A publication promoting excellence, ethics, professionalism, and leadership in dentistry

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Mission

The Journal of the American College of Dentists shall identify and place before the Fellows, the profession, and other parties of interest those issues that affect dentistry and oral health. All readers should be challenged by the Journal to remain informed, inquire actively, and participate in the formulation of public policy and personal leadership to advance the purposes and objectives of the College. The Journal is not a political vehicle and does not intentionally promote specific views at the expense of others. The views and opinions expressed herein do not necessarily represent those of the American College of Dentists or its Fellows.

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The American College of Dentists, in order to promote the highest ideals in health care, advance the standards and efficiency of dentistry, develop good human relations and understanding, and extend the benefits of dental health to the greatest number, declares and adopts the following principles and ideals as ways and means for the attainment of these goals.

A. To urge the extension and improvement of measures for the control and prevention of oral disorders;
B. To encourage qualified persons to consider a career in dentistry so that dental health services will be available to all, and to urge broad preparation for such a career at all educational levels;
C. To encourage graduate studies and continuing educational efforts by dentists and auxiliaries;
D. To encourage, stimulate and promote research;
E. To improve the public understanding and appreciation of oral health service and its importance to the optimum health of the patient;
F. To encourage the free exchange of ideas and experiences in the interest of better service to the patient;
G. To cooperate with other groups for the advancement of interprofessional relationships in the interest of the public;
H. To make visible to professional persons the extent of their responsibilities to the community as well as to the field of health service and to urge the acceptance of them;
I. To encourage individuals to further these objectives, and to recognize meritorious achievements and the potential for contributions to dental science, art, education, literature, human relations or other areas which contribute to human welfare—by conferring Fellowship in the College on those persons properly selected for such honor.
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From the Editor

How Thornless Blackberries Got Big Fruit

The art and science of dentistry are advancing briskly, but not necessarily arm-in-arm. Perhaps dentists would not be embarrassed if introduced as "reflective practitioners" or "women or men of science"; but few would describe themselves that way. It is not the highest form of praise. Only the frauds and quacks knowingly practice contrary to science, but we all expect to be forgiven if we don’t toil into the night to advance it.

The founders of the American College of Dentists were clearly focused on promoting and recognizing the science of dentistry as an essential component of professionalism. (It remains one of the objectives of the College, as described on the overleaf of this journal; although it may be more accurate to say we are now hurrying to see which way it went rather than pushing to be first in line for advancing it.) The first Fellows warned of the dangers that could come from segmentation in the profession. Was it really wise to delegate research to the academy and then to industry? The price in communication, simply reading the literature, that must be paid now to avoid crippling narrowness is ballooning as the research enterprise grows independently of dentistry.

Try this test. It is required by the Food and Drug Administration that advertisements making therapeutic claims be accompanied by disclaimers; these appear on the second page of drug ads. Read any such disclaimer with a pen in hand and mark every term or concept you cannot confidently define. Why is it that evidence-based dentistry sounds like something someone else does—perhaps an academic—and not something that happens in the dental office? Why is it that articles on EBD so frequently illustrate the concept with an example of a drug, when most of dentistry is based on materials and procedures? (The FDA classifies products that do not depend on a systemic interaction with the patient for their effect as devices; hence cements, composites, and even antiseptic mouthrinses are devices.) Can it be that research has gotten too good at the science of biology and dentistry too good at the art of patient care?

Unless we reunite the art and science of dentistry—in the person of the practitioner, and none other—there is a risk of returning to the days when craft and commercialism were the mark of the trade, and the public managed tooth pullers and elixir peddlers like they did horseshoers.

A key to understanding why much of our recent efforts have only made the problem worse comes from the story of the thornless blackberry. The report is found in “Small Fruits,” volume IV, in the collected works of Luther Burbank. Burbank was a practical botanist who developed many of the commercial varieties of potatoes, plums, squash, and other fruits and vegetables we know today. He lived in Santa Rosa, California, at the turn of the last century. Burbank was a friend of Theodore Roosevelt and Henry Ford and a quintessential exemplar of the Progressive Era, believing that science could be applied to raise the condition of mankind. He was the reflective practitioner of his day, with a garden that was his practice.

By the late 1890s, Burbank had selectively bred the Lawton, the Himalaya, and other commercially successful types of blackberry with desirable characteristics of size, flavor, mass, and early ripening. This was straightforward selective breeding using established principles of genetics—breed the best and discard the rest. In 1902, David Fairchild of the U.S. Department of Agriculture discovered a nearly thornless variety of blackberry in North Carolina. Burbank perfected the thornless nature of this line, again through selective breeding.

The genetic principle of purifying the line and advancing the most desirable characteristics have been known and applied in university and industry settings for years. Only the best scientists are funded (and encouraged to collaborate with other successful researchers) to maximize highly valued features. The same is true in professional schools where very high standards of selective admissions and retention are used to advance the profession. The process continues to some extent through the natural competition in practice. Professions are advanced by selective breeding.

The story of the thornless blackberry would be completed at this point through this process of purification in breeding except for one unfortunate circumstance. The berries on the thornless variety were few, small, and tasteless. Burbank’s early attempts to correct the problem were predictable.
Evidence-based dentistry is beginning to look like a failure on the same grounds. It is attractive to think that progress can be manufactured quickly by crossing a purified form of research with a highly advanced form of practice—but that is poor science. The progress will come in the next generation when some of the researchers who have a recessive affinity for the problems of practice collaborate with some of the dentists who have a recessive affinity for disciplined inquiry. These crosses, to be fertile, will take place in nontraditional settings where they are free of the fierce “ethnic cleansing” that takes place when progress is associated with breeding true to form.

Perhaps dentists were confused by a May 2006 insert on “Professionally Applied Topical Fluoride” in JADA (www.ada.org/goto/ebd). The subtitle is “Executive Summary of Evidence-Based Clinical Recommendations” and one-third of the report is a discussion of what “best evidence” (in the pure research sense) means. This has become the mantra of the EBD community. Greater weight is placed on purification through selective breeding than on enhanced utility through hybridization. To be fair, the ADA statement on evidence-based dentistry (available at the same Web site) states that EBD takes place in the dental office and combines research findings, practitioners’ experiences, and patients’ values. The statement on topical fluoride is correctly labeled as EBR—evidence-based recommendations.

Purification of the lines is what is advancing briskly now in the art and science of dentistry. The two parts are moving apart through adherence to two sets of very different standards for what counts as excellence and even what counts as practice or research at all. This is necessary work in some preliminary sense, but it is naive to assume that highly enriched research will be recognized or found of value to practitioners or that highly enriched practice situations will be at all interesting to scientists.

The new work that needs to be done now, what Burbank called hybridization, involves working with the second generation of these purified strains in natural settings to combine the best features of both. NIDCR has already taken steps in this direction with a research emphasis on practice-based clinical trials. The ADA is looking for useful approaches. The dental schools are a natural incubator—but probably not the research-intensive ones.

The founding vision of the American College of Dentists is as vital today as it was in 1920. Dentists must exhibit both the art and science of dentistry; those are not functions that can be delegated. Thornless blackberries should have big fruit.
I HAD TO BE AN AMERICAN WOMAN ACTIVIST

Cecelia L. Dows, DDS, FACD
Short Hills, New Jersey

My mother was born in Poland, the eldest of five children, and was sent at age nine years to learn elementary sewing in Krakow. She was stranded on what was intended to be a brief visit to New Jersey, and so the story begins.

My mother sewed for women who literally adopted her and became her American family. She progressed from using commercial patterns to designing her own, eventually becoming a designer for a New York salon in the early 1940s. Among the passions I inherited from my mother were creativity, hard work, and enjoyment of handwork.

As a child in Bayonne, I had the advantage of learning leadership through volunteer work with the Red Cross and the Council of Social Agencies and received an excellent high school education. In college at Fordham University, I was a member of the first class to include female students and was the first woman science major. My job after college was doing chemical analysis for the Standard Oil Company at their Bayway Refinery (again the first female to hold such a position), but I sensed that something was missing. My mother and sister convinced me to apply to dental school. Only two (Columbia and New York University) of the seven schools to which I sent applications were accepting women. I was the only woman in my class and the first in a rotating general internship at the Jersey City Medical Center Hospital.

I began my solo general practice in Bayonne in 1948. Part of my work was supported by the Belleville Foundation, and one and one-half days each week I conducted a clinic for indigents and collected epidemiological data that formed the basis for reports to the foundation. I met and married a Native-American veteran in 1952 and we shared forty-seven happy years.

I relocated my practice to Short Hills, New Jersey, in 1955. I also taught at the University of Medicine and Dentistry of New Jersey as a clinical instructor and as the full-time Director of Auxiliary Personnel, leading the effort that resulted in full accreditation for that program.

There is no shortage of opportunities to serve the profession of dentistry, and I did so in the chairs of the Esse County (New Jersey) Dental Society and in various roles with the New Jersey Dental Association. I also enjoyed my work as president and editor of the Pierre Fauchard Academy of New Jersey. During my lifetime I have seen a dramatic change in the role of women in dentistry. At first, I was the only woman in the room when I looked around to see who was becoming a professional and who was stepping forward to serve. Now I am in wonderful company.

There is no mystery why I want to support the American College of Dentists. The College does good work and is the epitome of human integrity and commitment. There is no shred of prejudice in this group. The College welcomed this American woman activist.
Abstract

Permanent paresthesia following a local anesthetic injection is a possible adverse event. Epidemiological studies have suggested that the 4% solutions used in dentistry, namely prilocaine and articaine, are more highly associated with this occurrence. This article reviews the epidemiological evidence regarding articaine and paresthesia.

Local anesthetics are very safe drugs. Even though this is a correct statement, adverse events occur simply due to the sheer volume of injections given. Dentists in the U.S. administer over 300,000,000 cartridges every year (Malamed, 2004). Thus, even rare events, such as permanent paresthesia, will be noted. The first study to suggest the possibility that articaine is more highly associated with paresthesia was published in 1995 (Haas & Lennon). Since that time the scientific literature has been slowly accumulating that considers the possibility that local anesthetic neurotoxicity itself can cause paresthesia. The purpose of this article is to review the epidemiological evidence for the association between articaine and paresthesia in dentistry.

Paresthesia

What is meant by paresthesia that results from an intraoral injection of local anesthetic? Paresthesia is part of a more general grouping of nerve disorders known as neuropathies. These may manifest as a total loss of sensation (i.e., anesthesia), a burning or tingling feeling (i.e., dysesthesia), pain to a normally non-noxious stimulus (i.e., allodynia), or increased pain to all stimuli (i.e., hyperesthesia). For the purposes of this article, the term paresthesia will be used to describe prolonged complete anesthesia or an altered sensation that persists beyond the expected duration of action of a local anesthetic injection. Paresthesia is a known risk from oral surgical procedures and it is assumed that the cause in that case is direct trauma to the nerve. However, paresthesia can also occur following nonsurgical dentistry, when local anesthesia is achieved to permit operative dentistry or scaling. The majority of these cases are transient and resolve within eight weeks. Those that last beyond that time frame are usually considered irreversible. It is the latter that are clearly the main concern, as there is no definitive treatment of this neuropathy. The focus of this article is on the nonsurgical permanent paresthesias that occur in dentistry.

There are several proposed mechanisms for paresthesia following local anesthetic injection. These include hemorrhage into the neural sheath, direct trauma to the nerve by the needle with possible scar tissue formation, and neurotoxicity of the local anesthetic. Only if the latter mechanism is correct could one find potential differences based on the type or the amount of local anesthetic used.
Epidemiological Studies
Articaine has been available in Germany since 1976 and in Canada since 1983. In 1995, there was a publication of a retrospective study conducted to look at the incidence of permanent paresthesia from 1973 to 1993 inclusive in Ontario, Canada (Haas & Lennon, 1995). The database accessed was from the group that administered malpractice insurance to all licensed dentists in that province. At the time of the study there were approximately 6,200 dentists in Ontario. Only prolonged (i.e., permanent) paresthesia from nonsurgical cases was counted in this study. The conclusion was that there was an overall incidence of one irreversible paresthesia out of every 785,000 injections. Compared with the other local anesthetics, a higher incidence was noted when articaine or prilocaine were used. The lingual nerve was involved in 64% of the cases, with the inferior alveolar nerve involved in the vast majority of the remainder. There was no association with any other factor, such as needle gauge.

A follow-up study was done using the same methodology with the data from 1994 to 1998 inclusive (Miller & Haas, 2000). For this time period, the incidence of nonsurgical paresthesia in dentistry was 1:765,000, very similar to the previous finding. The conclusions were the same in that prilocaine and articaine were more commonly associated with this event compared to the other local anesthetics. The lingual nerve was involved in 70% of the cases, with the inferior alveolar nerve involved in the vast majority of the remainder. It was estimated that the incidence of permanent paresthesia from either prilocaine or articaine approximated 1:500,000 injections for each drug, which was five-fold higher than that found with lidocaine or mepivacaine. In both studies, there were no reports of paresthesia from bupivacaine.

The reasons for these findings were speculative. What articaine and prilocaine have in common is that they are the only 4% solutions used in dentistry. This means that the concentration of the drug is 40 mg per mL. The other agents available in dental cartridges in the U.S. and Canada are all more dilute. Lidocaine is a 2% solution, mepivacaine is either 2% or 3%, and bupivacaine is 0.5%. This led to the consideration that it was not the specific drug that was the factor, but maybe the concentration administered.

In Vitro Studies
Is there evidence for a dose-dependent neurotoxicity of local anesthetics? Several in vitro studies support this hypothesis. As early as 1976, it was noted that rats injected with lidocaine at the trigeminal ganglion exhibited inhibition of rapid axonal transport in distal nerve segments in a dose-dependent manner (Fink & Kish, 1976). An investigation of the effects of lidocaine on resting membrane potentials and action potentials in single crayfish giant axons showed a dose-dependent effect resulting in irreversible conduction blockade with complete loss of resting membrane potential at higher doses (Kanai et al., 1998). High concentrations of local anesthetics, such as 5% lidocaine, have been shown to result in irreversible conduction block, an effect not found with 1.5% lidocaine (Lambert et al., 1994).

Histologic studies have primarily supported the hypothesis that local anesthetics have neurotoxic potential (Kalichman et al., 1989; 1993), although one study using microinjections into rat sciatic and cat lingual nerves showed no significant effect (Hoffmeister et al., 1991). This latter study, however, suffered from a potential methodologic problem of using no control group, using a...
sample size of five for each group, and injecting only twenty microliters of local anesthetic into the rat sciatic nerve. Conversely, the opposite findings to this latter study were shown when a saline control group was used, the sample size increased to sixteen, the volume injected in the rat sciatic nerve was increased to fifty microliters, and the effects assessed electrophysiologically (Cornelius et al., 2000).

In a study investigating neuronal cytoplasmic calcium concentrations and neuronal cell death, it was shown that lidocaine in concentrations less than 1% caused minimal changes, whereas 2.5% and, to a greater degree, 5% lidocaine caused much larger changes and cell death (Johnson et al., 2002). When the concentrations were kept the same, lidocaine and prilocaine had equivalent neurotoxicity in rats (Kishimoto et al., 2002). In a study looking at lidocaine, mepivacaine, bupivacaine, and ropivacaine, all of these local anesthetics produced growth cone collapse and neurite degeneration (Radwan et al., 2002), suggesting that neurotoxicity is not restricted to one agent. A proposed mechanism for this irreversible nerve injury is membrane disruption, characteristic of a detergent effect (Kitagawa et al., 2004). Other studies also support the hypothesis that all local anesthetics have the potential for neurotoxicity, an effect that is dose-dependent (Selander, 1993; Kalichman, 1993).

Clinical Studies

Articaine was introduced in the U.K. in 1998. Since that time a number of letters to the editors of British journals reported an apparent increase in prolonged paresthesia following articaine administration (van Eden & Patel, 2002; Pedlar, 2003). A follow-up letter identified only a small number of official reports regarding articaine and paresthesia with the U.K. Committee on Safety of Medicines and asked dentists to use this reporting system as required (Randall, 2003).

Articaine’s introduction into the U.S. in 2000 coincided with a publication of its efficacy (Malamed et al., 2000), and shortly thereafter followed by a publication on its safety (Malamed et al., 2001). These two studies were based on the findings from a multi-center randomized controlled trial (RCT) on 1,325 subjects comparing administration of 4% articaine with 1:100,000 epinephrine to 2% lidocaine with 1:100,000 epinephrine. The study on efficacy showed that articaine was comparable to lidocaine for mandibular blocks, a finding replicated in RCTs published since that time (Malamed et al., 2000; Claffey et al., 2004; Mikesell et al., 2005; Ram & Amir, 2006). The study on safety concluded that the adverse event profile was similar to that found with lidocaine.

A prospective study of nonsurgical permanent paresthesia conducted in the U.S. just prior to articaine’s release found that lidocaine was the drug used in 48% of the cases and prilocaine in 47% of the cases when the type of drug was known (Pogrel & Thamby, 2000). They estimated that, at the time of their writing, lidocaine accounted for 62% of all local anesthetics used by dentists and prilocaine accounted for 13%. This higher proportion for prilocaine was consistent with that previously reported (Haas & Lennon, 1995). The authors also determined that 79% of the cases involved the lingual nerve, a finding also consistent with that reported previously by Haas and Lennon. It was estimated that the overall incidence of permanent paresthesia for each inferior alveolar nerve block ranged from 1:26,762 to 1:160,571. Malamed and colleagues concluded that “Perhaps every full-time practitioner will find that he or she has one patient during his or her career who has permanent nerve involvement resulting from an inferior alveolar nerve block.”

One interesting question is why is the lingual nerve the most common nerve affected? To answer this, an elegant study published in 2003 examined the histologic characteristics of lingual nerves in twelve cadavers (Pogrel et al.). This study showed a range in the number of fascicles present within this nerve; anywhere from one to eight inclusive. Four of them (33%) had only one fascicle. The authors speculated that a unifascicular nerve may be injured more easily than one with multiple fascicles. To date, this appears to be the most plausible explanation for the finding of the predilection of the lingual nerve for permanent paresthesia.

In 2003, a review of paresthesia associated with administration of local anesthetics was published (Dower, 2003). This review analyzed previous studies (Haas & Lennon, 1995; FDA, 1998; Miller & Haas, 2000; Malamed et al., 2000; 2001; CRA, 2001) and by making a number of alternative assumptions determined an incidence of paresthesia for articaine of 1:220,000—higher than that previously reported. Specifically, it was stated that articaine had a twenty-fold higher rate of paresthesia than lidocaine and that prilocaine had a fifteen-fold higher incidence. Articaine’s rate for paresthesia for lingual or mandibular blocks was estimated to be as high as 2% to 4% when used for mandibular or lingual blocks.
Articaine was introduced in 2000 in Denmark. Recently, a Danish study (Legarth, 2004) was conducted that used a format similar to the one carried out by Haas and Lennon in Canada in 1995. Using data from the Danish Dental Association’s Patient Insurance Scheme, the author reviewed reports of paresthesia from 2002-2004 in that country. In this time period, thirty-two lingual nerve injuries were registered. Articaine was given in 88% of the cases, even though it constituted only 42% of the market. Mepivacaine, as the 3% formulation, was given in the other 12% of cases, and it constituted 22% of the market. Lidocaine, with 22% of the market, had no reports of paresthesia. Prilocaine had 12% of the market, and no reports of paresthesia. Interestingly, in Denmark, prilocaine is formulated as a 3% solution, not 4% as found in the U.S. and Canada. This incidence of paresthesia was 1:140,000 for articaine and 1:540,000 for mepivacaine.

Another recent publication used standardized tests of neurosensory function to determine the cause of injection injury to the oral branches of the trigeminal nerve (Hillerup & Jensen, 2006). This prospective study of fifty-six consecutive patients demonstrated neurologic evidence of neurotoxicity, not mechanical injury, which resulted in irreparable damage. Consistent with previous clinical studies, the lingual nerve was the most common nerve involved, accounting for 81% of the cases, with the inferior alveolar nerve making up the rest. There was also a significant difference in the drugs associated with this neurologic injury. In these patients, articaine was shown to contribute to more than a twenty-fold increase in paresthesia compared to all other local anesthetics combined. The authors noted a substantial increase in the number of injection injuries since articaine was introduced into the Danish market.

The conclusions of these authors were subsequently questioned in a letter to the editor, pointing out that the paresthesias almost exclusively involved the lingual nerve during a traditional mandibular block and rarely other nerves or other blocks (Malamed, 2006). Yet, this letter did not explain why articaine was still the most common local anesthetic associated with the damage of this one nerve compared with other agents that are also used to block this nerve. Furthermore, Hillerup and Jensen demonstrated that their neurological assessment demonstrated neurotoxicity and not mechanical injury. As well, the statement in the letter, “At this time there exists absolutely no scientific evidence to support the concluding comment regarding the use of other local anaesthetics for mandibular block analgesia in place of articaine 4%,” could be considered to be not quite correct. While it is true that no RCT has made this demonstration, a number of other scientific studies have, be they prospective (Hillerup & Jensen 2006) or retrospective (Haas & Lennon, 1995). RCTs are not the only scientific studies used to guide clinical decision making, as will be discussed below.

Most recently, in the U.S., two new RCTs were published that compared the formulations of articaine with different concentrations of epinephrine: 1:100,000 and 1:200,000, investigating cardiovascular effects (Hersh et al., 2006) and efficacy (Moore et al., 2006). The sample sizes were 14 and 126, respectively, and no differences in adverse events were noted between...
the two formulations of articaine with epinephrine.

**Clinical Application of the Evidence**

How does the practicing dentist make use of this information? Should a dentist wait for the publication of a RCT proving that articaine and prilocaine are more likely to cause permanent paresthesia than other local anesthetics? Because of the rarity of this event, elucidation of these local anesthetic risk factors is statistically problematic, a finding that has occurred elsewhere in the field of anesthesiology (Hopwood, 1993). With incidences estimated to be anywhere from 1 in 26,700 (Pogrel & Thamby, 2000), 1 in 140,000 (Logarth, 2004), 1 in 220,000 (Dower, 2003), to 1 in 785,000 (Haas & Lennon, 1995), it would take an unrealistically large RCT to detect a statistically significant difference. The largest RCT on articaine published to date had a sample size of only 1,325 (Malamed et al., 2000), far too small to be able to detect a statistically significant difference if one were to exist. None of the RCTs involving articaine or prilocaine published to date has a sample size large enough to detect this potential difference. No conclusions regarding permanent paresthesia should be made from these particular studies. To quote Hillerup and Jensen (2006), “Since the incidence of injury as such is extremely rare, the finding of nerve injury in a clinical trial is comparable with the finding of a needle in a haystack.” Given this reality, they go on to say, “This feature imposes a methodological obstacle to the power of conclusion from prospective clinical studies on injection injuries, and circumstantial evidence, experimental research and retrospective surveys on great number of patients must be taken into account.”

**Conclusion**

In conclusion, the scientific data are strongly suggestive that the 4% local anesthetic solutions used in dentistry, namely articaine and prilocaine, are associated with an increased likelihood of permanent paresthesia. It appears that it is not the drug per se that is responsible, rather the higher concentration that predisposes these formulations to this possibility. This outcome most often involves the tongue, and can leave the affected patients with an incapacitation for the rest of their lives.

Dentists must always take into account the risks and benefits when determining the appropriateness of every procedure and therapeutic decision. In 2005 the Royal College of Dental Surgeons of Ontario, the governing body for dentists in that province, published an advisory to its members and concluded, “Until more research is done, it is the College’s view that prudent practitioners may wish to consider the scientific literature before determining whether to use 4% local anesthetic solutions for mandibular block injections.” (Royal College of Dental Surgeons of Ontario, 2005) Their conclusion is warranted. Unless there is evidence of a demonstrable benefit to the use of these particular drugs, their risks make their selection difficult to justify for mandibular or lingual blocks. Today, unless extenuating circumstances are present, the available epidemiological evidence appears to support a dentist’s decision to avoid the use of articaine and prilocaine for mandibular and lingual blocks, and to restrict their use to other injections.

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None of the RCTs involving articaine or prilocaine published to date has a sample size large enough to detect this potential difference. No conclusions regarding permanent paresthesia should be made from these particular studies.
The Ethics of Adopting a New Drug: Articaine as an Example

Bruce Peltier, PhD, MBA and James S. Dower, Jr., DDS, MA

Abstract
The introduction of articaine as a local anesthetic agent and the number of reported cases of paresthesia are used to develop issues surrounding dentists’ responsibility to investigate the evidence associated with product claims and to evaluate the use of treatments through various appropriate ethical lenses. The evidence on safety and efficacy of articaine are reviewed, followed by a discussion of various relevant ethical perspectives, including standard of care, professional codes, normative principles, weighing interests, and a hierarchy of core values. The authors recommend against the use of articaine.

New products continuously appear in dentistry. They are generally most welcome, as they promise to enhance dental practice and improve patient care. However, the process that dentists use to decide about new products and whether to incorporate them into daily practice has not been elucidated very clearly in the literature. When a new product becomes available, how does one decide if it is safe and efficacious? What responsibilities do dentists and others have to ensure that patients are consistently treated in safe and effective ways?

While there are numerous sources for information about new products, all sources are not of equal value or validity and dentists may not always be willing or able to effectively access them. Some of these sources of information can be difficult to decipher and others downright misleading. Yet all would agree that dentists must take personal and professional responsibility for the products that they use in the treatment of patients.

This essay uses the controversial and interesting case of articaine to explore ethical aspects of the introduction of a new product into dental practice.

Background
For the past century, dentists have used local anesthetics routinely and frequently with nearly no serious adverse effects. Until recently, there were five such anesthetics available for use by American dentists. Because adverse effects were so rare, few statistical data were available for scrutiny. Most dentists felt that any dangers associated with local anesthesia were likely the result of overdose or perhaps a paresthesia caused by direct needle contact with a nerve. Paresthesias related to local anesthesia were generally thought to occur about once in a dentist’s career, if that. Paresthesia is typically defined as persistent numbness or anesthesia that lasts well beyond normal expectations. Such numbness is thought to resolve, on average, within eight weeks, but can last longer and in rare cases become a permanent condition. There is no current treatment that can reverse or remedy this damage.

Until recently, American dentists primarily used lidocaine and mepivacaine and less frequently, prilocaine, bupivacaine, and etidocaine. Articaine (Septocaine) has been available for use by Canadian dentists since 1985 and for some European dentists before that. In 1995, Haas and Lennon published a...
retrospective study of twenty-one years of nonsurgically induced paresthesia from Ontario in the *Journal of the Canadian Dental Association*. They found that factors such as patient age, gender, or needle gauge were not correlated with frequency of paresthesias, but that two local anesthetics, articaine and prilocaine, both used in a 4% solution, were associated with significantly more paresthesias than the other anesthetics. In a follow-up study a year later, Miller and Haas (1996) found that these significantly different rates of paresthesias continued to exist. A subsequent Canadian study by Miller and Haas (2000) again showed that use of articaine and prilocaine between 1994-1998 was associated with significantly higher rates of paresthesia. During this same time period, a laboratory study in experimental neurology (Kalichman et al., 1993) injected rats with varied concentrations of four local anesthetics and concluded that increased concentrations were associated with higher levels of nerve injury.

Articaine became available from Septodont for use in a 4% solution in the United States in April 2000, and it has been met with enthusiasm here. Articaine has a good reputation among many dentists who are likely to report that they miss fewer mandibular blocks resulting in fewer follow-up injections, and sometimes they use infiltrations for anesthesia of teeth on the mandible.

A pharmacology project thesis on articaine and lidocaine written by a Norwegian dental student provides an example of the kind of anecdotal “buzz,” based on the clinical experiences of dentists that often passes for evidence in dentistry (Johansen, 2004). “One of the reasons why articaine instantly became so popular in many countries was due to its excellent efficacy. Dentists claimed that they seldom missed with the inferior alveolar nerve block, and that buccal infiltration in the maxillary arch often was enough before an extraction of a molar, because of articaine’s bone penetration properties. This seemingly excellent efficacy is reported from many dentists from around the world, based on their daily clinical practice.”

The problem is that no controlled, empirical evidence exists to support the perceived benefits to dentists, and evidence exists that seems to point to increased risk to patients.

The product insert from the manufacturer’s (Septodont) FDA study of articaine described 11 paresthesias associated with 882 patient visits (one paresthesia in every 88 visits). The insert also includes a second, additional list of adverse events that occurred in one or more patients “at an overall rate of less than one percent.” (One percent would equal eight or nine patients in the 882 studied.) Included on this list are “paresthesia, hyperesthesia, and neuropathy.” This additional list seems to imply that more than eleven total paresthesias actually occurred. Using the same data, the “Safety Summary” from Septodont’s FDA application (Septodont, 1998) for approval of articaine reported 21 paresthesias in the 882 patient exposures to articaine (Section 8.5.3.5). This represents one chance in 44 of paresthesia per exposure.

In May 2000, JADA published an article by Malamed, Gagnon, and Leblanc (2000) that reported on this same study but did not mention the numerous neuropathies seen in the product insert or the 21 paresthesias reported to the FDA by Septodont in their application. The authors of the JADA study concluded that “4% articaine was well tolerated in 882 subjects.” This article also reported that articaine produced no significant improvement in efficacy when compared to lidocaine. In a second report on the same FDA study data Malamed, Gagnon, and Leblanc (2001) concluded that “articaine is a well-tolerated, safe, and effective local anesthetic for use in clinical dentistry.” This “safety report” was, however, not published until nine months after the original article on the same data (Malamed, Gagnon, & Leblanc, 2000). Also, the 2001 “safety report” listed the adverse events during the study as being 11 paresthesias and 7 hypesthesias (not hyperesthesias as listed in the product insert).

A recent report by Danish researchers (Hillerup & Jansen, 2006) examined 56 patients with injection injury to oral branches of the trigeminal nerve which were “caused by unilateral administration of inferior mandibular nerve block for conservative dental procedures” and found that “articaine produced a more than 20-fold higher incidence of injection injury when applied for mandibular block analgesia.” They noted the “decisive role of the concentration of analgesic solution” and went on to write that “the association of an increased incidence of injection injuries with the introduction of articaine 4% also in Denmark is remarkable.”

Given the above, one might forgive the general dentist for being confused.

**Ethical Considerations**

The history, data, product insert, and reports in the literature beg the question: Should American dentists use articaine? If so, why, and how should it be used? What ethical obligations do dentists and others have when a new product becomes available, how should they make decisions about using it, and what should they say to patients?

There are several generally accepted tools in bioethics that can be applied to
this problem, but no such discussion should begin without reference to that well-known and well-worn adage, “Primum non Nocere,” (First, do no harm). This principle seems immediately relevant and helpful, but upon closer examination, it is less useful than one might imagine. The principle is fine, but much too limited to be of great value. Obviously, we do not want to harm patients, and they certainly do not wish to be harmed, but avoidance of harm is not enough. One recent analysis in the medical literature described non nocerum as “laudable but obviously deficient.” (Smith, 2005) As Louis Lasagna put it forty years ago, “To observe this advice literally is to deny important therapy to everyone, since only inert nostrums can be guaranteed to do no harm.” (Lasagna, 1967) Our patients don’t come to us so that we will not harm them; they come to us for help. We have to provide an important service while managing the inevitable potential dangers in some effective way.

**Standard of Care**

Most conscientious doctors would answer the articaine question in general terms in the following way. “Don’t use any procedure, product, or drug that you don’t understand. Make sure that you are trained adequately and that you are clear about the risks and benefits to patients before adopting something new. Check things out and make sure that the new drug is safe when used in the way that you intend to use it. Ensure that you can competently apply that new drug, product, or procedure before you expose patients to potential harm.”

That said, every dentist knows of instances when a colleague (or even himself or herself) has attended training on a weekend and begun to use a new procedure on Monday. Patients are rarely aware of the fact that dentists learn much of their profession by treating them. One recent survey of surgeons regarding something called “innovative surgery” came to the following conclusions: “Respondents (doctors) expressed a fairly prudent stance when judging hypothetical innovative scenarios”; and “Some forms of innovation (meaning surgery) clearly fall under the current regulations for human subject research...” (Reitsma & Moreno, 2005)

It seems clear that while the standard of care requires that we practice safely at all times, it does not help us to decide where to draw difficult lines about what is new or innovative and what is completely safe or safe enough.

**ADA Principles of Ethics and Code of Professional Conduct**

It is somewhat surprising to note that the current ethics code of the American Dental Association (ADA, 2005) does not specifically address the issues discussed in this paper. In closely related topics, the code recommend that the dentist keep knowledge and skills current and know one’s own limitations (Section 2). The code warns against making “unsubstantiated representations” to patients about treatments that are not based upon “accepted scientific knowledge or research...” (Section 5.A.2.) When discussing the sale of products to patients, the code says “In the case of a health-related product, it is not enough for the dentist to rely on the manufacturer’s or distributor’s representations about the product’s safety and efficacy. The dentist has an independent obligation to inquire into the truth and accuracy of such claims and verify that they are founded on accepted scientific knowledge or research” (Section 5.D.2.)

With regard to adverse events such as paresthesias, the code also requires...
that dentists make a report when they suspect that an adverse effect has taken place, and the code specifically mentions a report to the FDA in cases of “serious adverse events.” (Section 5.D.1.)

Beyond the generally accepted standard of care and formal ethics codes, the three formal methods of analysis that bioethics has to offer are these: a) deontological approach, using normative principles; b) utilitarian analysis, which weighs competing interests; and c) Ozar and Sokol’s “central values of dental practice.” Each will be considered in turn.

**Normative Principles**

This relatively simple method of ethical decision-making is popular in organized dentistry. The American College of Dentists (2000) and the American Dental Association (2005) both use normative principles in their official guidelines and codes, and the ADA’s current code of ethics is essentially organized around the principles of patient autonomy, nonmaleficence, beneficence, and veracity, weighted in that order.

The goal in using this decision-making method is to practice in alignment with the principles and to use them as guidelines when faced with an ethical challenge. Analyzing the use of articaine using the principle of non-maleficence, one would ask: “Does the use of this anesthetic have the potential to cause harm to patients?” The answer to that question is certainly “yes.” A more salient question has to do with the likelihood or probability of harm (what are the real-life chances of this happening?) along with the question of seriousness and longevity of damage.

The next principle, beneficence, requires that dentists act on behalf of patients’ interests and do some positive good. The differential benefit of articaine relative to the other available anesthetics must be rated and it must be shown that articaine, indeed, provides benefits to patients that are similar or superior to the benefits that the other anesthetics provide. The ethical calculus that weighs benefits against risks is probably something that most dentists consider intuitively, but it is not an easy or tidy task, especially when benefits are difficult to define and studies are not available. Dentists commonly believe that articaine offers advantages and some even speculate that the molecular biology and pharmacology would dictate that articaine should be superior. But at this point in time, there is no clinical research to back up those widely held perceptions. At the same time, there is empirical evidence (as noted above) that articaine is more dangerous than other commonly used dental anesthetics.

Veracity mandates that we simply (or not so simply, sometimes) tell the truth. Assuming that no one is lying about the dangers or benefits of articaine, that patients are told the straight story in clear language, and that research reports do not intentionally distort or misrepresent data, this principle does not pose a problem.

The principle of patient autonomy brings up the challenging question of informed consent, and there is disagreement about this matter in the dental literature (Orr & Curtis, 2005; Dower, Indresano, & Peltier, 2006; Jacobsen, 2006). Because of patient autonomy, patients have a right to choose treatments, as they are the ones who must live with the consequences of that treatment. Participation is voluntary, and patients must have adequate information with which to make their choices. There are several components of informed consent, one of which is the requirement to provide information about risks, benefits, and alternatives to the treatment proposed by the dentist. From a legal standpoint, dentists must disclose material risks, that is, risks that might cause a reasonable patient to decline the proposed treatment. The ACLU’s guide to patient rights (Annas, 1989) interprets this to mean that “even a 1 in 10,000 risk of death must always be disclosed, but not a 1 in 10,000 risk of a two-hour headache.”

As Orr & Curtis (2005) observe, “…a healthcare professional ordinarily is not obligated to enumerate each and every complication that might occur secondary to a proposed treatment—only common and serious complications.” Dentists must ask themselves about thresholds of commonality or seriousness. At what point is a risk considered common? Is it important to talk to patients about the risk of paresthesia if it is only going to occur once in a dentist’s entire career? What if it is likely to occur in 11 out of every 882 times a drug is injected? What if it is likely to occur in 21 out of every 882 times a drug is injected?

At what point is a risk serious? If numbness is temporary, is it serious? What if the numbness lasts two weeks, or two months (a commonly used paresthesia benchmark)? What if it lasts forever? These are difficult and important questions. Given appropriate information, patients might opt for the use of a 2% rather than a 4% anesthetic solution.

In deciding about informed consent, dentists are sometimes encouraged to ask the question, “What would most dentists do in this situation? Would the reasonable dentist inform the patient about this particular risk.” (Rule & Veatch, 2004) There is evidence that most general dentists do not discuss local anesthesia alternatives with their patients, while specialists and dental
anesthesiologists are more likely to do so. (Orr & Curtis, 2005)

There is at least one more way to view the informed consent problem. Imagine what a reasonable and competent patient might decide if told the following by their dentist: “I intend to use a local anesthetic that I favor. In my experience, I don’t ‘miss’ my first injection to numb the lower teeth as often as with other local anesthetics, and I think that this new anesthetic tends to last longer. However, there is no scientific evidence to support my experience, and there are studies that seem to show that you are at a twenty-times higher risk of paresthesia than if I use the older anesthetics, even though the risk of that happening is still quite low, perhaps only 1 or 2 percent of the time.”

Weighing Interests
A utilitarian approach begins with identification of sets of interests held by various parties. Whose interests are at stake, what are they, and how weighty or important do they seem? With local anesthesia both the patient and dentist have important interests. The dentist is desirous of quick, reliable, profound anesthesia of adequate duration, and while these things are important to patients, the typical patient’s most pressing interest is to have the most comfortable experience possible. Dentists, based upon numerous anecdotal reports, seem to think that they are less likely to “miss” their first mandibular block injection if they use articaine. These dentist interests are weighed against any advantage or danger faced by patients. As noted above, there is evidence that the risk of adverse events from articaine is significantly higher than that of other anesthetics, and such events can include temporary or permanent problems. Patients can experience lip or tongue numbness or dysfunction, speech impediment, drooling, loss of taste or perverted taste, loss of feeling in half of the lower lip and a lip or tongue that feels several times the normal size. Besides the more common paresthesias, the patient also risks having a permanent lingual nerve dysesthesia experienced as a scalded sensation on the tongue. These are not trivial problems, to be sure.

It would be unfortunate, of course, and arguably unethical, if the time, comfort, or efficiency-related interests of dentists overruled the health risks to patients of use of this anesthetic, especially when other drugs have worked safely and well for years.

Ozar and Sokol’s “Central Values”
This method asserts that dentistry, like all other professions, has a set of specific values that members of the profession generally agree upon. Ozar and Sokol (1994) rank the six most important values and propose that their hierarchy be used to make ethical decisions. In other words, higher values trump lower ones. The values, in order of importance are:
1. The patient’s life and general health.
2. The patient’s oral health.
3. The patient’s autonomy.
4. The dentist’s preferred pattern of practice.
5. Esthetic values.
6. Efficiency in the use of resources.

The hierarchy demands that threats to life and general health be given the highest priority, followed by dangers to a patient’s oral health. This implies that if paresthesia concerns about a “new” drug like articaine are non-trivial in frequency and seriousness, that drug should not be used, even though its use is perceived to honor values found lower
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in the hierarchy, such as “the dentist’s preferred pattern of practice” or “efficiency in the use of resources.” In this model, dentists are not permitted to favor a preferred practice pattern or time efficiency over the patient’s general or oral health.

Discussion of Articaine

The adoption of a new procedure or product (particularly a new drug) is taken seriously by any professional, as there is much at stake, and it is difficult to forget the cautionary examples (e.g., Thalidomide, Fen-Phen, and Vioxx).

In general, a new drug must be evaluated in the following ways. First, it must not cause common or serious harm. Second, the benefit-to-risk ratio of use of the new drug must be equal to or better than that of other available drugs. Third, the interests of involved parties must be identified and weighed, and patient interests must be weighted at or above the level of the interests of doctors. Fourth, the question of informed consent must be considered: Does the risk require that patients be alerted and given options?

First, the question of how common the harm. The data indicate that articaine is significantly riskier than previous anesthetics, especially those used in a 2% or 3% solution. Articaine, a 4% solution dental anesthetic, seems to pose a significantly higher risk of paresthesias when used in mandibular block injections than other local anesthetics, especially lidocaine, mepivacaine, and bupivacaine.

Based on the data in the Haas and Lennon (1995) study, Dower (2003) estimated that articaine was twenty times more likely to cause a paresthesia than lidocaine. This assertion is supported by other reports (Haas & Lennon, 1995; Miller & Haas, 1996, 2000; Hillerup & Jensen, 2006). The increased paresthesia rate with articaine has been noted by dental clinics (Clinical Research Associates Report, 2005); governmental agencies (U.K. Mersey Adverse Drug Reactions Newsletter, 2003/4; see also Denmark Medicines Agency Pharmacovigilance [www.dkma.dk] study of adverse reactions from anesthetics for dental treatment, 17 August 2005); and dental insurance carriers (Emery & Webb, Inc. 9/5/2006; Royal College of Dental Surgeons of Ontario, Canada, Dispatch 2005; Milgrom P. et al., 2000). It should be noted that the agency recording adverse events with drugs for the European Union, Eudravigilance, does not publish or report adverse events.

Based on this information, it seems ill-advised to use this drug for mandibular blocks, although it may have other important uses in general dentistry that pose little significant risk. Even if the occurrence of paresthesias in the study were only the 11 listed in the table of the product insert, an 11/882 paresthesia frequency would be an astonishing statistic. For example, at the University of the Pacific there are about 170 dental chairs. If a general dentist treats ten patients each day during a four-day work week, he or she might produce two paresthesias each month if articaine were used exclusively.

The issue of seriousness of harm is difficult to discuss. American dentists historically have little experience with or exposure to paresthesias. Prior to 4% solutions, dentists expected, at the most, one paresthesia in their career, and they typically figured that it was a result of physical needle contact with a nerve. Also, when they thought about paresthesias, they expected that the numbness would resolve shortly. But if the aforementioned FDA study, along with the Canadian and Danish reports, are to be believed, dentists should prepare themselves for the eventuality of “adverse events” related to their use of articaine.

At the risk of alarmism, it must be noted that these events can be life-changing for patients unfortunate enough to experience them. It must also be noted that they have a significant impact as well on the life and career of the dentist involved. No dentist wants to be responsible for the kinds of things that people with paresthesias or dysesthesias experience.

The next ethical question inquires as to whether risks are outweighed by potential benefits of using articaine for mandibular block injections. There are two parts to the answer to this question. The first has to do with “whose risks?” (which party is subjected to possible harm), and who gets the benefit? It seems possible to make the case that it is the dentist who receives most of the benefit (in terms of time and general efficiency) and it is the patient who is subjected to most of the potential danger. There are exceptions to this conclusion, to be sure. Patients who truly hate each moment in the dental chair certainly benefit from a speedier appointment. Conversely, dentist put themselves in legal harm’s way if their use of articaine exposes them to lawsuits and anecdotal experience shows that dentists experience great sadness when one of their patients endures a serious “adverse event.”

The second part of the question has to do with the amount of benefit. Based on scientific studies, including Septodont’s own study (1998), there is no evidence of increased benefit in terms of the amount of product used, onset of anesthesia, duration of anesthesia, or pain relief compared to other available local anesthetics. If the relative risk of a paresthesia is increased approximately
twenty-fold, would not there have to be a concomitant increase in benefit to patients to justify a switch from lidocaine to articaine? Fortunately, the likelihood of a paresthesia with the use of a 2% and 3% local anesthetics is extremely small. Given that, it seems clearly unethical if dentists use a more dangerous anesthetic for reasons of their own convenience or professional comfort. Patient well-being interests must carry more weight than the practice pattern interests of doctors. The authors recommend that dentists refrain from using articaine for inferior alveolar blocks until additional research can document adequate safety for patients.

**General Recommendations: Adopting New Products**

Every dentist is confronted with new drugs, products, and procedures in their career, and it is reasonable to assume that the pace of innovation is accelerating. In the case of local anesthetics, only a handful have been available to dentists over the past several decades and their safety has not been much of an issue. As a result, it is possible that dentists have been “lulled to sleep” regarding the risks that might be associated with a new drug. They are not used to taking a rigorous and independently cautious approach to any new drug, especially local anesthetics. Dentists are understandably eager to adopt any new product or procedure that will enhance the experience of the dental appointment for their patients or streamline care, and most of the products that come onto the dental market are not of the kind that could pose much risk or danger to patients.

A local anesthetic is different. It is injected directly into a patient’s body tissue and is potentially quite dangerous. As Orr asserts (in Malamed, 2004), “local anesthetic administration involves injecting or otherwise administering potent pharmaceutical agents.” Thus, it is fair to assert that dentists have a greater duty to ensure that they understand the drug and its characteristics prior to its use. Orr goes on to write “it is incumbent on the healthcare professional to also make an independent and reasonable effort to identify potential disadvantages to new modalities.”

The introduction of articaine into American dental practice provides a good example and, perhaps, a cautionary tale. Here are recommendations that logically derive from the case of articaine.

First and foremost, dentists need to examine risks related to the adoption of any new product into practice. They must conduct this examination themselves. They should be cautious about the sources that they rely upon. Luckily, there are only a few dental procedures that are potentially truly dangerous. Others pose important risks to a patient’s dentition or esthetic appearance, but local anesthetics are in a category of special importance. Since there are only five local anesthetics available for use in the United States now, it seems reasonable to expect every dentist to examine each of the drugs in detail before using it, and most of this learning process takes place in dental school. However, the vast majority dental students’ clinical experience is with 2% lidocaine with 1:100,000 epinephrine and their didactic instruction in the various local anesthetics is rather brief and may well be in advance of their clinical experiences. Dower (1998) conducted a survey of fifty-three local anesthesia course directors in the United States and found the “typical” program consisted of fifteen hours of didactic instruction covering all aspects of local anesthesia. When a new anesthetic comes into the market or is new to a dentist’s use, he or she needs to put reasonable and adequate time and...
effort into some independent research. At the very least, every dentist should study the product insert that comes with a new drug. This does not seem like much to ask, as such inserts are typically only two pages long (of admittedly small print) and are readily available.

Second, dentists must read any product reviews published in mainstream, peer-reviewed journals in the literature. This is a common and easy recommendation to make, but it is not as simple or straightforward as it might seem. Dentists need to read more than just the abstract and conclusions sections of research reports, as authors do not always come to the same conclusions that readers might come to, given the same data. Published studies regarding the safety and efficacy of articaine in *JADA* (Malamed, Gagnon, & Leblanc, 2000; 2001) provide an example of this problem, as some of the data could only be characterized as alarming, or if not alarming, certainly noteworthy. The first *JADA* article written by Malamed, Gagnon, and Leblanc in April of 2000 highlighted the following in large-font, italicized bold print set out in the middle of the page: “We found articaine to be well-tolerated in 882 subjects, and that it provided clinically effective pain relief during most dental procedures.” A dentist who is only scanning this article would certainly read that statement and perhaps move on, coming to the conclusion that the study had demonstrated that articaine was a superior new drug that is quite safe. The last sentence of the article concludes that, “Articaine can be used effectively in both adults and children.” If they did not read through the entire paper, readers would have missed the statement that “furthermore, we observed no significant difference in pain relief between subjects in the 4 percent articaine with epinephrine 1:100,000 group and those in the 2 percent lidocaine with epinephrine 1:100,000 group.”

There is certainly room for reasonable people of integrity to come to differing conclusions about this study, the data, and the reports, but it is indisputably difficult for the practicing general dentist to come home after a long day at the office and sift through these data. Even so, these questions do not relieve the dentist of responsibility for the drugs he or she injects into patients.

A related recommendation is that dental schools spend curricular time reviewing the basics of scientific methods and research design, with an emphasis on evidence and empirical data. Students should be explicitly taught how to read product inserts. Such an emphasis might also have the effect of stressing the responsibility to do so throughout one’s career.

More research on articaine is needed if disputes are to be resolved and answers to critical safety questions are to be had. This is unlikely to happen, however, as the drug is FDA approved, and there is little motivation for the manufacturer to fund future research. It is really up to academic centers to conduct research now, and experimental designs may have difficulty getting approval from institutional review boards (IRB) or human subjects committees. Any research that is done ought to also address the possibility that articaine is “safe” in some uses and “risky” in others (i.e., mandibular block injections). Any future research should be designed and reported in a way that isolates mandibular block data from other kinds of injection results, since nearly all paresthesias are associated with block injections. This would clear up some of the existing confusion, given the possibility that articaine is more dangerous in block injections only. It is certainly possible, even likely, that articaine is capable of providing enhancements and advantages to dentists and patients when used in the safest ways.

We recommend that dentists think hard about whether the use of a new local anesthetic requires a discussion of the rationale and risks with patients, especially if they intend to use articaine for a mandibular block. Orr’s chapter on “Legal Considerations” is again helpful (in Malamed, 2004). “The prepared healthcare professional should be able to articulate exactly what the goal of the administration of a local anesthetic is and how that is technically accomplished. For instance, why was a particular anesthetic and needle chosen?” One important question is this: Should patients have a role in the decision to choose an anesthetic that makes it easier for a dentist to successfully perform a block if there are empirical data implying a twenty times higher risk of paresthesia? Given adequate information, it seems reasonable to imagine that some patients might respond with, “No thanks, Doc, I’d prefer that you go ahead and use good old lidocaine, the one that you’ve used so safely and effectively for my dentistry in the past.”

Dentists are also urged to be cautious about their sources of information. Although this may seem obvious, it is worth mentioning: Information about new products in “glossy” dental trade magazines that are not peer reviewed must be treated as suspect, especially if they are presented in the form of an advertisement. Manufacturers of dental products do not have the same orientation to patient safety that dentists must...
maintain. Pharmaceutical companies operate in the ethical domain of the commercial marketplace, while dentists use the “ethics of care” to guide their practice. The underlying dimensions of these two disparate ethical domains are fundamentally different (Nash, 1994; Peltier, 2002). Commercial companies are expected to compete and deliver profit. Dentists are expected to maintain a transparent and cooperative relationship with patients and other professionals. Patients, unlike “customers” are not in a position to adequately evaluate the drugs and procedures that dentists use, so they are forced to trust us. Therefore, we have an obligation to be trustworthy and open.

Likewise, endorsements by high-profile figures should not be absorbed without personal scrutiny. Dental experts sometimes have a vested interest in one product over another. It is the end-user’s responsibility to decide for himself or herself, based upon a reasonable examination of the science, whether or not to expose patients to new products or especially, to new drugs. Dentists must also beware of the “buzz” that often surrounds new products, procedures, and drugs in dentistry, as it can be persuasive, but does not qualify as “science.” Here is an example of the kind of information that contributes to the “buzz.” It is from a Web site that is presented as a dentist’s site:

“Septocaine is a new form of local anesthetic for difficult-to-numb teeth. It is twice as strong as normal Novocain, and, because it diffuses into the soft tissue faster and more completely, it is much more effective. I first discovered Septocaine about three years ago, when a patient of mine presented with a severe toothache and I was worried about whether or not I could get her numb. I called a friend of mine—an endodontist in Fresno—and asked him what he would use. He told me about a wonderful new anesthetic, Septocaine, which he said he used routinely in his endodontic practice. I used it in this difficult case, and we have been using it ever since.”

This is simply not the kind and quality of information that is acceptable for adoption of a new drug that will be injected into the tissue of patients. It is remarkable, partly because this dentist claims to have chosen to use a new drug based simply on the recommendation of a colleague, after apparently conducted no independent inquiry into the new drug’s safety or efficacy. We owe our patients much more than this.

A recent editorial in a pathology journal (Myers, 2006) makes a powerful closing argument for caution by quoting the Institute for Medicine’s 1999 report: “It is simply not acceptable for patients to be harmed by the same health care system that is supposed to offer healing and comfort. There will be no excuses; the levels of safety with which we have contented ourselves are not the standard to which we will be held accountable as we go forward.”

References


The authors recommend that dentists refrain from using articaine for inferior alveolar blocks until additional research can document adequate safety for patients.
Selection of Local Anesthetics in Dentistry: Clinical Impression versus Scientific Assessment

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Abstract
Since its introduction to the United States about six years ago, 4% articaine with 1:200,000 epinephrine has been used by dentists as a local anesthetic agent. This article reviews three claims that have been advanced regarding articaine: high diffusibility, reduced incidence of failure in block injections, and effectiveness in achieving anesthesia when used in cases involving irreversible pulpitis.

This issue of the journal brings into sharp focus the challenges that daily confront dentists with regard to the rational selection of newly-introduced products. As a dental local anesthetic which had been associated with very attractive clinical properties at the time of its introduction in the United States in 2000, articaine (Septocaine) promised to be a pharmacologic tool with which the practitioner could increase local anesthetic success rates, reduce or eliminate the need for palatal/lingual injections, and overcome anesthetic failures associated with irreversible pulpitis, primarily by token of a unique chemical feature (the presence of a thiophene ring in the place of a benzene ring).

Reports persist of the unique advantages of articaine over established products, such as lidocaine, both as clinical impressions and findings in clinical studies and have been reinforced periodically in dental trade publications, in which some clinicians claim to have increased their mandibular anesthesia success rates to 99% or 100% after switching to articaine. While there is no doubt that a dentist’s experience with local anesthetics is variable due to the inherent variations in drug response, neuroanatomic variations, and other factors, individual claims of increased effectiveness must be evaluated critically, using the best scientific evidence at hand before agents with a long history of safety and efficacy are replaced with a new product (Blanton & Jeske, 2003).

In this spirit, the present article briefly considers clinical and scientific evidence, at times contradictory, for three claims commonly associated with articaine: 1) “high diffusibility,” 2) decreased failure rates of mandibular/inferior alveolar block injections, and 3) the ability to overcome failures of local anesthesia associated with irreversible pulpitis.

“High Diffusibility”
One clinical observation commonly believed to indicate the extent to which a local anesthetic diffuses into sites of action is its success rate in producing excellent local anesthesia by infiltration in the mucobuccal fold at the level of the apex of the tooth to be instrumented, and by penetration to soft- and hard-tissue sites not ordinarily anesthetized.
with this technique, e.g., palatal anesthesia following buccal infiltration in the maxilla. Additional claims associated with articaine in this regard include its ability to produce pulpal anesthesia of mandibular teeth by simple buccal infiltration over the relatively more dense cortical plate of bone that characterizes the mandible.

Long before its becoming available in the U.S., a well-designed, scientific study showed that articaine produced only a 5% incidence of palatal and lingual anesthesia after buccal infiltration, which was the same low rate as the comparator drug prilocaine under identical conditions (Haas, Harper, Saso, & Young, 1990). The same study demonstrated that articaine produced no significantly greater success rate for pulpal and soft tissue anesthesia, and had no significantly more rapid onset than prilocaine. Shortly afterward, Vahatolo and others reported that 4% articaine with 1:200,000 epinephrine did not result in statistically superior onset of anesthesia in maxillary lateral incisors when compared to lidocaine 2% with 1:80,000 epinephrine (Vahatalo, Antila, & Lehtinen, 1993). Similarly, another study failed to show differences in success rates for infiltration anesthesia of maxillary canines (Oliveira, Volpato, Ramaciato, & Ranali, 2004), and a study in pediatric patients did not reveal differences in local anesthetic outcomes among mepivacaine, prilocaine, and articaine (Wright, Weinberger, Marti, & Plotzke, 1991).

Shortly after its introduction in the U.S., Malamed and others (2000; 2001) published results of a randomized, double-blind, multi-center clinical trials that compared the clinical characteristics of 4% articaine with 1:100,000 epinephrine versus 2% lidocaine with 1:100,000 epinephrine. In these well-designed scientific studies, articaine was shown to be equally efficacious with lidocaine, with comparable efficacy, volumes, time to onset, and duration of action, none of which were statistically significantly different from values for 2% lidocaine with epinephrine. These reports concluded that 4% articaine “is an effective agent acting in the standard lidocaine-epinephrine-mepivacaine range,” and further concluded that articaine’s clinical performance was not sufficiently different to qualify it as a replacement for lidocaine.

Shortly following publication of outcomes of the multi-center trails of Malamed and colleagues, Clark et al (2002) reported that administration of 1.8 mil lidocaine 2% with 1:100,000 epinephrine infiltrated labially significantly improved local anesthesia of mandibular lateral incisors following conventional inferior alveolar block. This report confirmed that earlier generation anesthetics, such as lidocaine, which purportedly lack the diffusibility of articaine, can be effective when used for mandibular anterior infiltration. However, the contribution of contralateral mental nerve crossover innervation, with penetration of sensory fibers into the buccal cortical plate of the anterior mandible, cannot be discounted, since blockade of such sensory fibers would not be depend on penetration of the anesthetic through the bony cortical plate.

Two more recent studies (Berlin et al., 2005; Kanaa et al., 2006) exemplify the continued contradictory finding involving claims of superior clinical characteristics (e.g., diffusibility) of articaine. In the first study, the efficacy of 4% articaine with 1:100,000 epineph-
rinsine was compared with that of 2% lidocaine with 1:100,000 epinephrine for periodontal ligament injections of non-diseased mandibular first molars. While articaine showed a slight advantage in onset time (1.3 minutes vs. 2.2 minutes), local anesthetic success rates were not statistically significant, although somewhat better values (were reported for articaine (86%) than for lidocaine (74%) (Berlin et al., 2005). A later study reported the comparative success rates of these two agents in producing pulpal anesthesia of mandibular first molars following buccal infiltration. In this report, 4% articaine with 1:100,000 epinephrine produced significantly higher success rates (64.5%) than 2% lidocaine with the same vasoconstrictor concentration (38.7%) (Kanaa et al., 2006).

Since 1962, at least three studies of ocular complications of dental local anesthesia have been reported, implicating the diffusibility of the local anesthetic as a contributing factor (Cooper, 1962; Penarrocha-Diago & Sanchis-Bielsa, 2000; Magliocca, Kessel, & Cortright; 2006). Penarrocha-Diago and Sanchis-Bielsa (2000) suggested that the “improved anesthetic diffusion” of articaine through soft tissue and bone could account for many of the ophthalmic findings. Most recently, Magliocca and others (2006), using two 1.7-ml cartridges of 4% articaine delivered to the posterior superior alveolar nerve and the greater palatine nerve, reported a case of transient diplopia following these maxillary injections. This group did acknowledge that the various bony and vascular anatomical pathways could explain the occurrence of such ophthalmologic complications. These studies raise the question of enhanced anesthetic diffusion through soft tissue and bone as well as the potential of the volume of solution or the specific chemical properties of 4% articaine in playing a role in neurological (often transient) disturbances.

**Increased Success Rates of Mandibular Anesthesia**

As noted previously, multi-center controlled clinical trials conducted in the U.S. did not establish a significantly higher rate of success for articaine than that seen with other amide agents when anesthesia was tested by performance of a variety of invasive dental procedures (Malamed, Gagnon, & Leblanc, 2000; 2001). Recently, in a well-designed double-blind, randomized, crossover human study, Mikesell and others (2005) compared local anesthetic outcomes in fifty-seven human subjects using the same agents for their comparison. When administered using conventional inferior alveolar nerve block technique, no significant differences in success rates between articaine and lidocaine were observed, although considerable variations between molar, premolar and incisor teeth were noted.

**Improved Local Anesthetic Success Rate in Irreversible Pulpitis**

Perhaps the most challenging situation for pain control in dentistry is the need for producing profound local anesthesia of a tooth or teeth that exhibit the signs and symptoms of irreversible pulpitis (“toothache”). In this chronic inflammatory state, neural expression of local anesthetic-resistant, voltage-gated sodium channels and peptide mediators would be expected to impair local anesthetic effectiveness (Robinson, Boissonade, Loecher et al. 2004). In that regard, one study has scientifically evaluated the comparative success rates of articaine and lidocaine for inferior alveolar nerve block in patients with documented irreversible pulpitis in mandibular posterior teeth. Neither anesthetic produced clinically acceptable success rates, which were 24% and 23% for articaine 4% and lidocaine 2%, respectively (Claffey, Reader, Nusstein, Beck, & Weaver, 2004).

**Summary**

In toto, the scientific evidence from dental clinical studies neither refutes nor confirms a superiority of articaine over other agents in routine dental local anesthesia or its ability to improve success in the presence of irreversible pulpitis. However, statistical outcomes of such studies may not outweigh clinical impressions of practitioners whose practice of local anesthesia is believed to be positively impacted by a new agent. There are likely several reasons for these apparently “clinically significant” observations, including increased vigilance of clinical outcomes and closer attention being paid to technique of administration, among others. Is a one- to two-minute faster onset of local anesthesia onset clinically significant? That question, and other relevant ones, can be answered only by individuals and for their individual reasons. Is an overall success rate of 64% for articaine, when compared with 38% for lidocaine, clinically significant? If observed in a single dental practice over a relatively short period immediately following a switch to a new primary local anesthetic, the answer would most likely be “yes.” Such observations would be felt most significantly in the patient who has frequently experienced failed anesthetic blocks but exhibits excellent local anesthesia upon administration of the new agent. In such cases, previous anesthetic failures have
been documented to be predictive of future failure (Kaufman, Weinstein, & Milgrom, 1984) and it is likely that both the patient and the practitioner would prefer the most recently administered local anesthetic and block technique for future injections.

Tests of anesthesia used in the studies of Malamed and his colleagues (2000; 2001), in which the subjects ranked anesthetic efficacy during both “simple” procedures (single extractions and routine operative procedures) and “complex” procedures (multiple extractions, alveolectomies, muco gingival procedures), all in a double-blind manner, are robust, as are tests which use electric pulp testers, with appropriate unanesthetized controls. These clinical-scientific gold standards should be applied in the clinician’s decision-making process when a new local anesthetic is being considered for incorporation into a dental practice. However, clinical judgment and experience are equally relevant factors for an individual practitioner in selecting from the relatively few but safe and efficacious injectable amide local anesthetics currently available.

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Abstract

Case report articles or any articles that report serious consequences from a particular therapy should be evaluated with reasonable suspicion. The concerns of these articles may prove to be correct or not in time and therefore, it is necessary to take a wait-and-see posture. In time, the publication of similar case reports should generate further concern, or the lack of secondary case report articles backing up the initial report would tend to dismiss concern. Obvious failures in critical thinking and information gathering should be noted.

As I remember the story, Chicken Little was frightened by falling flotsam and jetsam and ran around the neighborhood warning everyone that the sky was falling. He encouraged everyone to take cover or risk injury. Of course, within the context of the story, Chicken Little happened to be wrong. The story was about abject panic and individuals who do not collect and process information in a reasonable manner and thereby encourage other individuals to panic.

It is true that meteors and space junk (flotsam and jetsam) sometimes descend onto the earth. Ultimately, this space material presents a potential risk for anyone outside the protection of a sturdy shelter. There is always some infinitesimal probability that one of us could be beamed by a meteor and experience serious health consequences. But should the threat prevent anyone from leaving his or her shelter and going for a walk? The answer to this kind of question requires formulating a risk-benefit analysis. This kind of analysis is also critical for the clinician’s decision-making process with regard to formulating patient therapies. Is the benefit worth the risk? Personally, I don’t think twice about going for a walk, because the chance of being hit by a falling meteor or other space debris is drastically insignificant. But there are other concerns that might make me think twice. Journal editors and authors have a responsibility to provide the readership with balanced, unbiased results and sufficient information so clinicians can determine both benefits and risks.

There are many recent articles in dental journals that suggest possible serious issues and concerns. Such articles often advise restraint or avoiding expressing professional opinions regarding particular therapies or caution concerning the use of medical histories, materials, or drugs. Caution is a hallmark of incomplete science as well as the personal views of authors. Advice not to act has both positive and negative potential in the clinical setting. Some research studies have the potential to educate clinicians in safeguarding the health of patients. Others warn practitioners off from actions that are beneficial to patients. It is also possible that unnecessary therapies—costing time and money and having unsatisfactory side effects—will be used because of
misconceptions about available alternatives. It is certainly important for clinicians to be aware of the potential health consequences reported by in the literature. But it may be even more important for clinicians to use critical thinking to evaluate the relevance of the risks and the fears presented. Critical thinking is paramount in evaluating the accumulated evidence provided by research studies, epidemiologic studies, commentary articles, and case reports.

**True Negatives**

Continuing with the Chicken Little analogy, it is important for clinicians to realize that sometimes the sky is really falling. Marx (2003) reported in 2003 that avascular necrosis secondary to bisphosphonate therapy for cancer appeared to be a clinical problematic side-effect of the cancer pharmacotherapy. Migliorati (2003) followed a month later with another alert concerning this potential problematic condition. However, Tarassoff and Csermak (2003), representing Norvartis Pharmaceuticals, countered shortly thereafter that Marx and others were incorrect. They reported that their search of the literature did not reveal any association between bisphosphonate administration and osteonecrosis in either humans or animals. They cited several references regarding the successful treatment of osteonecrosis with bisphosphonates. In time, further case reports accumulated evidence that avascular necrosis is indeed a side effect of bisphosphonate administration and appears to be a significant risk factor for patients on bisphosphonates (Migliorati et al., 2006, 2005). Presently, even Norvartis has noted approximately 600 reported cases of bisphosphonate-induced osteonecrosis. The conclusion is that the clinical observations of Marx and others concerning a possible association with the drug category of bisphosphates and the side effect of avascular necrosis were correct. Sometimes the sky is falling.

But in my opinion, it is unfair to criticize Tarassoff and Csermak as being unethical merely because they were incorrect. In rereading their response, their opinions appear to be reasonably supported by their arguments and the literature available at the time of the response. Certainly, their opinions may have been colored by their relationship with Norvartis. But they openly disclosed this connection.

**False Negatives**

But oftentimes the sky is not falling, and it was only flotsam and jetsam. Several examples are presented demonstrating articles in which readers were alerted to potential problems which, with the present evidence available, have not been demonstrated to be health concerns. Silver or dental amalgam restorations have been controversial almost from their first use. In the nineteenth century, many dentists considered dental amalgam to be substandard. But with G.V. Black’s research, dental amalgam became the mainstay of restorative dentistry. Several dentists promoted the concept that because mercury is toxic, therefore dental amalgam had a toxic effect. This particular viewpoint has been advocated for over a hundred years.

When composite restorative material became a viable alternative, fears of toxicity became more pronounced. Composite material certainly has a vastly improved esthetic and cosmetic appearance compared to dental amalgam. However, research and epidemiological studies have repeatedly demonstrated the safety and efficacy of dental amalgam. When compared to composite dental restorations, dental amalgams last considerably longer and are less expensive. A recent investigation by the Food and Drug Administration (Associated Press, 2 September 2006) once again pronounced dental amalgam a safe and effective dental restorative material.

Economic considerations may have become entangled with evaluation of safety of amalgam restorations. Dentists charge more for composites and composites generally do not last as long as amalgams. Under such circumstances it may be difficult to get a fair hearing for the safety of amalgam. Many dentists have only a limited understanding of heavy metal toxicology and mercury and dental amalgam toxicology issues. A favorite trick of the Chicken Little crowd is to assert that there is “no safe level of a potentially hazardous material” or alternatively “there is no acceptable level of risk.” As stirring as such slogans appear, they make no practical sense as all of us accept risk in heating our houses or driving to our offices. Toxicity is related to dose, and trace amounts of a toxic material below the minimal levels of toxic exposure are not problematic. To date, there are only a few reports of adverse reactions secondary to allergy and lichenoid reactions with regard to the mercury within dental amalgams and certainly no serious life-threatening medical conditions have ever been reported (Abraham et al., 1984; Mackert, 1991; Mackert & Berglund, 1997; Magos & Clarkson, 2006; Vimy & Lorscheider, 1985; Vimy & Lorscheider 1996; Wahl, 2001a; 2001b). With regard to dental amalgams, it appears that the sky is not falling.

The issue of drug interactions between local anesthesia formulations containing the vasoconstrictor epinephrine and other drugs has also received unreasonable concern in the dental literature (Yagiela, 1999; Goulet et al., 1992). Many articles have discouraged...
clinicians from utilizing epinephrine local anesthetic formulations concomitantly with tricyclic antidepressants and nonselective beta adrenergic blocking drugs. Mito and Yagiela (1988) reported a case of drug-induced hypertension possibly due to the combination of propranolol, a nonselective beta blocker, with the vasoconstrictor levonorderfin used in a local anesthetic formulation. However, levenordorfin happens to have very little beta-two adrenergic receptor activity which makes its effect on blood pressure more similar to norepinephrine than epinephrine. Both norepinephrine and levenordorfin have much greater beta-one receptor activity compared to their beta two activity. Beta-one adrenergic receptor activation increases blood pressure and beta-two adrenergic receptor activation decreases blood pressure. There are numerous case reports of increased hypertension due to norepinephrine local anesthesia formulations even without combining with non-selective beta blockers. Epinephrine-containing local anesthesia formulations have not been implicated in significantly increasing blood pressure (Brown & Rhodus, 2005; Rhodus & Little, 2003). Furthermore, there has never been a reported case of increased hypertension due solely to an epinephrine-based local anesthetic formulation combined with a nonselective beta blocker with regard to medications used by millions of patients (Brown & Rhodus, 2005). Nevertheless, this so-called interaction between epinephrine containing local anesthesia formulations and tricyclic antidepressants is often cited in myriad articles and texts (Brown & Rhodus, 2005).

A recent publication dramatized concern regarding long QT syndrome (LQTS) and dentistry (Karp & Moss, 2006). LQTS is associated with torsade de pointes arrhythmia and sudden death syndrome in adolescents and in regard to particular drug toxicities and drug interactions. A history of syncope was noted as a possible finding in patients with LQTS. The recommendation was made to refer dental patients with a history of routine syncope for complete cardiovascular work-ups. This would result in the considerable health dollar expense with unknown gain. Certainly particular drug interactions have been implicated in dental treatment as morbidity and mortality factors with regard to the torsade de pointes arrhythmia. (Carlson & Morris 1996; Gallagher et al., 1998; Walker & Hendeles, 1979; Wynn, 2005). Therefore, such drugs as terfenadine, erythromycin, digoxin, cisapride, theophylline, sevoflurane and ketoconazole are implicated as problematic with respect to inducing torsade de pointes arrhythmia when combined with one another or at toxic dosage levels.
Patients with LQTS are at greater risk with regard to these drug interactions and torsade de pointes arrhythmia (Cubeddu, 2003; Tong et al., 2001).

However, in a review of the English language case reports, there are at present only two case reports with clinical dental implications which may be related to LQTS (Strickland et al., 1993; Gallagher et al., 1998). Neither of these cases was related to routine dental therapy. Both cases were anesthesia or surgical hospital cases; one related to a partial glossectomy and selective neck dissection and the other related to the drug sevoflurane.

Furthermore, epinephrine infusions in concentrations relevant to dental therapy are currently utilized with respect to the diagnosis of LQTS (Vyas et al., 2006). However, epinephrine and local anesthesia formulations have not been implicated clinically as problematic. On the contrary, epinephrine within local anesthetic formulations with respect to the utilization of two to three cartridges appears to be safe and effective for medically complex patients with cardiac disease (Brown & Rhodus, 2005; Rhodus & Little, 2002). Epinephrine in local anesthesia formulations have never been reported to contribute to LQTS sudden death. Therefore, as epinephrine containing local anesthetic formulations have been used in millions upon millions of patients, if there was even the slightest risk of such a causal relationship, lethal cases would tend to have been reported in the literature. Certainly, it is important for dental clinicians to consider LQTS as a medical diagnosis particularly with regard to drug toxicities and interactions, but once again, the sky does not appear to be falling.

Discussion

With regard to “true negatives”, clinical observation would tend to demonstrate repeated cases in which the procedure or drug resulted in negative consequences. Certainly, negative consequences in the field are not always reported. However, if the particular concern is clinically significant, it is expected that enough negative cases would be prevalent to allow for continued publication of negative case reports.

With regard to “false negatives”, the lack of clinical significance is demonstrated with the lack of published case reports. The lack of the documentation of further incidences of negative findings in regard to a particular drug or therapy is initial evidence that the drug or procedure does not tend to have clinically significant negative consequences. Almost all drugs and procedures have the potential for negative consequences. Reports concerning the negative clinical aspects of a drug or procedure without backup case reports should be questioned especially when the drug or procedure has been utilized for an extended period of time.

Clinicians and journal editors have an ethical responsibility to report and publish reports concerning risks associated with clinical practice including adverse drug reactions.
It is also the ethical responsibility of authors quoting such articles and studies to provide an objective prospective of the topic quoted in order for the readership to have a balanced view of the risks and benefits and an appreciation for critical thinking.

References


Commercialization of Dental Education: Have We Gone Too Far?

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Abstract
Early U.S. dental training involved a closer relationship between commercialism and education, which was strongly counteracted by university affiliations at the beginning of the twentieth century. With recent decreases in public support for higher education, schools have become increasingly dependent on private revenue sources, including corporate support. There are ethical risks as well as benefits from dental schools establishing business partnerships with corporations. In 2002, a private, for-profit company was responsible for the inception and direct funding of an orthodontic postgraduate program at a private U.S. university. In the last four years, this company has begun funding two additional orthodontic programs, both associated with U.S. public dental schools. Such partnerships with academic institutions represent unique corporate relationships with dental education that are fraught with ethical risks. The dental profession needs to preserve the appropriate autonomy of dental education from commercial influences in order to prevent erosion of academic and ethical standards that are critical to professional integrity and public trust.

Early U.S. dental education involved a more intimate relationship between commercialism and training than it does today. Until the mid-nineteenth century, the conventional educational model was the European one dating back to the Middle Ages where dentists were informally trained artisans with their education consisting of an apprenticeship for two or three years under a dental practitioner. Although some dentists had previously completed limited medical training, most had none and their prior education ranged from minimal literacy to a college degree. Medical education was faced with similar circumstances. Physicians were the first to formalize medical training by creating academic institutions, helping legitimize medical practice as a profession rather than a trade. Dentistry followed suit in 1840 when two physicians who later became dentists founded the first formal dental institution in the world, the Baltimore College of Dental Surgery. However, the first dental schools were created as proprietary institutions with no actual university affiliation.

Following medicine’s lead to further professional legitimacy, the first U.S. dental school was placed within a university in 1868 at Harvard University. Subsequently, most dental schools were founded in affiliation with universities. This association with higher education has provided academic credibility for dental education during the twentieth century and university policies have been a valuable source for dental schools to assist in maintaining their own academic and professional integrity. This affiliation also has provided a degree of separation from the influence of corporate culture that had been so dominant in mainstream American society since the Industrial Revolution. However, this independence from corporate influence required a growing dependence on government funding through the mid-twentieth century in order to meet U.S. public oral healthcare needs.

Substantial reductions in government support for higher education began in the late 1970s. Academic institutions have faced progressively declining state and federal financial support since that time, combined with increased competition for scarcer resources and accelerated change that is requiring innovative tactics to survive and prosper. There are mounting demands by the

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public for dental schools to become more efficient and financially self-reliant, requiring schools to supplement their traditional revenue sources with alternatives to maintain and enhance their academic, research, and service missions. This has created a climate where dental institutions have become vulnerable to corporate interests. Commercial companies have become an obvious potential alternative revenue source, resulting in a trend where business partnerships that link academic and corporate cultures are increasing (Bok, 2003).

Analyzing Relationships

Individuals engaged in academics and those involved in business have very disparate missions. The academic culture prides itself on the altruistic academic values of seeking truth and communicating knowledge and understanding, whereas corporate culture is focused on production and profit as its principal purposes. Dental deans have historically been trained in research and teaching to serve as intellectual leaders rather than trained to supervise large organizations as business managers. Business success is quantifiable in terms of cost per production unit and investment return, whereas academic success has much less reliable indicators to determine teaching effectiveness or research value. Academics and businessmen have traditionally had opposing views on the value of openness. Academics strive to develop a more comprehensive base of knowledge and to publish to enhance the common good, while businesses typically profit from keeping secrets from their competitors. Academic research has typically been characterized by curiosity-driven investigation that is viewed as superfluous in the corporate environment, where measurable productivity is what matters.

Despite these dramatic differences in mission and motivation, dental education, as well as the rest of higher education, has a long history of association with commercial enterprises. Perhaps the greatest influence has been in the area of research. Although some degree of corporate funding of dental academic research has been present for most of the last century, legislation such as the Bayh-Dole Act of 1980, which permitted universities to license patents from research paid for by public funds, and the expansion of the biogenetics industry have created a surge of corporate support for dental research in the last quarter century (Thursby & Thursby, 2003).

Outside of research, most corporate funding in dental schools has been limited to support of the physical facilities and clinic operations with donations for capital projects, such as buildings, clinics, or research centers, and donated or discounted dental materials. Although there has been much less history of corporate funding for dental school teaching and service missions, there has been growth during recent decades in partnerships between dental institutions and industries that support these activities. Educational activities such as endowed professorships, symposia, educational materials, scholarships and fellowships have received corporate funding. While there are many instances of eager companies underwriting continuing education programs sponsored by dental schools, there is minimal evidence of this activity affecting the formal dental or postgraduate academic curricula. Although commercial influence is present in some service activities, such as “Give Kids a Smile” or “Bright Smile, Bright Future,” they do not appear to be affecting the direction of the service mission for dental schools.

Academic institutions have faced progressively declining state and federal financial support since that time, combined with increased competition for scarcer resources and accelerated change that is requiring innovative tactics to survive and prosper.

It is useful to consider the range of business partnerships that exist between dental schools and corporations. Perhaps the most limited partnership is where a business donates money, dental materials, or equipment for undesignated use by the institution. Although such a partnership does not stipulate how these donations must be used, their acceptance usually permits the company to advertise their association with the dental school. This association serves to improve the credibility of the corporation, increasing their competitive position in the marketplace by implied endorsement from the academic institution. This relationship also indirectly enhances the corporation’s public image by virtue of the dental school’s own public reputation.

A deeper level of partnership is where the corporate funding has a designated use to support the educational, research, or service mission programs. While the dental school has less flexibility with how they can use the money or materials, it still bears some obligation to the corporation. Examples would include...
The response of dental education to these pressures should include caution as well as creativity and innovation.

funding for educational activities limited to one dental specialty program, funding for research conducted in one specific area or restricted to a particular line of research, or funding for a program to provide clinical care to the local indigent population. This level of commitment by the school does not include any supervision by the corporation over the conduct of these sponsored activities nor does it require specific services in return.

An even deeper level of partnership is where the funding has a designated use and there is a reciprocal obligation for services, restrictions on product use, or display of the corporate logo or name by the dental school. A common example of this type of commitment would be corporate research funding in return for product testing or technology transfer. Although private funding of dental research has been present for most of the history of dental education, the Bayh-Dole Act has increased this level of commitment. This level of corporate obligation is substantially discounted or free dental products, ranging from clinic chairs to dental implants to mouthwash and toothpaste, in exchange for their exclusive use in the clinics. A final example would be funding of capital construction in return for naming a building, room, or clinic after the corporation.

The greatest level of corporate obligation by the dental school is where the institution is required to permit some extent of corporate participation or management of the educational, research, or service activities in return for corporate support. An example would be joint participation of corporate research and development employees with dental faculty researchers on a project whose outcome is important to corporate product development. Another circumstance would be if the corporation has any influence on recruitment or selection of, or contractual employment obligation to the company by, faculty, students, or staff. Corporate participation in development or implementation of the educational curriculum is another example of this extreme level of partnership.

It is of vital importance that the benefits and risks of corporate relationships with dental schools be identified in order to determine the appropriate level of commitment by the institution to the company that can justify the revenue obtained. The potential benefits are principally related to finances while risks involve intangibles such as reputation (see sidebar).

A simple risk-benefit analysis to determine the prudence of corporate funding for dental schools is a challenge, particularly due to the greater difficulty in quantifying the ethical risks against the more easily measurable financial benefits. Revenue is immediate, tangible, and useful to meet pressing needs. Values such as integrity and public trust are more intangible and their compromises accumulate over time so that they often are not obvious until much later.

Dentists and dental educators should carefully reflect on the ethical issues that are relevant in determining the appropriate relationship that corporations should have with dental academic institutions. The integrity of our dental schools is dependent on the maintenance of institutional autonomy of their educational, research, and service mission activities. If this integrity is compromised, the subsequent decline in public trust will increase the risk of government intervention that may further limit dental school autonomy.

What are the appropriate boundaries that should be maintained between a corporation and a dental school to assure adequate autonomy? Most would agree that recruitment of students or faculty should be independent of any corporate influence. Similarly, it is an ethical breach to have any corporate involvement in the development or content of predoctoral or postgraduate dental curricula. However, there are subtler ways that our educational activities may be influenced. Exclusive use of specific dental products in the clinic or avoiding the presentation of alternative products in the classroom limits student exposure to the range of possibilities, undermining the educational values of objectivity and critical inquiry. In terms of the school’s research mission, corporate-sponsored research is vulnerable to erosion of the values of openness, independence, and objectivity that good science requires. Even corporate-supported service activities of the dental school may be affected in a way that compromises its integrity if the service is portrayed in a manner that appears as advertisement for the company rather than benevolent in nature.

A Contemporary Example

In 2002, a unique corporate partnership with dental education was initiated by a private company to fund an orthodontic specialty program at a private university. This new for-profit business, described by its founder as a “practice transition/staffing company,” provided the opportunity for selected academic institutions to have orthodontic postgraduate programs supported by the company.
In the subsequent two years, the company funded the construction of facilities for new large orthodontic graduate programs in two additional locations at public dental institutions. In 2004, a failed attempt was made by the company to expand the existing orthodontic program at a third public dental school.

This new corporate-dental academic business partnership involves unprecedented amounts of commercial financial support for the academic institution in exchange for specific obligations to the company. The company promised over $3 million of initial money to each school to develop an accredited orthodontic postgraduate program and to accept a minimum of twelve applicants each year willing to work for the company following graduation. The selected orthodontic residents that were funded by the company during their academic program are contractually obligated to provide orthodontic care for a salary at locations designated by the company for seven years duration following their graduation.

This corporate-academic partnership represents a new, unique, and dangerous paradigm for dental education, since it includes direct corporate funding of education and capital construction in exchange for corporate involvement in recruitment and corporate obligations by the graduating student. One dental administrator has characterized the contractual agreement with the orthodontic residents as being comparable to existing postgraduate scholarships offered by the U.S. armed services, the Indian Health Service, and the National Health Service Corps (Landesman, 2004a; 2004b). However, the purpose for these government programs is to provide a cost-effective method of training dentists as specialists to work for these public service organizations. Public service rather than profit is the motive for the funding and the number of students recruited varies based on need rather than producing specialists to assure an ever-expanding market share.

The company’s founder and spokespersons from each of the two public dental schools to become contractually involved have characterized the aims of the company as being altruistic in nature and have promoted them in

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**Sidebar: Benefits and Risks to Dental Education of Corporate Partnership**

**Benefits**

- Undesignated revenue in the form of funding or commercial products.
- Enhanced resources, improving recruitment and retention of students, faculty, and staff.
- Revenue designated for teaching or research support.
- Revenue designated for service activities, enhancing public visibility and support for the institution.
- Gaining advantage over competing dental schools by establishing contracts with specific companies first.

**Risks**

- Conflicts of interest, undermining individual faculty and institutional integrity (e.g., suppression of research results that were not in the commercial interests of the corporation).
- Damage to the morale of the dental academic community from the loss of collegiality and trust (e.g., resentment and loss of respect if faculty are engaged in activities primarily for the good of the corporation rather than the dental school).
- Decreased public trust in, and professional reputation of, the dental school (e.g., perception that the institution has compromised its objectivity or impartiality of research and teaching activities).
- Dependence on corporate support leaves dental school vulnerable to change in partnership (e.g., change in the corporate management or mission due to market changes; partnership no longer viewed as profitable by corporation; or corporate financial difficulties prevent it from continuing funding).
- Compromised reputation of dental school if corporation becomes involved in illegal behavior (e.g., corporation exposed for attempting to maintain profits or stockholders with unlawful activities).
It is of vital importance that the benefits and risks of corporate relationships with dental schools be identified in order to determine the appropriate level of commitment by the institution to the company that can justify the revenue obtained.

This manner in the media (Ellis, 2003; Knight, 2003). They have asserted that the corporate-educational partnership is a means of addressing the current shortfall in the number of U.S. orthodontists being graduated to replace retiring orthodontists (Johnston, 2002; Landesman, 2004a). The company’s founder has stated that another purpose for the corporation is to address the lack of “U.S. qualified” orthodontic faculty by providing them with “increased salaries” as compared to the conventional level (Johnston, 2002). It was further stated that the program will increase the diversity of orthodontists since they will recruit dentists who are “from diverse and economically disadvantaged backgrounds” who “could never afford an orthodontic specialty program.”

A final altruistic aim is that the program residents will provide care to “economically disadvantaged patients” and graduating orthodontists will “provide low-cost care to children in underserved areas” (Landesman, 2004a). No mention was ever made in the press releases of the company’s clear profit motive.

Although it is maintained that the company-recommended applicants selected for twelve positions each year are qualified by university standards, a spokesperson for one of the public dental schools stops short of saying they are as competitive as the dentists who apply through the conventional process for their four remaining positions, admitting that there are two separate applicant pools. The inevitable consequence of this type of admission agreement is that less-qualified applicants who are willing to sign a corporate contract will be considered for selection over more qualified applicants who are not interested in a corporate obligation. It is a paradox that such an arrangement promotes the partnership with the company in part for its intention to enhance the overall diversity, and therefore quality, of orthodontists by admitting financially disadvantaged dentists. In fact, it is hard to imagine that any qualified and competitive applicant has been prevented from accepting an offer for specialty training due to financial circumstances. Federal student loans always are available for residents and the combined debt incurred with predoctoral and postgraduate training is easily managed in the lucrative specialty practice of orthodontics following graduation. Another promotion of the partnership is that cheaper orthodontic care will be made available to the local indigent population, a boast that can be made by any orthodontic program. The assertion that the orthodontic graduates that work for the company will provide low-cost care in practice remains to be seen.

Although the ADA Commission on Dental Accreditation has determined that this type of partnership falls within the scope of their standards in terms of following the letter of the law, it has been under dispute whether it falls
Within the spirit of the law (Fox, 2003). It seems apparent that the CDA did not write their rules having imagined this circumstance. Because it is legal and no rules were foreseen to prohibit it does not necessarily make the arrangement ethical or prudent from the standpoint of the dental profession or dental education. The intent of the accreditation standards is to exclude outside entities from influencing the selection, training, or professional opportunities for dental students and residents. It seems that when a business contract is cunningly written to circumvent a strict adherence to the letter of the regulation, it is disingenuous to consider it acceptable to the professional and academic community.

There are two important concerns that this new corporate relationship presents for our profession, one which is financial and practical in nature, and one which is related to the integrity and autonomy of the profession. First, with the academic institutions receiving the company’s funding appearing to be dependent on that ongoing support for program infrastructure for the long term, the possibility of the company’s insolvency or bankruptcy over the thirty-year commitment makes the institution highly vulnerable. Indeed, since the original submission of this manuscript, there is evidence that this fear has been realized (Littlefield, 2006a; 2006b; 2006c; Howard, 2006). The second concern is the precedent this type of corporate-sponsored dental education represents for our profession. If a private, for-profit corporation is permitted to fund an orthodontic program to produce corporate employees, what would keep companies from doing the same for the other dental specialties? Perhaps insurance companies would be interested in funding dental students or residents to produce adequate providers and internal referrals for their own companies.

**Summary**

Academic dental education was created in the U.S. during the nineteenth century within proprietary institutions that had no university affiliation. By the twentieth century, dental schools had become affiliated with higher education, developing autonomy from private enterprise. Unfortunately, public support for higher education has been steadily decreasing since the late 1970s, causing dental education to become increasingly dependent on private revenue sources, including corporate support. The response of dental education to these pressures should include caution as well as creativity and innovation to preserve academic autonomy that is vital to its ethical integrity.

We believe that the recent partnerships with academic institutions by the company described in this article represent not only a significant departure from the way dental education has been funded in the past, but one that is fraught with ethical risks. Corporate involvement in student recruitment and corporate contractual obligations as a requisite for admission both cross a boundary that compromises our basic academic principles. Dental practitioners as well as dental educators and researchers should work together to develop ethical parameters for establishing corporate-academic partnerships that maintain the essential traditional academic values and the independence of our dental schools from excessive commercialism. The profession of dentistry needs to preserve the appropriate autonomy of dental education from commercial influences in order to prevent erosion of academic and ethical standards that are critical to professional integrity and public trust.

**References**


Ethical Reflection in Dentistry: First Steps at the Faculty of Dental Surgery of Toulouse

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Abstract

The goal of this work is to contribute to ethical reflection in the dental profession through the example of a survey of ethical reflection and ethical issues in dentistry conducted at the dental school of Toulouse. A written survey was given to the heads of departments and to the sixth-year students and also to the dental faculty at the hospital dental clinic in order to estimate their level of understanding and concern about these topics.

Since the end of the 1960s and the advent of autonomy for the faculties of dental surgery in France, the teaching of dentistry has evolved significantly in parallel with scientific progress (Hervé, 1998; Hervé & Canoui, 1993). During that period of time, there has been development in the evolution of the reflection about medical topics in relation to dental practice (muscular dystrophy, AIDS). In addition, because the public is better educated, there has been a significant increase in the kinds and quantity of questions and requests for explanations from the patients in our dental surgeries (information on recently developed therapies or the quality of materials used) (Béry, 1996). In these respects, developments in dentistry have paralleled those in medicine. But this is not as true in the case of reflection on issues in ethics.

The most recent medical-legal work on patients’ rights results from the law of March 4, 2002, known as “Kouchner’s Law.” Respect for the autonomy and dignity of the patients constitutes the central theme of this law, which has had the effect of instituting participation, information, and consent relating to medical treatment undertaken. It is a new way for medical practitioners to consider their patients as co-actors of their treatment. This principle of consent was accepted as ethically fundamental in the field of biomedical research from the time of the code of Nuremberg and is now also expressed in the laws pertaining to bioethics. Because of this, it is now firmly established in the daily practice of general medical practitioners as regards care or prevention.

We wanted to raise the question of the role of ethics in the training of oral health professionals and their aptitude to respond to these social requests, and to do so in a rigorous, valid, scientific way that was devoid of any condescending or preconceived attitude. We selected as our research site the Faculty (School) of Dentistry of Toulouse. We wanted to...
learn whether and when this kind of reflection arises in dental practice and whether there might be a possible consensus on various ethical questions in dentistry. We also wanted to see if there were any connections between these matters and current university education in dentistry and the practice of oral health care in the hospital training clinic. To this end, we surveyed, by means of a written survey, the department heads, the students, and some of the teachers of the Faculty of Dentistry of Toulouse. (Toulouse is one of sixteen French dental schools and is part of the second-largest university in France).

**Summary of the Study**
The work was carried out through an investigation involving the students of the sixth year (which is the final year of their dental studies), the university heads of departments, and the dental teachers at the hospital oral health clinic. The quantitative aspect of the results was obtained by using a written questionnaire which made it possible to obtain a large number of responses.

The following results were found with regard to students:
- Fifty-one questionnaires were collected from a group of sixty students, 85% responded.
- A very large positive majority answered the question: “Does the teaching of ethics seem desirable to you”? 88% for, 8% against, 4% without opinion.
- Positive answers to the question “Do the following sets of themes concern ethical issues”? are expressed as percentages in Table 1.

The following results were found with regard to teachers:
- The responses collected did not differ significantly between the heads of department responsible for university education and the hospital clinic teachers. For simplicity, only the answers the hospital-clinic faculty are presented here. These consist of responses from seventeen clinical faculty.
- Eighty-eight percent of the respondents are favorable to the teaching of ethics.
- The attempts to define ethics are similar to the students’ efforts.
- Positive answers to the question “Do the following sets of themes concern ethical questioning”? are expressed as percentages in Table 1.

**Discussion**
There seems to be a very broad consensus in favor of the development of a university program focused on ethical reflection in dentistry. There were, however, no suggestions for how to structure it. The question of the legitimacy of the teachers in charge of this mission was posed, but no suggestions were made about how to address it.

The absence of teaching or continuous training on the topic of ethics undoubtedly explains the hesitations and confusions encountered in the respondents’ attempts to define ethics. However, there were no points missing from the proposals of the students compared with those of the teachers; in fact, some of the students’ responses were more informative. It appears that the few exchanges on ethical questions that do take place during various lessons in the dental curriculum (during sessions on medical rights, medical psychology, etc.) interested the students.

The survey also asked respondents to identify the ethical problems in dentistry. Comparison of answers to this question leads the authors to these remarks.

Agreement appears on the topics of information and consent. Perhaps the dental profession has an advantage on this subject compared to other medical specialties insofar as the conventional obligation to provide a financial estimate for prostheses and other treatments has been a reality in dental practice for many dentists still perceive the formal requirement of informed consent as a constraint and not as the pursuit of the ethical ideal of a decision shared between the dentist and his patient.
It is advisable, however, to insist on the fact that the signed document only gives an illusion of informed consent. The way in which the consent is obtained and what the patient understands and deliberately consents to certainly counts as much as the consent form legally, and is ethically more important. In this connection, however, two problems remain, even regarding financial matters. Many dentists still perceive the formal requirement of informed consent as a constraint and not as the pursuit of the ethical ideal of a decision shared between the dentist and his patient. Therefore, continued evaluation of the information delivered to the patient, the quality of comprehension by the patient, and the manner of this communication is needed. Clearly, even if the informed consent obtained is genuine as far as the financial charges for, for example, a prosthesis, is concerned, there still remains an immense amount of work to be done about the consent concerning all the other types of activities carried out in a dentist’s surgery.

A quarter of all people questioned did not consider the taking into account of pain as an ethical problem. For some, pain still seems to be only a technical problem, solved by treatment. The differences between pain and suffering, physical and psychical, must be carefully studied and incorporated into dentists’ ethical reflections.

Agreement was also general on the ethical importance of questions about access to and exclusion from care. Nevertheless, although the principle and the benefit of the French “Universal Medical Coverage” program are widely affirmed, some imperfections of the system were inevitably underlined. Some respondents also noted that these ethical issues are connected with the question of the possible duties of the patients.

The survey question relating to ethical fees yielded conflicting, even negative opinions. Nevertheless, it seems intimately connected to the preceding question. The question of the ethical justification of remuneration for practitioners also depends on a dialogue with all concerned that would include explaining to the lay participants the complexity of our work as dentists.
The question relating to the dignity and respect of the person demonstrated a consensus. But, with regard to the definition of ethics, there was a lack of precision in respondents’ answers on the meaning of the concept.

Varied answers were obtained on the specifically ethical important of three other points: quality of care, procedural safety and safety of materials. Especially on the first point, respondents identified a link with the matter of fees, not only as a technical matter, but also from an ethical perspective.

Other ethical issues relevant to dental practice did not appear in the results of the survey. But the authors propose that the following issues nevertheless deserve to be addressed. The marketing authorizations of the biomaterials used in dentistry constitute an important ethical subject in themselves. There are also ethical questions related to the consent of patients when such a product is being used by a dentist for the first time (independently of the issue of informed consent, etc., in formal research), especially with the diversity of the products currently available to dentists.

Oral implant surgery has been expanding rapidly in France in recent years. This technique makes it possible to avoid resorting to removable prostheses, which are often badly perceived by patients. The cost is relatively high and the amount covered by health insurance is nil. One teacher mentioned his embarrassment at the idea that the hospital’s dental clinic was not able to offer such treatment for patients who were sometimes young and often socially disadvantaged as well.

The obligation for continuing education is now in place in our profession. But it is still common to hear some practitioners say that it is better to use an older but well-mastered technique rather than a recent poorly assimilated one! Who does that favor: the reassured practitioner or the patient who does not receive the technically most recent care? The principle of equity towards our patients clearly raises a serious ethical question about such a view.

As genetics moves forward, our patients’ susceptibility to certain diseases with oral repercussions is likely to become a source of difficult ethical questions. The impact of our actions on the environment and its protection certainly constitutes an ethical question for dentistry. Proper disposal of waste products (heavy metals in particular) has become a matter for ethical consideration in recent years; but many other environmental issues (ionizing radiations, for example) deserve careful ethical consideration.

Conclusion
Dental ethics has a rightful place within the general field of ethics. Medical ethics does not constitute a separated entity from the practice of medicine. The same follows when applied to dentistry. Dental practice is characterized by a very particular bond between human beings that is structured around the problem of suffering. Thus, training in professional ethics can lead health professionals from a dissymmetric relation to their patients towards more reciprocity and exchanges.

Certainly, one objective of the university, and therefore of the State that supports the university, is to train technically qualified practitioners capable of caring for the population with the greatest possible efficiency. This must be a goal, especially when most dental professionals will be in independent practice, out of the public institutions, for the university that trains them. The quality of the meticulous work carried out by dentists is dependent on the motivation of those who perform it and this motivation depends on the development of the dentist’s self-esteem as a health professional. The presentation of the ethical objective to students, together with a caring attitude towards the other person, is a very much needed part of the dental curriculum. Moreover, the education of dental surgeons as citizens, conscious that the institution has trained them is an institution of the public that entrusts them with a mission of public health, constitutes a priority for dental schools.

This objective will not be achieved without a global view of the only subject of fundamental importance with which the practitioner is faced, namely the person and not just the mouth. Awareness of the social sciences, relevant aspects of psychology, and dental ethics, is the condition for this.

The survey reported on here has demonstrated that the demand for an introduction to dental ethics, if not spontaneous, is nevertheless real and is something supported by both students and teachers. To this end, the authors propose to support and develop ethical reflection with determination within the discipline of dentistry. The next step is to define, in cooperation with our teaching colleagues and dentists in practice outside the academy, all that is at stake in the ethics of dental practice.

Références


Friendly Competition

The growing commercialization of America, and with it all professions, is uncovering some paradoxes. Among the more interesting is the oxymoron “friendly competition.” This will obviously be governed by the “rules of war” and “regulated free market activity.” The Olympic Games are the oldest example that pops into mind. And they were a pungent blend of rest periods in the pattern of internecine strife and individual glory mixed with bribery and scandal.

Why are the great diamond houses of Philadelphia huddled together within a few hundred feet along Sansom Street? The best shopping in London has always been on Bond Street. Silicon Valley is a synonym for high tech. Wall Street means financial institutions and Madison Avenue means advertising. (That we still believe this despite the virtual absence of ad companies on Madison Avenue speaks to the power of the concept of concentrated competition). Cooperative competition, concentration of competitors, conspicuously resembling those seeking the same customers—in a word, “friendly competition”—is the norm and not the exception.

It may not be easy to give a concise definition of friendly competition, but there are certainly common characteristics that typify it. As these characteristic are mentioned, I will give examples from dentistry, since all professions are composed of friendly competitors.

Informal Rules
Some competitive practices are acceptable and others are not. Cabs can pick up fares on the street; livery services can only be engaged by prior arrangement. In most cities, the rules about territory for taxies, street vendors, and union activity are clear and strongly enforced. Dentists are expected to compete based on their personalities, the attractiveness of their office and their staff, location, technical quality, and the profile of services offered. It is frowned upon to compete on price, promised outcomes, or by disparaging colleagues’ work. It is legally actionable to compete based on certain manipulations of insurance contracts or by performing substandard work, even if undetected by the public. Often the rules of competition are explicit. There is a manual for scoring competitive figure skating (which may come as a surprise to some). There are union contracts, practice acts, and codes of ethics. In the professions, ethics codes were first known as “code of professional etiquette,” acknowledging the fact that they spoke primarily to relationships among professionals and not to professional obligations to patients.

Regardless of what might be in print, the rules of friendly competition can never be made completely explicit. There will always be a personal and unspoken (unspeakable) understanding of what is expected. That is why it is critical to participate in organized dentistry. This is also a source of concern over constraint of traded. The Federal Trade Commission sued the California Dental
Association in the 1990s over the CDA’s assertion that its members aspire to high standards. It required years of litigation and the U.S. Supreme Court to affirm the principle that there are valid rules of friendly competition that cannot be made entirely explicit.

**Membership**
Competition generally is open to all comers in the public interest, especially in the United States. The limitations that are set on free-for-all competition concern the relationships between competitors and customers. Friendly competition takes place with voluntary collaboratives such as the trade associations for agricultural or manufacturing groups, collaboratives of universities that vie for the same pools of applicants, groups of community organizations that jostle for limited funding to deliver services to the same underserved and professional groups.

Formal membership in groups that promote friendly competition is based on legal status and rigorous qualifications and on agreement to abide by written rules and codes. Actual membership lists exist. In reality, the boundaries are vague and porous. They can best be understood by observing the pattern of information and interaction. Those that break or bend the rules of friendly competition find themselves on the edge. They do not hear about the new opportunities until they become publicly known; they are not invited to participate in the good deals. In dentistry, those who compete in an unfriendly fashion get few referrals, are kept outside the informal channels where new materials and regulations are discussed, and are not invited to the policy table.

**Concentration**
In friendly competition, there may be skirmishing for who gets the soft seats or how sits in the bow of the boat, but there is also a clear understanding that all will take their turns at rowing and will bail like mad if the water gets too choppy. It is understood that a rising tide benefits all.

Friendly competitors congregate because they recognize that they can win by getting a relatively bigger piece of pie or by making the pie bigger for all competitors. The Magnificent Mile for shopping in Chicago and a Professional Plaza in Anywhere, America, achieve a presence in the public’s mind that scattered individuals cannot. Concentration has the further advantage of enhancing intergroup competitive position. Dentists do not so much compete with each other for the few hundred dollars they are paid per family as they do with appliance stores, vacations, saloons, and sporting events. Dentists do not so much hassle over regulations and acceptable practices with each other as they do with state and federal agencies, consumer advocacy groups, and the uninformed public.
Concentration among friendly competitors is grounded in the belief that there is substantial benefit to coordinated competition between united members of the group in their dealings with other groups.

**Friendly Competition with Gorillas**

My father gave me good advice about learning to play basketball. He suggested that when I went to the YMCA to get into a pickup game, I should first watch the general level of competition in the various games that were going on simultaneously. He said if I wanted to have fun I should pick a game where the general talent level was almost as good as my own. On the other hand, if I wanted to get better I needed to get into games where the play was on a little higher level than my own. Does anyone remember the laughing predictions when it was announced that the AFC was going to play the established, “much stronger” NFC in the Superbowl? Over time, we all compete at the general level of the league we play in. Prudence suggests that we compete with the best.

But what about extremes? Who can compete with Wal-Mart? It is undeniable that Wal-Mart has reorganized much more than the merchandizing of commodities in America. More than 90% of Americans have shopped Wal-Mart in the past twelve months. On food alone, the typical American who shops there saves 15% per year. The presence of a Wal-Mart also stimulates savings generally. If there is a Wal-Mart in town, but you do not buy food there, you save 10% on your annual food bill compared to your counterpart who lives in a town without a Wal-Mart—but there are not many of those. Ninety percent of Americans live within fifteen miles of a Wal-Mart store, and the company employs 1.8 million Americans.

But the effect is greater. Wal-Mart has stimulated innovation in manufacturing, transportation, and inventory control. It has certainly put some firms out of business. But research shows that it is not all bad for competitors. When small players engage in friendly competition with giants they actually do better than previously if they are located near the competitive goliath and if they offer a differentiated product. Whole Foods and other upscale gourmet markets are thriving in the shadow of Wal-Mart. Anybody—tire stores, stationers, and dentists—does better when located near a major draw. That is why radiology services, testing laboratories, and medical equipment rental organizations are found near hospitals. The support services these organizations provide explains why, thinking in the other direction, there are entire buildings devoted to medical and dental services in most large cities.

**Rewards of Friendly Competition**

Why is there so much more high-quality computer software for the Microsoft format than for the Mac (Mac only excels in the tight market for professional grade graphics)? Why is open-source software such as Java worrying Microsoft? Why are Americans better informed about the workings of our government than almost any other country? Why are we overweight? Why are our universities better than our grade schools? Why is American dentistry the best in the world? The answer in each case is a robust system of friendly competition. It benefits customers, suppliers, the public, and the competitors.

**Spillover**

Some knowledge is transferred formally, as in schools or at CE courses. Much knowledge is passed informally, by contact. This is what my father had in mind when he urged that I play with basketball players who were better than I rather than reading books about basketball. We learn as we play and the more we play, the more we learn. Innovations spread most quickly in informal networks (even faster than in formal ones). This is why the hallways and not the lecture rooms at state scientific sessions are the hot places. It is also why dentists who practice in isolation are least likely to be up to date on techniques that work, things to avoid, market and regulatory trends, and reliable information about unfolding political events. There is no effective formal system for furnishing this information to them.

In the technology literature, this is known as the spillover effect. The valuable knowledge and precautions are higher among organizations that interact (and compete) than among isolated similar
organizations. This can only be explained by assuming that benefits spill over and become generally available to all who are close enough to catch it. Lawyers and bail bondsmen congregate in county seats and state capitals and they add to what the legislators can accomplish (I guess). High tech concentrates around major universities in the Silicon Valley, Route 128 near Boston, and outside Seattle. They are there for the spillover.

Innovation

Personally, I believe the best dental practices are disproportionately group practices. That environment encourages discussion concerns, rapid sharing of ideas, consideration of alternatives, and competition against standards. All of this leads to innovation. Good enough cannot long hide from public scrutiny, and the scrutiny of one’s peers is both knowledgeable and apt to be stimulating. Study clubs have served the same function of driving innovation in an atmosphere of supportive competition.

Protected, anticompetitive markets dampen innovation as any dentist knows who lives where he or she can only receive service from one vendor for dental supplies or for the family car. Perhaps the young dentists who are trying to shoulder their way into already saturated suburban markets while avoiding the rural and urban markets know something. The management literature on high-end start-up firms demonstrates that they have a better chance of survival in a highly competitive market than in an underserved one. The reason is that competition forces the innovations that lead to strength. Market share is a small issue compared to market viability.

Customers and Suppliers

Dentists are not alone in confusing price with cost. The fee for a crown is only part of what it sets a patient back to get that care. There is lost work, transportation, child care, and a welter of psychological factors. In some urban areas, the cost of parking is approaching the cost of a prophy. When patients can cluster their health behaviors, they become less daunting, and the patients are more likely to become engaged. Think for a minute how tempting it is to put off shopping for a new lawn mower if there are four stores in town and they are as far away from each other as they can be. All four stores will do better together because customers are more likely to come out.

The same is true of suppliers. In fact, that is why Microsoft whips Mac. Microsoft gives away the knowledge of its operating system to vendors who write software and Mac keeps it to itself. More software for you and me to choose from; more computers (by far) that run on Microsoft. If dentistry appears to be a somewhat homogeneous and accessible market to manufacturers and suppliers, it will receive better support.

Standards

Competition promotes uniformity. Not only is there less difference between the best and the worst when they are in an environment of friendly competition, there is better agreement on acceptable approaches and what constitutes good outcomes. Reasonable uniformity is essential for driving out the uncertainty of economic risk. Patients know enough to stay away from procedures that have not been standardized. (Remember the Sony Beta versus VHS videotape wars.) Suppliers are unwilling to invest in serving markets that are segmented. The ADA even has a council that addresses issues of standards, although progress has been slowed by fear of the insurance industry.

While there are dangers in common standards, the benefits should not be overlooked. Standards that are known in a field protect individuals and organizations by making known which practices are acceptable. This reduces guessing and surprise and offers some protection against arbitrary charges of substandard performance. Standards also speed the diffusion of innovation. It is easier to
recognize an improvement where there are common ways of taking about performance, common methods to comparing outcomes, and less variation among claimed results.

Generally, dentists who avoid friendly competition with each other open themselves to greater risk in their involvement outside the profession. They are less likely to understand both the formal standards and the informal ones (such as the standard of care). What is more, they take a pass on the opportunity to have a hand in crafting standards they prefer.

**The Earth Is Not Flat**

Thomas L. Friedman’s brilliant 2005 best seller affirms that it is. Freidman’s argument is that electronic communication has enabled globalization on such a scale that universal competition is inescapable. When we call with questions about a malfunctioning panarex, the voice on the other end may be in Bangalore, India, or rural Utah. The machine was made with parts from six different countries, but probably not Japan or the United States where the company is headquartered. We will be instructed to ship part of the machine by FedEx for repair. Although the bill comes from the manufacturer, none of their employees have touched it. Contract technicians working on the FedEx air hub in Memphis, Tennessee, actually perform the repairs.

Many experts think Friedman is wrong. Greater interconnectivity and distributed knowledge and productivity do not make the world flat or even homogeneous. The evidence is actually to the contrary; the work is becoming spiky. Two-thirds of the world’s patents still go to the U.S. and Japan. Capital, both financial and intellectual, conglomerates at an increasing rate in about eight centers in the U.S. Fewer people make more important decisions. Even in India, the call centers are not uniformly distributed; they are concentrated in Bangalore.

I am not betting on massively distributed, impersonal, pure competition. The friendly type of competition—complete with its personal understandings that will forever defy electronic capture, concentration of resources, and a delicate balance of innovation and standardization—appears to hold a more promising future.

**Unfriendly Competition**

There are a few things to look out for. Each of the three defining characteristics of friendly competition can be carried to excess, with consequent negative effect. The railroads established high standards that they all abided by for numbers of employees required for each task (in order to “protect the public”). That drove up costs and prevented adaptation to a changing environment. That is a risk all professions face. When membership is made too restrictive, friendly competition suffers. The American Medical Association now represents about 30% of physicians and cannot speak with a clear voice to public issues. Kicking out any member who is swimming against the norm is, at some level, self-defeating.
the group, deviants both resent the way they were handled and no longer recognize the power of the group to sanction them. Concentration of resources can also be exaggerated to the point where innovation is stifled and new recruits no longer feel welcome.

**Defeating versus Destroying**

Friendly competition honors winning the game at the same time it repudiates damaging one’s competitor. Dentists try to work this distinction in offering needed dental care to patients whose former dentist appears to have negligent while avoiding disparaging the previous dentist. Good sportsmanship requires giving the other guy a chance and avoiding any action that will damage a competitor’s capacity to continue effective competition. This means not taking unfair advantage when others are down, not destroying their capacity for future work, and not impugning their reputations.

Friendly competitors want to win the round but not end the game. The goal of the board game Monopoly is not to knock out the opponents. If that were done at the beginning of the game, the winner would only have the resources dealt when the game began and a little more. By continuing to play many rounds, everyone succeeds since the bank adds to the game $200 every time any player passes “go.” In dentistry, it is participation in the profession that matters, not appearing to make more than one’s colleagues.

**The Amazing Mississippi Riverboat Pilot Monopoly**

Riverboat pilots on the Mississippi were highly trained, contentious men, who steered the steamers the entire up-river or down-river passage of an ever-changing and sometimes dangerous journey. Membership in the club was managed loosely by the pilots themselves through an apprenticeship system. Throughout much of the 1850s, pilots earned a princely $250/month. As river traffic, especially the glamour trade increased, the pilots saw an opportunity. They formed and association, entirely voluntary, with a few rules such as a $15 initiation fee, prepaid funerals and relief for widows, prohibition against working with non-association partners (all riverboats had two pilots), and a common wage initially set at $400 a month and eventually reaching about four times that amount. They also established a written system for sharing up-to-date information about the condition of the river that was shared among association members but not among others.

At first, only the poor quality and unemployed pilots joined and they got no work. That would have been the way it remained except for the fact that the market was rapidly expanding. (A boom market does not always favor various forms of friendly competition.) Because the apprenticeship system had purposefully kept the number of pilots low and demand was quickly exceeding supply, captains had no alternative but to replace non-association pilots with pairs of association pilots. Because of the safety information sharing system developed by the association pilots, there were fewer accidents with association pilots, and eventually the insurance companies refused to underwrite riverboats with non-association pilots. All pilots joined, salaries soared, increases were passed through to farmers and travelers, and friendly competition for the best positions turned into joyous competition.

The whole system collapsed within about a year. Someone figured out that freight could be taken down the Mississippi on cheap rafts guided by tugs (little freight went up) and passengers came to prefer the faster, less expensive, and more direct and flexible train. The Civil War shipwrecked what was left of the pilots’ glory.
Multiple Games

We participate in many games at the same time. Some run the marathon for the fastest time (or at least for a time fast enough to satisfy corporate sponsors). Some are trying for a personal best. Others just want to finish. Many are thrilled to be there and be noticed. Friendly competition allows for multiple rules in a single game. It is a strength in a profession such as dentistry that there are multiple standards for success (laying aside, of course, irreducible minimal standards for being in the game). Thank goodness the specialist, the director of a clinic on an Indian reservation, the small-town dentist and the downtown dentist, the practitioner who is driven to show a slide of a brilliant eight-unit reconstruction, and the practitioner who puts back together a ravaged mouth as well as possible without hope of adequate compensation can all be part of dentistry.

What is unacceptable in friendly competition is to play by private rules or to damage others’ chances for success by doing things the group as a whole would not approve of. That is called cheating. Cheats do not stay out of the game as they play, but they expect to use private rules that favor them.

The Problem of Change

Friendly competition is conflicted over the matter of innovation. The characteristics of concentration (standards, progress, and access to customers and suppliers) and membership provide context that promotes innovation. When

Abuses of the Rules of Friendly Competition

<table>
<thead>
<tr>
<th>Cheating</th>
<th>Free ride</th>
<th>Selective Application</th>
<th>Bundling</th>
<th>Partial Monopoly</th>
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<tr>
<td>Attempting to gain advantage by actions that are against the rules while disguising the act and hoping not to get caught</td>
<td>Claiming the benefits of group membership without accepting the responsibilities</td>
<td>Using a subset of rules that favors oneself or disadvantages others</td>
<td>Grouping common, high profit tasks with rare specialized ones</td>
<td>Excluding other providers for whole market but only serving part of it</td>
</tr>
<tr>
<td>Overtreating; practicing without a license</td>
<td>Advertising as an unrecognized specialty; avoiding organized dentistry</td>
<td>Upcoding insurance claims</td>
<td>Preventing auxiliaries from offering partial services</td>
<td>Practices that exclude classes of patients</td>
</tr>
</tbody>
</table>
professionals gather at state and other association meetings they celebrate what is new and promising, and the pride is personal as well as attached to the innovator. At the same time, friendly competitors close ranks quickly against some kinds of changes. Don’t expect, for example, the car industry to come out with a truly fuel efficient and long lasting automobile anytime soon. And look for more features you don’t use on your laptop before you see any dramatic increases in reliability or reductions in cost.

The seeming paradox can be unraveled by distinguishing between incremental innovation and disruptive innovation. Friendly competition is designed to promote enhancements within a market; not to create new markets. Potential innovations will be embraced, more or less, as they are seen as offering potential to the majority of those already in the friendly competition group. If they are recognized as creating new rules of competition, this signals that new players will gain advantage.

The movie industry wants higher definition in visuals and sound to enhance the theater experience, but not miniaturization that would vastly extend entertainment. Where did the public phone booth go, or the travel agent? What about the independent pharmacist? Friendly competition is about gradual expansions of the market using better examples of existing technology. Much attention goes into deciding which forms of competition are acceptable and which should be forbidden. The use of auxiliaries in dentistry (embraced in orthodontists’ offices and nursing homes and reviled in other contexts) is less a matter of health benefit than market integrity.

**Competition is Good**

Dentistry understands friendly competition and performs well under its sway. Friendly competition has been good for the profession in terms of promoting reasonable innovation, raising the standards of oral health, ensuring a strong form of self-regulation, and elevating the dignity of the profession in the eyes of the public and patients. This is a legacy that organized dentistry and the honoraries such as the American College of Dentists have worked hard to build, and it should not be allowed to erode or molder through ill-advised action or neglect.

That said, there are other forms of competition that must be understood and mastered. There are three issues that will define the future of the profession over the next quarter century. The current generation of leadership will have a hand in framing the debate, but those just entering practice now will be the decision makers. These issues are the role that the new biology will play in dental care delivery, access, and commercialism. I confidently predict that all three issues are outside the realm of friendly competition. ■

Competition is defined as participation in activities where one or a few succeed at the expense of others. Social science evidence and logical argument are used to show that competition reduces productivity and enjoyment, causes overall loss of self-esteem, and poisons our relationships with others. It is argued that competition is not an inevitable manifestation of human nature, but a social construct and an individual habit learned through social reward.


Although knowledge spillover (availability of useful information about the industry to competitive organizations in close geographic proximity or with whom there are frequent interactions) benefits members of an industry or group or organizations generally, different kinds of potential spillover are managed differently. Formal relations (licenses and contracts) dominate where spillover could be widely beneficial. When reputation is involved [as in the professions], there is pressure to avoid subcontractors and seek to extend control of employees who might learn valuable information.


A true classic. Many MBA students are familiar with the seminal concepts of generic competitive strategies, industry life-cycles, buyer selection and strategic groups without realizing that one man introduced them together in a single book. The outline structure of the text is easy to follow and the writing is crystal clear. This is a combination of economics, marketing, and business strategy. It explains how firms work.


“The performance of any company in a business can be divided into two parts: the first attributable to the average performance of all competitors in its industry and the second to whether the company is an above- or below-average performer in its industry” Porter makes a strong argument for the advantage of industry cooperation and geographic concentration. He also presents an unusual case that government efforts directed toward urban revitalization are self-defeating and renewal can only be achieved by an economic engine.


The story about the botched attempt of riverboat pilots to create a monopoly.