Intravenous sedation: an adjunct to enable orthodontic treatment for children with disabilities

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SUMMARY Intravenous (IV) sedation has become established as an important and preferred alternative to general anaesthesia (GA), in order to overcome difficulties in patient management encountered in the delivery of routine dental treatment of the disabled. However, its potential for the delivery of orthodontics for this group has never been exploited.

The present pilot study describes the use of IV sedation with propofol to enable the performance of certain complex orthodontic and surgical procedures, which require strict control of the oral environment for prolonged periods, in a group of 10 of the most-difficult-to-manage disabled patients. The use of IV sedation provided a satisfactory management modality in these patients, who had previously been referred for GA. The parents reported complete satisfaction and general agreement that the same modality would again be welcomed.

IV sedation significantly reduces the use of GA and makes treatment more readily available to a larger number of disabled patients.

Introduction

The relationship between a displeasing dental appearance and a negative emotional impact is well established (Shaw, 1981). Physically and/or mentally disabled children represent good examples of such a relationship. Over the past 20 years, there has been an increasing trend towards caring for this population in the home environment, within the community (Waldman et al., 2000), and this change in attitude has significantly increased the demand for more sophisticated dental treatment. Although need and demand for orthodontic intervention are extremely high in these children (Oreland et al., 1987), the prospect of it being offered and fulfilled is remote (Becker and Shapira, 1996; Chadwick and Asher-McDade, 1997; Becker et al., 2000; Becker, 2001). Many disabled patients express exaggerated negative reactions and perceive orthodontic intervention in the oral cavity as anything from unpleasant to abhorrent.

The modes of behaviour management used in the orthodontic treatment of disabled children and the criteria for preferring one over another have previously been studied and a scoring system devised to evaluate new patients and to assist in the choice of the appropriate behavioural management mode (Chaushu and Becker, 2000). Each of the methods used for pain and anxiety control [such as oral or intra-muscular agents, inhalation with nitrous oxide and oxygen, intravenous (IV) sedation, and general anaesthesia (GA; Malamed, 1995)] may be potentially useful for enabling the delivery of certain poorly tolerated procedures, which may be an integral part of orthodontic treatment.

Conscious sedation with nitrous oxide/oxygen, used as an adjunct to behaviour management, has become a useful technique for the management of disabled patients undergoing routine dental treatment, because it is inexpensive, and has favourable pharmacokinetic and cardiovascular
advantages; however, it is limited in its anaesthetic/amnesic potency and may generate nausea (Malamed, 1995). Its use in orthodontics has been reported elsewhere (Becker and Shapira, 1996). Unfortunately, a significant proportion of these patients cannot be adequately managed by this technique. Accordingly, GA has been used for the difficult procedures during orthodontic treatment of the most challenging cases within this patient group (Chaushu and Becker, 2000).

The disadvantages of GA include the need for hospitalization, specialized operating theatre and recovery room, and potential intra- or post-operative respiratory and cardiovascular complications (Malamed, 1995). These complications lengthen the recovery period and prolong hospitalization, increasing the morbidity and overall cost.

Propofol is an IV anaesthetic agent characterized by a rapid and particularly clear-headed recovery, even after prolonged infusions. Previous studies have shown that propofol provides excellent sedation for patients undergoing regional anaesthesia (Wilson et al., 1988).

Although IV sedation has been widely used for dental treatment (McCann, 1994; Cillo, 1999), a review of the literature has failed to show its employment and usefulness in orthodontic treatment. The purpose of this article is to introduce the use of IV sedation for difficult procedures during orthodontic treatment of children with disabilities. The indications, contraindications, and clinical experience with this preliminary group will be described.

**Subjects and methods**

Ten consecutive patients with disabilities (seven girls and three boys) treated during the past year at the Center for the Treatment of Craniofacial Disorders were sedated by a specialist anaesthetist (DG) for procedures that could not be performed under routine chairside conditions because of extreme apprehension, involuntary movements, inability to sit still, drooling, or an exaggerated gag reflex. The mean age of the patients was 13 ± 3.8 years with a range of 9–23 years.

The medical diagnoses are listed in Table 1. Their anaesthetic risk rating was assessed according to the anaesthetic risk physical status rating (ASA; Dripps et al., 1961). The ASA rating was II in all patients studied. With one exception, each of these patients was scored over 80, according to the behaviour management classification of Chaushu and Becker (2000), indicating a need for GA for the poorly tolerated or long session appointments. Patient ZR scored 60, but IV deep sedation was preferred to conscious sedation for this subject due to the complexity of the surgical procedure (four extractions and two impacted canine exposures), together with bracket bonding in both arches

<table>
<thead>
<tr>
<th>Patient</th>
<th>Sex/age</th>
<th>Diagnosis</th>
<th>Medication</th>
<th>ASA</th>
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<td>EA</td>
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<td>110</td>
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<td>M/9</td>
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<td>–</td>
<td>II</td>
<td>85</td>
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<tr>
<td>GM</td>
<td>F/12</td>
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<td>MB</td>
<td>M/12</td>
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<td>II</td>
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<tr>
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<td>F/14</td>
<td>Petit mal epilepsy, mental retardation</td>
<td>Anti-convulsant</td>
<td>II</td>
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<tr>
<td>AE</td>
<td>F/12</td>
<td>Cerebral palsy</td>
<td>–</td>
<td>II</td>
<td>100</td>
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</table>
with archwire placement, which were undertaken at a single visit.

Three patients were receiving treatment with anti-convulsive, anti-coagulant, or thyroid-replacement drugs (Table 1). They were instructed to continue all routine medications prior to the sedation procedure. They fasted for six hours prior to the procedure, but were allowed clear fluids up to two hours before.

Informed consent was obtained from the parent/guardian after a thorough explanation of the rationale for use of this treatment modality had been given.

EMLA cream (Eutectic Mixture of Local Anesthetics, Astra Pharmaceuticals Ltd, Sobrertalje, Sweden) was placed on the dorsum of the patient’s hand on arrival at the orthodontic department, and one hour later they were sedated for the orthodontic procedure. In five patients pre-medication was performed with 0.5 mg/kg of midazolam per os, in sugar solution, 30 minutes before the procedure, to successfully overcome their fear of venepuncture. The anaesthetist established IV access and, through it, introduced 1–1.5 mg/kg of 1 per cent lignocaine (Briggs and White, 1985) to minimize any pain that may be experienced on the administration of the propofol (McCann, 1994), which followed immediately.

Induction of sedation was accomplished by IV administration of a bolus of 0.5–1 mg/kg propofol. Maintenance of deep sedation was subsequently achieved with a continuous infusion of 2.5–5.2 mg/kg/h propofol, supplemented with intermittent boluses as necessary. An extra bolus of propofol was usually required in response to signs of inadequate anaesthesia or prior to surgical intervention, while the local anaesthetic was given.

The relative depth of sedation/anaesthesia was assessed using the following system of classification:

1. fully awake and orientated;
2. drowsy;
3. eyes closed, rousable on mild physical stimulation;
4. eyes closed, rousable on strong physical stimulation.

It is pertinent to emphasize that breathing was independent at all times and the vital reflexes remained intact even at the deepest sedation level achieved in this group of patients.

The radial pulse, oxygen saturation level, and end-tidal CO₂ were recorded continuously using a pulse oximeter (Nellcor, Puritan Bennet Inc., Pleasanton, CA, USA) and a capnograph (Nellcor; used as apnoea monitor), at 10-minute intervals. Breathing rate was measured periodically. Oxygen was administered via a nasal canula, during the entire treatment.

In the event of any signs of respiratory distress being observed, treatment was temporarily suspended, the neck extended, and the mandible manoeuvred to re-establish an adequate airway.

Additional recordings included:

1. induction time (from start of infusion to sleep);
2. treatment time/sedation time;
3. recovery time (from end of propofol infusion to full awakening);
4. discharge time (from full awakening to time of discharge).

The orthodontic procedures performed in each sedation session are listed in Table 2. Whenever necessary, extractions, routine radiographs, restorative and endodontic treatment were performed during the same sedation session. Rubber dams, individually ligated to each tooth (Chaushu et al., 2000), were used in three subjects, and indirect bonding was performed in three patients. In the other individuals, the oropharynx was protected by a gauze pack, and high volume suction was employed to avoid aspiration and possible laryngospasm.

The infusion was terminated at the completion of the procedure on instruction from the orthodontist, and the patient remained in the dental chair until such time as he/she could be accompanied to a regular waiting area.

The anaesthetist judged the fitness for discharge in line with the Sedation Task Force Standards (1997), which are as follows:

1. Prior to discharge, the child’s level of cognition/function should be returned/progressing toward baseline.
2. Vital signs should be stable and within the patient’s baseline.
3. Prior to discharge the patient and/or their legal guardians will be provided with post-procedure written instructions.

In order to simplify the recording of the difficulties and complications and identify when these occurred, the total sedation time was divided as follows:

1. Pre-operative period: between the time the patient was seated in the dental chair and the start of the orthodontic treatment.
2. Operative period: the time between the start and the end of the orthodontic procedure.
3. Post-operative period: the time between the termination of the procedure and the discharge of the patient home.

Table 3 lists the number of complications encountered during the procedure.

The parents were polled for relative satisfaction with the outcome of the procedure and post-treatment sequelae, 3–6 days later.

**Results**

The induction dose of propofol ranged between 40 and 100 mg (mean = 83.5 ± 20.9 mg) with supplemental doses ranging from 0 to 240 mg (mean = 119.6 ± 66.6 mg). The mean total dose of propofol was 373 ± 126.8 mg (range 185–520 mg).

IV sedation was unsatisfactory in one patient. He had excessive secretions due to chronic purulent respiratory infection, which could not be overcome with high-power suction. This compressed the airway and resulted in the IV sedation in this Down syndrome patient being abandoned (Desai, 1997). The patient was referred to a pulmonary clinic, where he was treated with a suitable antibiotic regimen, which minimized the excessive inflammatory secretions, making successful IV sedation possible at a later appointment.
Two patients, one with Pierre Robin syndrome and the other with severe kyphoscoliosis, presented with a potential anatomical hazard and it had been necessary to perform emergency intubation during the sedation. These patients were subsequently treated with GA and were not included in this study.

The small difference between the mean duration of propofol infusion (93.8 minutes) and the mean duration of the orthodontic procedure (85.6 minutes) emphasizes the shortness of induction and recovery. The mean induction time was $26 \pm 11$ seconds and the mean recovery time was $7.8 \pm 2.5$ minutes.

Transient fluctuations in heart rate were observed during the sedation, which were related to pain or other extraneous stimuli, and were controlled with additional boluses of propofol. These changes did not suggest cardiovascular instability.

Adequate operating conditions were present in all the patients although, in order to maintain the airway, extension of the patient’s head was necessary, which was not always comfortable for the orthodontist.

During the orthodontic procedure, the level of sedation was maintained at score 3 (eyes closed, rousable on mild physical stimulation). At this level of sedation, the patients were unable to carry out verbal instructions given by the orthodontist. When painful manoeuvres had to be performed, such as extractions or other invasive procedures, the sedation was temporarily deepened to level 4.

No aspiration problems were encountered, and laryngospasm, respiratory obstruction, or apnoea were not observed. Oxygen saturation remained within normal limits.

The mean discharge time was $58.7 \pm 12.9$ minutes.

A follow-up telephone call to the parents/guardians, 3–6 days post-operatively, revealed that all patients had had complete amnesia of the sedation and orthodontic procedure. There had been no complaints of pain or discomfort at the site of the IV infusion, and there was complete satisfaction with the IV sedation and general agreement that the same technique again would be of benefit for future procedures, if needed.

**Procedural difficulties**

The only serious pre-operative problem that occurred quite frequently was an exaggerated fear of the insertion of the IV canula. This was successfully overcome by pre-medication with midazolam.

In the operative phase, excessive salivation and water spray potentially endangered the airway, causing coughing. This was dealt with by ensuring extension of the head, posturing the mandible forward, using high power suction and assuring the continuity of the oxygen supply through the nasal canula. The use of a rubber dam and/or an oropharyngeal pack was considered essential. The employment of an indirect bonding technique, besides shortening the bonding time, minimized the risk of inhaling loose brackets. Occasional head and limb movements were seen, either in response to pressure or pain stimulation, or were involuntary. These were eliminated by deepening the sedation.

Post-operative features included isolated incidences of dizziness, headaches, fatigue, and a feeling of cold (caused by a peripheral vasodilation). Two subjects had delayed recovery, which was determined when the time from completion of treatment to ability to open the eyes exceeded 10 minutes. Changes in behaviour (being drowsy or subdued), which lasted up to 24 hours post-operatively, were reported by the parents of one patient, at the follow-up telephone call.

Table 4 describes the modalities chosen to overcome the difficulties imposed by the long session appointments over the past 13 years. Two patients were treated initially by GA and subsequently by IV sedation, in 1999 and 2000.

**Discussion**

Over the last few years several management modalities have been developed to overcome difficulties encountered during complex dental procedures or for routine treatment of patients with extreme phobia. Various studies have examined the use of propofol sedation in dentistry in general and in routine dental treatment of the disabled, in particular as a
preferred alternative to full GA. However, the potential for its use in orthodontics for the disabled has never been reported, largely because disabled patients are rarely offered orthodontic treatment, even though the severity of their malocclusions usually exceeds that of the general population (Oreland et al., 1987). Most routine visits for the adjustment of orthodontic appliances can be performed using behaviour modification techniques alone, but certain procedures, such as placement of fixed orthodontic appliances, require strict control of the oral environment for prolonged periods and any adverse behaviour must be overcome.

The present study describes the use of IV sedation as an alternative to GA, to enable the delivery of orthodontic treatment to the most-difficult-to-manage disabled patients. Most of these patients were scored over 80 in the scoring system described elsewhere (Chaushu and Becker, 2000), which indicates the need for GA to carry out more difficult or prolonged procedures.

GA for procedures in the oral cavity is potentially hazardous, since it is accompanied by the loss of the protective vital reflexes, and wide-ranging steps need to be taken to protect the airway. During sedation, on the other hand, the protective pharyngeal and laryngeal reflexes should remain intact at all times so that the patient is able to breath independently. Since the possibility always exists that an exaggerated level of central nervous system depression might develop, the drugs and techniques employed must carry a wide margin of safety, and the anaesthetist should be particularly careful to render the loss of reflexes unlikely. This is especially true in some of the disabled patients who are chronically medicated, which could alter their response to certain sedative drugs (Malamed, 1995). Propofol is a safe and effective anaesthetic agent in both short- and long-duration procedures (Cillo, 1999).

The level of sedation used in the subjects in this study is termed deep unconscious sedation, meaning the level of drug-induced depression of the central nervous system in which the patient is asleep and unable to respond to verbal commands. However, the reflexes remain intact and the patient may be aroused by mild stimuli (level 3). This level of sedation, while adequate for orthodontic treatment, was insufficient for invasive procedures, for which it had to be deepened to level 4. At this level the patients still maintained reflexes, but could only be aroused by strong stimuli. Only the gag reflex was altered in these patients. Normal and disabled patients who suffer from exaggerated fear of dental

<table>
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<th>Year</th>
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<th>Conscious sedation with N₂O/O₂ inhalation</th>
<th>General anaesthesia</th>
<th>Deep IV sedation with propofol ± midazolam</th>
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</table>
procedures often have an over-sensitive gag reflex and the two phenomena appear to be closely related. With sedation, there is a loss of fear and this is, in turn, accompanied by a marked reduction or complete absence of the gag reflex (Malamed, 1995), which permits improved access for treatment.

By delivering a continuous infusion of propofol, all patients showed remarkable haemodynamic stability. Supplemental boluses of propofol, as needed, easily and rapidly controlled the depth of the sedation.

Due care and the application of specific safety measures are still needed to prevent debris, water, saliva, blood, or orthodontic materials entering into the airway and producing laryngospasm, or possible infection of the trachea or bronchi. In specific handicapped groups, such as those with cerebral palsy or muscular dystrophy, the cough reflex is impaired and the danger of aspiration is even more important, in order to minimize the risk of the respiratory complications (Malamed, 1995). A rubber dam may be a useful aid and an effective safeguard in bracket bonding during IV sedation, as recommended for GA in the disabled (Chaushu et al., 2000). An oropharyngeal pack is mandatory when rubber dam placement is impossible (for impression-taking, band fitting, or appliance cementation, such as palatal/lingual arches), although care must be exercised to avoid obstructing the nasal airway with the pack. Indirect bonding of brackets (Thomas, 1979) is faster, reduces sedation time, and minimizes the possibility of aspiration. Nevertheless, an oropharyngeal pack is still needed, to block fluids and small particles (brackets) from entering the upper respiratory tract.

Smooth and rapid induction and recovery times are known attributes of propofol (Dembo, 1995), and this is supported by the results of the present study, where the mean induction time was 26 seconds and the mean recovery time 7.8 minutes. Nevertheless, delayed recovery was observed in two patients who required relatively larger doses of propofol for additional invasive procedures, including extractions. McCann (1994) found faster recovery times when oral surgery procedures were performed, with only 6 per cent of the 100 patients studied experiencing a recovery time of more than 5 minutes. In the present investigation, longer recovery times may have been related to the longer operative time (mean 85.6 minutes) that is frequently needed for orthodontic procedures, compared with oral surgery procedures (mean 32 minutes). The longer recovery time could also have been due to the method of drug administration (continuous drip) versus intermittent bolus. Prolonged infusion times with larger doses might lead to an accumulation of the drug in poorly perfused tissues, thus requiring a longer period for its dispersal (McCann, 1994).

Recent studies indicate that propofol and midazolam act synergistically, improving the sedation efficacy and lowering costs (due to a presumed lower total dose of propofol needed). On the other hand, this combination has been associated with a slower recovery after therapeutic endoscopy, than sedation with propofol alone (Seifert et al., 2000). Due to the small number of patients in the present study, it has not been possible to confirm whether the addition of midazolam, working synergistically with propofol, had an effect on recovery time.

One of the most frequent problems encountered during the operative period was the occurrence of body movements. Exacerbation of involuntary movements found in two patients with involuntary movement disorders, during sedation with propofol, has also been reported elsewhere (Robb and Hargrave, 1997). In the present study, movements occurred in a large number of patients (seven out of 10), with no previous history. A mouth gag is recommended to prevent involuntary mouth closing on the operator’s hands in response to stronger stimuli. Additional boluses of propofol to deepen the sedation level helped to overcome these movements.

Long recovery periods can increase costs by prolonging the discharge time from labour-intensive areas such as the operating room or the post-anaesthesia recovery unit. In this respect, propofol sedation was superior to GA.

Because of the amnesic properties of propofol, the children’s post-operative experience was excellent, which was reflected in the later attitude of the parents regarding the spectre of
further procedures with this modality. Postoperative tiredness occurred for a few hours in three patients. Headaches and minor transitory behavioural changes, such as being unduly subdued, were unusual. A feeling of cold was experienced by three patients and is the result of the substantial peripheral vasodilation induced by propofol. This vasodilation is likely to facilitate core-to-peripheral redistribution of heat (Ikeda et al., 1999).

IV sedation is an excellent alternative to GA for orthodontic treatment of disabled patients. The main advantages are:

1. The need for hospitalization and the use of the operating theatre are eliminated. This permits the use of IV sedation on demand, without the need for a specific operating session and surgical waiting list.
2. Treatment is carried out in a fully equipped orthodontic operatory, which is familiar both to the orthodontist and to the patient.
3. Induction and recovery are rapid, requiring minimal additional facilities.
4. It provides a safe level of sedation with minimal side-effects.
5. With the use of routine safety measures, the risk of aspiration and other medical emergencies is extremely small.
6. Because the vital reflexes are maintained during the entire procedure, intubation is rendered unnecessary and post-anaesthetic respiratory complications are consequently reduced.
7. The overall cost is significantly reduced.
8. There is an increased patient intake capacity (Table 4).
9. The ability to accept patients with more complex malocclusions is also increased.

The definition of the stages of sedation between full consciousness and GA differs from country to country, as do professional and statutory regulations that govern their provision. For the purposes of the present discussion, the definition of the terms used are as follows: during conscious sedation, verbal contact is maintained throughout sedation and operation. This differs from deep sedation in which the level of sedation is such that the patient is asleep and unable to respond to verbal commands; and it contrasts with GA insofar as the protective reflexes remain intact.

While these levels are clearly distinguishable to the anaesthetist, the law may not recognize that deep unconscious sedation differs from full GA and may apply unnecessarily conservative restrictions dictating that these procedures be performed only in a properly equipped hospital operating theatre. Accordingly, the reader is advised to familiarize themselves with the terms of the law in the country in which they practice, before clinically applying the recommendations proposed.

Conclusions

IV sedation with propofol simplifies the delivery of orthodontic treatment to children with disabilities and reduces morbidity in comparison with GA. By reducing dependence on GA, treatment may be more readily available to a larger number of this population. During the 1987–1999 period, 23 per cent of the compromised orthodontic patients required GA to control behaviour during the more difficult procedures. Recent experience has shown that IV sedation has almost entirely replaced GA during the past year. The ability to perform treatment in the regular orthodontic clinic without the need for GA may allow clinicians to offer treatment of a more complex nature to a larger number of severely disabled patients. At the same time, concerned parents may be more ready to accept treatment without the increased stress and risk posed by GA. Two patients (RM and GM), who had been treated in 1999 under GA, were treated in 2000 with IV sedation. Their parents reported fewer problems and much greater satisfaction with IV sedation.

It is believed that this modality may be useful for providing therapeutic access to the disabled population on an out-patient basis. This should be carried out preferably in a specialized orthodontic clinic, within a hospital setting, with the sedation performed by a competent anaesthetist.
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