MARTIN CLEARWATER & BELL LLP

DEFENSE PRACTICE UPDATE

SUMMER 2010

DEFENDING A LACK OF INFORMED CONSENT CLAIM IN MINI-DENTAL IMPLANT SURGERY

BY: JEFFREY A. SHOR AND RYAN M. DONIHUE

Since the 1940s and 1950s, practitioners have utilized endosseous implants to provide functional support and esthetic enhancement for their patients. A particular advancement in implants has been the use of mini-dental implants ("MDI") for single and multiple tooth replacement. MDI were initially used in various forms for transitional and provisional purposes, but it has been subsequently established that these implants achieved osseo-integration. Since mini-dental implants obtained United States Food and Drug Administration approval in 1999 for a patient's ongoing and long-term use, there has been a significant increase in the number of MDI surgeries performed.

In addition to easier placement than traditional endosseous implants, the patient benefits of MDI are known to include reduced bleeding, placement into narrow ridges, immediate loading, decreased post-operative discomfort and shortened healing time.

Although there are clear benefits to using MDIs, there are contraindications, including current local infection, vascular impairment, uncontrolled diabetes, chronic high doses of steroids, clotting disorders, current anticoagulant therapy, metabolic bone disease, and other metabolic or systemic disorders that would affect bone or wound healing. Complications associated with MDI placement include infection, closure failure, abscess formation, bone loss, soft tissue irregularities, implant failure and fractures due to excessive loading and placement of the MDI in patients with an inadequate amount of bone.

OBTAINING INFORMED CONSENT PRIOR TO MDI SURGERY

An MDI dental malpractice case frequently involves two claims for the jury to decide: (i) whether the practitioner departed from the standard of care prior to, during and/or after the MDI surgery and, as a result, caused injury to the patient; and (ii) whether the practitioner failed to secure the necessary and proper

DEFENDING A LACK OF... *Continued on page 2*

informed consent from the patient prior to performing the MDI surgery and the lack of informed consent was a proximate cause of the patient's injury. Given that these are two separate and distinct causes of action, a jury could find that the practitioner conformed to the standard of care during the course of the MDI surgery, and yet still award the patient damages after determining the patient was not fully informed by the practitioner of the risks, benefits and alternatives to the surgery.

In order to understand the legal importance of obtaining informed consent from a patient prior to performing MDI surgery, an examination of the statutory provision addressing the cause of action for the practitioner's alleged lack of informed consent in New York State must be made.

In New York, a patient's cause of action for lack of informed consent in a dental malpractice action arises from Public Health Law § 2805-d. Specifically, Public Health Law § 2805-d(1) defines lack of informed consent as:

> ...the failure of the person providing the professional treatment or diagnosis to disclose to the patient such alternatives thereto and the reasonably foreseeable risks and benefits involved as a reasonable...dental...practitioner under similar circumstances would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation.

Public Health Law § 2805-d(2) outlines when a plaintiff has a viable cause of action for lack of informed consent against the practitioner. The provision states:

> The right of action to recover for... dental... malpractice based on a lack of informed consent is limited to those cases involving either (a) nonemergency treatment, procedure or surgery, or (b) a diagnostic procedure which involved invasion or disruption of the integrity of the body.

Finally, Public Health Law § 2805-d(3) establishes the quantum of proof necessary on a claim brought pursuant to Public Health Law § 2805-d and provides that:

> For a cause of action, therefore, it must also be established that a reasonably prudent person in the patient's position would not have undergone the treatment or diagnosis if he had been fully informed and that the lack of informed consent is a proximate cause of the injury or condition for which recovery is sought.

New York Courts have determined that a patient can maintain a cause of action for lack of informed consent in implant surgery cases.[1][2][3] Because MDI placement is a "non-emergent" surgery, the practitioner must obtain informed consent from the patient prior to performing the surgery. Specifically, in accordance with Public Health Law § 2805-d(1), the practitioner is required to discuss with the patient, at a minimum, the alternatives, "foreseeable" risks, and benefits of the MDI placement and surgery.

While a practitioner may believe that having the patient consent to MDI surgery on the day it is performed is sufficient, a jury will frequently find to the contrary. An informed consent discussion as early as the initial consultation provides the patient with a period of time to truly form a rational decision based on the information provided by the practitioner. Furthermore, having the discussion with the patient at such an early stage allows the jury to understand that the patient was provided the opportunity to fully commit to the placement of the MDI and surgery, thereby contradicting the patient's claim at trial that he was under duress, coerced or not afforded proper time or sufficient information when he agreed to the procedure.

The informed consent discussion with the patient should not be a boilerplate lecture by the practitioner of all of the risks, benefits and alternatives associated with the MDI and surgery. Rather, the practitioner should be fully aware of the patient's medical and dental history and be prepared to tailor the conversation to that particular patient. For example, if the patient has a history of a clotting disorder or unique amount of bleeding during the performance of an extraction, the practitioner will inform the patient that while MDI surgery has a reduced rate of bleeding, there is an increased and foreseeable risk that she/he may experience excessive bleeding during and after the surgery due to the patient's prior history. While the discussion is oriented toward the particular

1 Iazzetta v. Vincenzi, 200 A.D. 2d 209 (3d Dept. 1994)

2 Block v. Singh, 2009 N.Y. Misc. LEXIS 5101 (Sup. Ct. NY 2009)

3 Torres v. Stolzenberg, 2010 N.Y. Misc. LEXIS (Sup. Ct. NY 2010)

The conversation addressing alternative courses of treatment also must be specific and reasonable for that particular patient.

patient, the practitioner cannot forego informing the patient of the most commonly experienced and foreseeable risks associated with MDI placement and surgery. Specifically, the practitioner must communicate to the patient that infection, abscesses and fistulas can develop post-operatively; there may be difficultly with closure of the tissue at the location of the implant and surrounding surgical site; loss of bone at the implant site; the possibility of injury to adjacent teeth; and, most importantly, that the MDI could fail despite successful placement.

In addition to addressing the particular risks associated with MDI and surgery, the patient must be informed of the benefits and alternative treatment options to MDI placement. With regard to the benefits of the MDI, the conversation should again be directed to the particular reason for selecting MDI placement, rather than the traditional implant or any other treatment option available to the patient. Additionally, the practitioner should advise the patient that the known benefits of MDI include reduced bleeding during and after the surgery; immediate loading of the implant; decreased post-operative discomfort; shortened post-operative healing time; and increased survival rate of the MDI. The practitioner must also advise the patient as to the alternatives of placing MDI, which would include rendering no treatment at all. The conversation addressing alternative courses of treatment also must be specific and reasonable for that particular patient. For example, the patient may be a candidate for a partial porcelain prosthesis (while another patient would not benefit from that prosthesis) and this treatment alternative should be provided to the patient and discussed by the practitioner. The purpose of providing the patient with the benefits of the MDI placement and the availability of other treatment options is to permit the patient, not the practitioner, to make a fully informed decision as to the dental treatment that will be performed on her/his mouth.

Finally, it is advisable that the practitioner end the informed consent discussion by asking the patient whether she/he has any questions concerning the risks and benefits of the MDI placement and surgery or alternative treatment options that were discussed. This permits the patient to inquire regarding anything she/he did not understand during the conversation; address concerns that she/he may have regarding MDI, performance of the surgery or alternative courses of dental treatment; and feel like an active participant in the patient-dentist relationship.

INFORMED CONSENT DOCUMENTATION

While there is no particular requirement under Public Health Law § 2805-d that the informed consent discussion be documented in the office records or a separate "Informed Consent" form executed by the patient, such documentation should prevent the patient from denying at trial that the informed consent discussion took place.

The American Dental Association, professional dental societies, and most insurance companies have "Informed Consent" forms which can be utilized by the practitioner to document the fact and actual content of the conversation with the patient. Although these forms are typically generic, "fill-in-the-blank" forms, tailoring the form to reflect the type of procedure to be performed, the general and specific risks, the benefits and alternative treatment options discussed with the patient are preferable. Both the practitioner and the patient should sign and date the Informed Consent form, thereby reflecting that the detailed conversation occurred; that the patient was informed as to the risks, benefits and alternative treatment of MDI placement and surgery; and that all questions were asked and answered by the practitioner. Moreover, having a witness, such as a member of the office staff, execute the form at the time

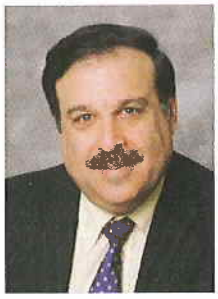
DEFENDING A LACK OF... *Continued on page 4*

Defending a Lack of Informed Consent Claim in Mini-Dental Implant Surgery

Continued from page 3

it is signed by the practitioner and the patient, gives the defense attorney a distinct advantage at trial. Once the Informed Consent form is complete, it should be placed in the patient's chart and an entry should also be made reflecting that the patient executed the form after a discussion pertaining to the risks, benefits and alternative treatments and all questions by the patient having been fully answered.

By practicing defensive medicine as early as the initial consultation, engaging in a full discussion and obtaining an informed consent from the patient, the practitioner has now set a precedent which will follow throughout the MDI surgery and post-operative care and treatment. With the adoption of these measures, the practitioner is afforded the best defense to a lack of informed consent cause of action, and the practitioner has further strengthened the patient-dentist relationship crucial to good care.



JEFFREY A. SHOR

Jeffrey A. Shor is a Senior Partner at Martin Clearwater & Bell LLP, whose practice encompasses all areas of medical and dental malpractice defense as well as the defense of professional liability actions. His case representation has been noted in *New York Magazine* and he is a frequently requested lecturer before various physician groups, professional liability insurance companies and major area teaching hospitals.

RYAN M. DONIHUE

Ryan M. Donihue is a Partner at Martin Clearwater & Bell LLP. He focuses his practice on the defense of dentists, physicians, hospitals and laboratories in medical malpractice litigation and other health care issues. He also represents health care professionals in professional disciplinary proceedings. Mr. Donihue has lectured on the defense of medical malpractice actions to health care professionals

Electronic Discovery and Your Practice

BY: GREGORY J. RADOMISLI AND NANCY J. BLOCK

Our world has changed greatly in the past ten years. E-mail, voicemail, computers, laptops, PDAs, BlackBerrys, MP3 players, cell phones, digital cameras, instant messaging – and the list continues. All are a part of our everyday world. All are designed to make our professional and personal lives a bit easier -- everything and everyone at your fingertips in an instant. But is there a price for such convenience? When it comes to litigation and discovery, there may be a very real and very significant financial cost.

Many of us enjoy these devices, as they allow us to offer immediate feedback and we can take pride in our responsiveness. Often, quick feedback is prioritized over accuracy. Likewise, as these devices are mostly utilized in private, it may be assumed that comments, suggestions and even playful give-and-take will remain confidential. This is not the case and cavalier attitudes should be tempered.

Now, in many cases, electronically stored information (ESI) is as discoverable as the patient's paper chart. It is, therefore, imperative that all potentially relevant electronic information be preserved as soon as litigation is reasonably anticipated. As Judge Shira Scheindlin stated in her most recent opinion on electronic discovery, "In the era where vast amounts of electronic information is available for review, discovery in certain cases has become increasingly complex and expensive. Courts cannot and do not expect that any party can meet a standard of perfection. Nonetheless, the courts have a right to expect that litigants and counsel will take the necessary steps to ensure that relevant records are preserved when litigation is reasonably anticipated, and that such records are collected, reviewed, and produced to the opposing party." *The Pension Committee of the University of Montreal Pension Plan, v. Banc of America Securities,* 2010 U.S. Dist. LEXIS 1839.

Thus, it is critical that when litigation is reasonably anticipated, all steps are taken to preserve all relevant electronic data. A Litigation Hold Notice should be immediately issued and directed to all practitioners and staff who are potentially involved. Judge Scheindlin reminds us of the harsh consequences for failing to preserve potentially relevant electronic information when she adds in her decision, "The duty to preserve means what it says and that a failure to preserve records – paper or electronic – and to search in the right place for those records, will inevitably result in the spoliation of evidence." *The Pension Committee, supra.*

It is also important to consider what electronic information, at minimum, must be preserved. Electronically stored information includes, but is not limited to, patient electronic medical records and radiology images stored on a computer, but may also include e-mail to/from the patient, e-mail to/from other medical providers about the patient, electronic calendars showing patient appointments, and so forth. The scope of what can be considered relevant electronic information is therefore much broader than "old fashioned" medical records, and includes a lot of documentation that might not ordinarily be considered part of a patient's "chart." Practitioners should be cautioned that this electronic information may be accessible even years later and is more than likely subject to disclosure in a malpractice suit. Thus, electronic communication to patients and colleagues should be as thoughtful as the entries in the patient's paper chart.

POTENTIAL PITFALLS IN ELECTRONIC MEDICAL RECORDS

Not only must records be preserved, but when producing electronic medical records, a healthcare provider must be aware that they are also producing data which would indicate whether a patient's records have been changed or whether entries have been amended. In contrast to paper records, where one might cross out a word and write "error," a party reviewing the hard copy printout of an electronic medical chart will not necessarily know that there was a change in the record unless the computer data is accessed. Moreover, the notes in some medical records may indicate "amended" or "revised," but only the most recent version of the note will be printed in hard copy. Those notations will inevitably tip off plaintiffs' attorneys to ask for that earlier information. Given that metadata (data about data) can show who did what, when and where, producing the electronic data will allow plaintiffs' attorneys to determine the number of times the note has been changed or amended, when the notes were changed or amended (e.g., several days later or an hour later), particularly in relation to what events occurred between the times the notes were amended, and where the notes were amended (if changes were made from home through an outside non-work affiliated remote connection, for example, plaintiffs' attor-

ELECTRONIC DISCOVERY... *Continued on page 6*

Continued from page 5

neys could request discovery of the healthcare provider's personal computer).

Significantly, when responding to such a request, the healthcare provider may not just have to produce the computer data for the amended notes, but may also have to produce the computer data for the entire record to be sure that no other changes were made.

Generally, when a physician, nurse, or other healthcare provider at a hospital accesses a patient's electronic records, that person will have to identify themself and there will be electronic data indicating that the person looked at the patient's records, even if the individual did not make a note in those records. That data may establish that the physician was either on the premises—or not; what other healthcare providers were aware of the patient's condition and what steps, if any, those healthcare providers took; what other healthcare providers were involved with the patient even if they did not make a note in the chart; whether protocols were followed (e.g., if a nurse has to check on a patient and make a note every 15 minutes); and how much of a patient's prior records were reviewed before treatment. In that regard, it will be easier to show when a healthcare provider failed to access a patient's history, and thereby would be vulnerable to the allegation that she did not consider the patient's history when evaluating and treating the patient. Conversely, it will be easier to defend that allegation if the electronic records demonstrate that a physician did access the patient's chart.

With the advent of electronic records, often institutions utilize "templates" which direct the practitioner through the completion of a note. This could make it look like a healthcare provider is "going through the motions," rather than actually assessing the patient's condition. Moreover, some electronic medical records will have "drop down menus" from which options can be chosen. Those options may be limited, forcing the healthcare provider to pick the closest answer instead of exactly what is needed. Furthermore, the healthcare provider could make a mistake when making a selection, thus erroneously documenting the chart. Similarly, it is much easier to "cut and paste" electronic records, so errors in the medical record, such as an incorrect history, will be carried over repeatedly. Again, care should be taken when creating electronic records.

For centuries, it has been noted that while progress can increase productivity, it is not without its perils. As healthcare providers increasingly make the transition from paper to electronic records, they should be aware that convenience may have a cost. Nevertheless, with proper preservation and understanding as to potential discoverability of electronic information, those costs can be alleviated.

GREGORY J. RADOMISLI

Gregory J. Radomisli is a Partner with Martin Clearwater & Bell LLP and focuses his practice on all aspects of medical, psychiatric and legal malpractice defense, as well as civil rights defense and nursing home defense. Mr. Radomisli has written on the topic of electronic discovery, and has given presentations on the particular issues electronic discovery presents in light of the burgeoning transition healthcare providers are making to electronic medical records, including at the Master's Conference in Washington, DC.

NANCY J. BLOCK

Nancy J. Block is a Partner with Martin Clearwater & Bell LLP. Her practice encompasses all aspects of medical malpractice litigation from inception through trail. She has defended some of the firm's largest hospital clients as well as individual physicians. She has worked extensively in complex multiparty federal and state litigation and is well versed in the requirements of electronic discovery and the preservation of electronically stored information and advises on these issues.