

Unconventional Dentistry: Part III. Legal and Regulatory Issues

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A b s t r a c t

This is the third in a series of 5 articles providing a contemporary overview and introduction to unconventional dentistry (UD) and its correlation to unconventional medicine (UM). UD presents issues of dental quackery, fraud and malpractice, and it also engenders professional concerns about public protection and professional risks. Case reports illustrate numerous issues. The reader is encouraged to evaluate the cases for problems related to malpractice, fraud, ethics, behaviours and professionalism. A discussion of ethical issues is beyond the scope of this paper.

MeSH Key Words: alternative medicine; dentistry; dentists/standards

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Case 1

A healthy 42-year-old woman presented to her general dentist with pain in the maxillary left quadrant. The dentist had provided general, preventive and cosmetic dental services to the patient's satisfaction for 2 years, and the patient liked the dentist's "amalgam-free" and "no unnecessary x-ray" dental philosophy. An abscessed maxillary tooth that had been endodontically treated by the dentist 3 months prior was diagnosed. Extraction was recommended, and the patient agreed. Before the procedure, the dentist gave instructions for an anti-inflammatory protocol before dental surgery to "prevent inflammation, swelling and pain, stimulate blood clotting and healing, prevent bruising and pain and... stimulate the body's immune system to prevent infections." Products were sold to the patient by the dentist, including a product composed of echinacea root extract (*Echinacea angustolia*), l-lysine, blue flag extract (*Iris versicolor*), and goldenseal root extract (*Hydrastis canadensis*). *Arnica montana* composé, a homeopathic herbal remedy, and others were also provided.

After the dental extraction, the patient was prescribed acetaminophen with codeine and instructed to continue the protocol medications. The patient experienced considerable pain after the extraction and 2 days later telephoned about the development of swelling under the left mandible. The dentist reportedly advised that this was "probably lymph nodes as the immune system kicks in," and recommended continuing the protocol medications.

Four days after the maxillary tooth extraction, the patient returned to the dentist with increasing left submandibular pain and swelling. The dentist advised the patient to eat active-

culture yogurt and expect improvement within 24 hours. The next day, the patient consulted her family physician. Infection was diagnosed, penicillin prescribed, and the patient referred to an otolaryngologist. Six days after the extraction, the patient was admitted as an emergency to the hospital with a diagnosis, confirmed by CT scan, of left submandibular abscess. An extraoral incision and drainage procedure was performed. The patient recovered uneventfully, and was discharged after 5 days of hospitalization. Further evaluation identified periapical infection of the mandibular left first molar to be the cause of the abscess, and successful endodontic treatment was performed.

The dentist did not obtain mandibular dentition radiographs. *Arnica montana* has been studied in dental extraction cases and found to give rise to greater pain and swelling than placebo¹ and to offer no benefit for pain, trismus, swelling or bleeding after extractions.² A lawsuit was settled out of court.

Case 2

An 81-year-old woman with a medical diagnosis of Alzheimer's disease was seen for routine care by a general dentist. A variety of non-specific symptoms were described, but no pain was complained of or identified. Periapical and panoramic radiographs were obtained and the dentist diagnosed neuralgia inducing cavitation osteonecrosis (NICO) — jawbone cavities — based on the radiographs. Subsequently, over a 3-month period, 4 surgical procedures were performed on 5 sites in 4 quadrants, with allogeneic bone placed in the surgical wounds and a collagen membrane placed

in one site. The dentist reported finding large NICO lesions in all areas, and specimens were accumulated and sent in one batch to a laboratory that was "the only laboratory that could diagnose NICO." All specimens were reported as NICO.

Two oral radiology specialists found no evidence of any bone lesions on the radiographs. The dentist justified the use of bone grafting and membrane techniques because similar procedures were "used in implantology" and because of the expectation that NICO bone cavities would not heal. The subject of NICO was not taught in the dentist's dental school. It was taught at a weekend course at a resort hotel. The literature provided at the course was the only information the dentist was aware of. The dentist reported treating between 10 and 100 cases of NICO after taking the course, with 100% diagnostic accuracy.

The dentist stated that infected jawbone cavities were the cause of facial pain, heart disease, arthritis and other systemic problems. The dentist belonged to an organization that claimed to cure these problems by scraping out jawbone cavities. The organization also supported the concept that all endodontically treated and vital teeth in a cavitation area should be removed. A pertinent case was documented in an investigative report;³ the suit involving a dentist was settled for "a substantial sum."⁴

Case 3

A 50-year-old woman presented with left cheek pain and swelling and difficulty sleeping. She reported that the pain and swelling were eased by herbal remedies. The patient related a 15-year-history of symptoms that started with left jaw and face pain and limited mouth opening. Eagle's syndrome was initially diagnosed by an oral and maxillofacial surgeon, who excised the left styloid process without symptom relief.

A prosthodontist diagnosed TMJ and provided a nighttime splint, which relieved symptoms when used. The prosthodontist then advised reconstructing the bite. Over a 4-year period, 24 crowns and 14 root canal procedures were performed. Multiple symptoms persisted and changed during the treatments, and an endodontist retreated several root canals and performed apical surgery. Overfilling was noted in 2 maxillary molars, and with persisting maxillary symptoms, a Caldwell-Luc procedure was performed by an oral and maxillofacial surgeon to explore the molar roots and remove the endodontic material. Symptoms persisted.

The patient was eventually seen at a university-based TMJ clinic, where diagnostic local anesthetic blocks did not fully relieve the pain. A bone biopsy was performed, and an oral pathologist reported normal bone. The TMJ clinic found no temporomandibular joint abnormality and clinically normal occlusion. One year after completing the dental reconstruction, the patient moved and came under the care of a general practising dentist ("TMJ specialist") who diagnosed neuromuscular dysfunction using surface electromyography and electronic jaw-tracking instruments. Bite-"repositioning" devices were provided for 24-hour use. Symptoms persisted.

During a 15-year-period of oral and facial pain and dental treatments, the patient saw a family physician, a specialist in internal medicine, a psychologist, 2 neurologists, a neurosurgeon and an otolaryngologist, all of whom offered diagnoses equating to muscle pain, anxiety, depression and probable neuropathic pain, with no neurologic abnormality or underlying systemic disease. The patient used numerous herbal and other remedies without satisfaction and consulted a physician in an alternative medicine clinic in Mexico, who diagnosed neuralgia. All of the non-dental practitioners recommended medical management and advised against dental treatments.

After mutispecialty pain evaluation, the patient was diagnosed with chronic pain disorder, mild depression, probable prior TMD consisting of myofascial pain and dysfunction, neuropathic pain with hyperalgesia and allodynia and iatrogenic malocclusion. No significant psychiatric disorder was found. The patient had rampant decay and a bilateral posterior open bite relationship related to the bite-altering appliance, which she depended on for chewing function. Recommendations were made for participation in cognitive and behavioural management within a multidisciplinary pain management program. Cost estimates to re-establish a functional occlusion and dentition were between \$30,000 and \$40,000. Estimated costs of medical management were similar.

The patient explained that, although she had submitted to numerous dental treatments that were not helpful and she received consistent medical advice against dental procedures, she believed in a dental diagnosis and she preferred the dentists' advice. The patient related her belief that her symptoms were dental and indicated her desire for additional dental treatments with extractions and implants.

Case 4

A 56-year-old man was referred for assessment of a white lesion in the left cheek. The lesion was biopsied and diagnosed as moderate dysplasia. Excision was recommended, but the patient attended a naturopathic physician who recommended supplements and advised that surgery was unnecessary. The patient returned after 6 months, and the lesion had increased in size and extended to the gingival margin. Intervention was refused. Six months later the patient presented with a persisting lesion with a more irregular appearance. A biopsy diagnosed an invasive carcinoma that was managed by local resection and post-surgery radiation therapy.

Quackery, Fraud and Malpractice

Quackery has been defined as "the fraudulent misrepresentation of one's ability and experience in the diagnosis and treatment of disease or of the effects to be achieved by the treatment offered."⁵ For dentists, physicians and laypeople, quackery may be broadly defined as "anything involving over-promotion in the field of health."⁶ This definition would include dubious ideas, products and services regardless of the promoters' sincerity.

Unproven methods, ideas and services may be experimental rather than quackery. Unproven methods require formal scientific study and the informed consent of patients to qualify as experimental rather than quackery. Dubious methods can be harmful physically, psychologically, emotionally and financially because of the treatment itself, because of the delay or failure to get treatment that might be helpful, or because of the resultant confusion.⁷ Quackery is also harmful in diminishing public confidence in science, medicine and dentistry, perverting science and public health and feeding a degeneration in professional ethics.

Health fraud is the deceptive promotion, advertisement, distribution or sale of a service, product or remedy for diagnosis, prevention, cure, treatment or mitigation of a disease (or other condition) or for the provision of a beneficial effect on health but which has not been scientifically proven safe and effective for such purpose.⁸ The term "fraud" usually implies intentional deception, without belief in the truth of the representation or, recklessly, without regard for the truth.⁹ Additionally, a practice promoted without adequate knowledge or understanding, notwithstanding sincere belief, may be considered fraud.⁸ Fraud is difficult to prove in court.

Malpractice means failing to meet the accepted standard of practice; it is the degree of skill and knowledge that would be expected of any reasonable provider in the profession under similar circumstances. Courts decide the standard of care for individual cases. Standards of practice in medicine and dentistry ideally reflect scientific knowledge and science-based methods. Licensed unconventional practitioners such as naturopathic physicians, chiropractors and massage therapists are judged by standards of practice in their professions, which may or may not be science-based. Non-licensed, unregulated practitioners such as herbalists, therapeutic touch practitioners and reflexologists do not possess any recognized school-specific standards and may be judged by lay standards that are difficult to define, assess and quantify.¹⁰

Quackery can overlap malpractice, and malpractice may not involve quackery. As examples, injuring the mandibular nerve while extracting an impacted mandibular third molar without warning the patient in advance may be malpractice, but is not quackery. Dental splints are used for preventing habit-related tooth wear, but promoting or using dental splints to cure dysmenorrhea may be quackery. To make matters more confusing, recommending homeopathic medication to prevent infection and swelling may be the standard of practice for naturopathy but might be quackery and malpractice for a dentist or physician.

Recent malpractice claim data for chiropractors, massage therapists and acupuncturists in the United States show less frequent claims and less severe injuries than for physicians.¹⁰ The most prevalent unconventional medicine (UM) cases currently in the Canadian court system involve chiropractors.¹¹ There appears to be a disproportionately small awareness of regulatory, disciplinary and legal cases involving unconventional dentistry (UD). With the growing emphasis in dentistry on evidence-based care and scientific standards of

care, licensed dentists practising UD may be more likely to be judged negligent in a claim.

Public Protection

Organizations entrusted to protect the public may not judge particular treatments because of legal concerns. Products may be subject to objective testing and approved for safety, unrelated to their validity or effectiveness in diagnosing or treating disorders. In both science and law, the responsibility for establishing the validity of a treatment, its efficacy and its safety rests with the promoter.

Diagnosing and managing temporomandibular disorders (TMD) provides an example of the problems with promoting unconventional methods while protecting the public. Based on scientific criteria and research, various electronic instruments have been found to lack theoretical validity, to have poor measurement validity and to have diagnostic validity worse than chance when used in the diagnosis or management of TMD.¹² In the scientific literature, these devices are considered inappropriate for such uses.^{12,13} Some of these devices have been granted the American Dental Association Seal of Acceptance "only as aids in the diagnosis of TMD."¹⁴ The disclaimer that "responsibility for proper selection of patients for diagnostic tests and the interpretation of results rests with the dentist"¹⁴ may give the erroneous impression that approved electronic devices have scientific merit, in spite of the U.S. Food and Drug Administration conclusions that these devices are not effective for diagnosis and that they often lead to overdiagnosis and unnecessary treatment.¹⁵

Health claims (e.g., "cures cancer") by promoters may be closely scrutinized by governmental agencies, but structural or functional claims (e.g., "boosts the immune system") may be meaningless and require very little evidence to comply with the law. Many unconventional products are promoted as "nutritional" and therefore do not require regulatory scrutiny comparable to medications. (See Part IV in a forthcoming issue for more specific discussion.) The activities, responsibilities, limitations and legal concerns of both governmental and professional bodies are not generally understood and add to the public's confusion.

Dental Quackery

Dental quackery, here considered as overpromotion of false or unproven health claims in dentistry for profit (including questionable ideas, products and services), is of concern to the profession.^{8,16,17} The history of dental quackery parallels that of medical quackery^{17,18} and shows the development of a particular language. The common use of semantic tricks such as "doublespeak" (improper use of words, thereby perverting communication in order to mislead, distort, deceive or circumvent), pseudomedical jargon (empty, impossible-to-measure terms) and "weasel words" (leading to accept as truth things that have only been implied or suggested) are often associated with the promotion of UD.¹⁹ Product advertising has risen to an art form of semantic deception.

In addition to an array of unproven inventions and misleading language, old concepts are recycled and reformulated in the promotion of dental quackery. An example is this dubious and unsupported claim: "Research ... demonstrated not only that root canal teeth always remain infected, but that these same teeth contribute to a number of degenerative diseases."²⁰ The association of dental infection with systemic disease (focal infection theory) is of continuing research interest, although there is no scientific evidence of a cause-and-effect relationship.^{21,22}

Lessons

Dentistry involves physical procedures with inherent risks of complications, thus inviting increased litigation. The cases described should be of concern to all dentists. Professional liability law on UM and UD is still developing.^{11,23} Published cases involving UD are rare, but UM case law is growing.

Dental regulatory authorities are concerned about the increasing numbers of complaints about unconventional care issues ranging from fees to patient harm. In Alberta, registered physicians who practice UM ("complementary health care therapy") are required to register with the College of Physicians and Surgeons for approval to practice UM,²⁴ and detailed practice guidelines for UM have been formulated. To the author's knowledge, there is no jurisdiction in North America regulating UD performed by dentists. ♦

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