.5 ± 4.0	80.4 ± 4.4	10.1 ± 2.1

Table 5. Cephalometric analysis

	Postoperative RDI		P value
	RDI (0-10)	RDI (10-20)	
Mandibular advancement (mm)	12.2 ± 2.2	9.2 ± 1.7	0.0001

border bicortical screws in the mandible (Leibinger, Kalamazoo, MI).

As previously stated, 36 patients (90%) had long-term clinical success (50.7 ± 31.9 months) based on polysomnographic and quality-of-life data. This success was in spite of the fact that the group, as a whole, showed a clinically significant weight gain (31.8 ± 6.6 to 32.2 ± 6.4 kg/m²). Previous reports have emphasized the deleterious effects of weight gain on OSA.²⁰ Larsson et al,²¹ in a 4-year follow-up after UPPP, noted two significant facts. First, patients with relapses showed a statistically significant weight gain; second, preoperative obesity (BMI > 30 kg/m²) was a negative predictive factor for successful outcome of UPPP. This surgically treated group of patients, who in general were morbidly obese, did not demonstrate this tendency. We did note a change in the incidence of snoring between the 6-months and long-term follow-up periods. At 6 months, no snoring was found in 32 patients (80%), and mild snoring was present in 20%. Long-term follow-up showed the number of nonsnorers decreased to 26 patients (65%), and the number of mild snorers increased to 11 patients (28%). One severe snorer and 2 moderate snorers were also reported. Levin and Becker²² examined long-term snoring (mean 44 months) results after UPPP using a similar method of assessment. Sixty-nine patients were examined. Initial

results showed an 87% (60 patients) success rate (no or mild snoring); however, the long-term success rate dropped to 46% (32 patients). Thirty-seven patients (54%) had recurrence of moderate or severe snoring, and failures occurred between 6 and 12 months.

In 4 patients the surgery failed over the long-term. A review of these failures noted that 2 patients had a severe weight gain (20 kg and 28 kg). Another patient had an initial maxillary and mandibular advancement of 6 mm followed by 25% relapse. This patient was treated in 1985 by wire osteosynthesis and 6 weeks of MMF without skeletal suspension. The primary reason for failure was probably the limited advancement. This patient was a 50-year-old, slender female (BMI 20 kg/m²). The advancement was limited because of thin atrophic maxillary walls. The fourth patient had a modest worsening of his OSA. His preoperative, 6-month, and long-term RDIs were 50, 3, and 11, respectively. His surgery was considered a failure because of the recurrence of EDS and the need for nasal CPAP.

Cephalometric data analysis showed the successful group had mean maxillary, mandibular, and genioglossus advancements of 7.25 ± 1.2 mm, 10.9 ± 2.5 mm, and 13.3 ± 1.8 mm, respectively. Skeletal relapse, in this discussion, focused on the mandible because of its relationship to the genioglossus muscle, tongue base, and hypopharyngeal airway. We considered the margin of