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Before the
State of Wisconsin
Dentistry Examining Board

In the Matter of Disciplinary Proceedings Against
Grant A. Lemke, D.D.S., Respondent

FINAL DECISION AND ORDER
Order No. ORDER0006275

Division of Legal Services and Compliance Case No. 16 DEN 059

The State of Wisconsin, Dentistry Examining Board, having considered the above-captioned matter and having reviewed the record and the Proposed Decision of the Administrative Law Judge, make the following:

ORDER

NOW, THEREFORE, it is hereby ordered that the Proposed Decision annexed hereto, filed by the Administrative Law Judge, shall be and hereby is made and ordered the Final Decision of the State of Wisconsin, Dentistry Examining Board.

The rights of a party aggrieved by this Decision to petition the department for rehearing and the petition for judicial review are set forth on the attached "Notice of Appeal Information."

Dated at Madison, Wisconsin on the 10th day of July, 2019.

Member
Wisconsin Dentistry Examining Board

Before The
State of Wisconsin
DIVISION OF HEARINGS AND APPEALS

In the Matter of Disciplinary Proceedings Against Grant A. Lemke, D.D.S., Respondent	DHA Case No. SPS-18-0015 DLSC Case No. 16 DEN 059

PROPOSED DECISION AND ORDER

The parties to this proceeding for purposes of Wis. Stat §§ 227.47(1) and 227.53 are:

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PROCEDURAL HISTORY

These proceedings were initiated on March 6, 2018, when the Wisconsin Department of Safety and Professional Services ("Department"), Division of Legal Services and Compliance ("Division"), filed a formal Complaint against Respondent Grant A. Lemke, alleging that Dr. Lemke engaged in unprofessional conduct by practicing in a manner which substantially departs from the standard of care ordinarily exercised by a dentist which harms or could have harmed a patient, in violation of Wis. Admin. Code § DE 5.02(5). Dr. Lemke filed an Answer on March 26, 2018. A telephonic prehearing conference was held on April 20, 2018, during which the parties agreed to a hearing date of September 19, 2018, and related deadlines.

On June 29, 2018, Dr. Lemke filed a motion in limine to limit testimony to the sole allegation within the Complaint that Dr. Lemke violated the standard of care by failing to place implants larger than 2.0 millimeters (mm) in diameter in place of Patient K.W.'s tooth #29.

On July 2, 2018, the Division filed a motion in limine to preclude improper evidence proffered as expert witness testimony, including expert witness affidavits and telephonic testimony, and a motion in limine to preclude improper lay witness testimony.

On July 11, 2018, an Amended Scheduling Order was issued. On July 16, 2018, the Division indicated it would not object to Dr. Lemke's June 29, 2018 motion in limine. On August 2, 2018, following briefing on the Division's motions in limine, the undersigned administrative law judge ("ALJ") issued an order on the motions which granted Dr. Lemke's motion to limit testimony and granted the Division's motions to preclude improper lay witness testimony and to preclude expert testimony by affidavit. The Division's motion to preclude expert testimony by telephone was denied.

On August 28, 2018, at the request of Dr. Lemke's attorney, the ALJ issued a second Amended Scheduling Order, rescheduling the hearing date to November 29, 2018.

A hearing was held on November 29, 2018, in Madison, Wisconsin, at which Division exhibits 1-5, 7, 10-12, 14, 16 and 18 were received, and Dr. Lemke's exhibits 100, 101, 103, 112-114, 120 and 129 were received. Consistent with discussions held at the close of hearing, a briefing order was issued setting deadlines for the parties' briefs, the last of which was filed on February 22, 2019.

FINDINGS OF FACT

1. Dr. Lemke is licensed in the State of Wisconsin to practice dentistry, having license number 2261-15, first issued on June 14, 1979, and current through September 30, 2019. (Complaint, ¶ 1 and Answer, ¶ 1)

2. Patient K.W. first registered as a patient at Dr. Lemke's office on May 14, 2012. K.W. had a porcelain veneer crown on tooth #30 that had been placed by another dentist several years earlier. Tooth #30 is in the lower (also known as mandibular[1]) right area of the mouth and is the first molar. (Ex. 1, pp. 2, 10; November 29, 2018 Hearing Transcript ["Tr."], pp. 74, 125, 167-68, 259)

3. On March 17, 2014, K.W. informed Dr. Lemke of pain on the right side of her mouth. Dr. Lemke took three periapical x-rays and a panoramic x-ray of K.W.'s mouth, which demonstrated that K.W.'s tooth #29 had a large cavity which went down to the bone level. Tooth #29 is adjacent to tooth #30 and is also in the mandibular (lower) right posterior of the mouth. (; Exs. 112, 114; Tr. pp. 160, 164, 167, 174-174)

[1] The lower jaw is referred to as the mandible and the upper jaw as the maxilla.

4. Dr. Lemke discussed options with K.W. for treatment of tooth #29, including extraction of tooth #29 and the placement of two "mini implants," also referred to as "narrow-diameter implants"[2] ("NDI"), in the area of tooth #29/30 and placement of a crown in the area. (Tr., pp.167-171)

5. An NDI is generally defined as a dental implant with a diameter of less than 3.5 mm, whereas standard diameter implants ("SDI") are those implants larger than 3.5 mm in diameter. (Ex. 10, p. 22; Ex. 11, p. 73; Ex. 12, p. 43; Tr., pp. 47, 53, 61)

6. K.W. was very concerned about the cost of her dental procedures. She was not going to proceed with any treatment that was not covered by her insurance. K.W. wanted the treatment completed on or before April 7, 2013 because she was switching jobs on that date and was concerned about changing insurance coverages. (Ex. 1, pp. 29, 81-82; Tr., p. 171)

7. On April 3, 2014, Dr. Lemke extracted K.W.'s tooth #29 and placed two NDIs in the area of tooth #29/30. The NDIs were 2 mm in diameter, with a length of 13 mm and 15 mm, respectively. Dr. Lemke cemented a temporary crown onto the two NDIs. (Ex. 1, p. 83; Tr., pp. 175-178)

8. The dental implants used by Dr. Lemke were Intra-Lock Dental Implants ("Intra-Lock"). Intra-Lock is distributed by Dr. Todd E. Shatkin, D.D.S., who also appears to be Intra-Lock's inventor. Dr. Shatkin is an inventor and proponent of mini-dental implants and conducts educational seminars on their use. (Ex. 1, p. 84; Tr., pp. 72, 141, 153, 177, 203-204, 257, 283-287, 296)

9. On May 20, 2014, Dr. Lemke replaced the temporary crown in K.W.'s tooth #29/30 area with a molar-sized permanent crown. The patient notes state: "Shatkin used for #29." The NDIs used were single piece, tapered screw-like devices with a ball attachment on the top. (Ex. 1, p. 84; Tr., pp. 169, 176-179)

10. On July 21, 2014, during a periodic exam, the Patient notes for K.W. reflect inflammation around the molars. The hygienist recommended using a waterpik and focusing on getting food out between teeth #29 and #30. K.W. did not see Dr. Lemke that day. (Ex. 1, p. 84; Tr., pp. 179-181)

11. On December 8, 2014, during a periodic exam, K.W. mentioned to Dr. Lemke that there was movement on the crown at the implant site in the tooth #29/30 area. Dr. Lemke observed the area and determined not to re-cement the crown until it came completely loose. Dr. Lemke's hygienist noted that K.W.'s brushing and flossing were "poor" and that K.W. stated she was not brushing and flossing daily because she had started to work at home and that she needed to get back into an oral hygiene routine. (Ex. 1, p. 85; Tr. pp. 181-182)

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[2] Some medical literature refers to mini-implants as those NDIs which are smaller than 3 mm in diameter. (Exs. 10, 11) In this decision, the terms NDI and mini-implant are used interchangeably, with the exception of Dr. Shatkin's use of the term mini-implants in his report, discussed below.

12. On March 30, 2015, Dr. Lemke saw K.W. for a periodic exam and K.W. complained of constant discomfort on the lower right and upper right areas of her mouth. K.W.'s patient notes state that food was impacted on the distal implant at the tooth #29/30 area and the gingiva was irritated. K.W. questioned whether the implant could be the cause of the pain and if recementing the crown would take care of the food trap under the implant. Dr. Lemke reimaged and remade the crown used to replace K.W.'s tooth in the #29/30 area. The remade crown was cemented in place on March 31, 2015. (Ex. 1, pp. 85, 182-186)

13. K.W.'s next visit to Dr. Lemke was August 10, 2015, at which time K.W. expressed interest in having implants placed for tooth #19 and 20 and wanted to know about the cost. The patient records do not reflect any complaints about the NDIs at issue at this appointment or at a subsequent appointment on December 7, 2015. (Ex. 1, p. 86; Tr., pp. 187-190)

14. On April 11, 2016, K.W. went to Dr. Lemke for a cleaning. K.W. expressed concern that her gums were swollen and there was pain near the implant site in the tooth #29/30 area of her mouth. (Ex. 1, pp. 86-87)

15. On April 13, 2016, Dr. Lemke performed a limited oral exam of K.W.'s tooth #29/30 area. K.W.'s patient notes state that K.W. had a hygiene appointment on April 11, 2016, where the hygienist said she removed food impaction. K.W. noted improvement since the impaction was removed. (Ex. 1, pp. 86-87; Tr., pp. 190-193)

16. On May 3, 2016, K.W. presented for a follow-up regarding her tooth #29/30 area. The patient notes indicate the area bled easily and K.W. stated she was taking over-the-counter pain reliever daily. Dr. Lemke took a radiograph of the area which he states showed that the implants were integrated well into the bone with no signs of infection. K.W. reported that her discomfort was "significantly better" but not completely gone, and that she had pain at times on the left side of her mouth as well. She agreed at that visit to allow Dr. Lemke to remove the crown on #30, allow the tissue to heal and to place a new crown. (Ex. 1, pp. 87-88)

17. On June 14, 2016, K.W. saw a second dentist, Dr. Michael Martin, D.D.S. Dr. Martin's notes reflect that he informed K.W. that the two mini-implants were inappropriate. Dr. Martin's notes from August 3, 2016 reflect that his office spoke with a representative from "SHATKIN FIRST." Dr. Martin's notes state: "THESE ARE WRONG!!! SHATKIN SAYS YOU CAN DO THESE BUT I DISAGREE!" (Ex. 2, p. 3)

18. On June 15, 2016, K.W. called Dr. Lemke's office to advise that she had seen another dentist, and stated, "YOU WILL BE GIVING me my money back for this tooth." She advised Dr. Lemke's office that the other dentist had told her that she did not have an implant but that she had "2 little posts and should only be one post." She told Dr. Lemke's office that the other dentist told her "she would never be out of pain with the implants that are currently present," and that "there should be just one" implant. She further stated that the implants Dr. Lemke placed should only be used on dentures. During that telephone conversation, K.W. advised Dr. Lemke's office that she now "DOES NOT TRUST DR. LEMKE," and she requested all of her records and files from Dr. Lemke's office. (Ex. 1, pp. 88-89)

19. Dr. Martin provided K.W. with a treatment plan dated August 10, 2016, for "removal of two mini implants, bone graft and membrane placement to correct where mini-implants were, placement of a K3 implant and restoration of such implant." The cost of Dr. Martin's treatment plan was $8,762, which included $1,360 for removal of the mini-implants. Dr. Lemke's treatment plan was $3,590. (Ex. 1, pp. 31-32; Ex. 2, p. 6)

20. Dr. Martin referred K.W. to Oral Surgery Associates for removal of the two NDIs Dr. Lemke had placed. The removal was performed by an oral surgeon, Dr. Kimmel, whose records note that area of tooth # 29/30 was tender to palpitation. On November 15, 2016, Dr. Kimmel removed the crown in the tooth #29/30 area. His notes reflect that he "trough[ed] around implants" and removed them. Dr. Kimmel's notes further indicate that K.W.'s pain and other symptoms resolved upon removal of the two NDIs. (Ex. 3, p. 8)

Division's Expert: Dr. Leslee C. Timm, D.D.S.

21. Leslee C. Timm, D.D.S., is an oral and maxillofacial surgeon and oral and maxillofacial prosthodontist, licensed to practice in Wisconsin. He is a Fellow of the American College of Prosthodontists. He earned his dentistry degree from Marquette University School of Dentistry and completed a residency with the Veterans Affairs Medical Center in Portland, Oregon, that focused on prosthetic devices and implant dentistry. (Ex. 4; Tr., pp. 22-23)

22. Dr. Timm also completed an oral and maxillofacial fellowship at UCLA in California between 2005 and 2006. The majority of that practice was helping cancer patients with oral and facial prosthetics. He commonly used dental implants or implant fixtures for stability, retention, and support of prosthetics. In conjunction with the UCLA fellowship, Dr. Timm worked with the Weintraub Implant Center and Dr. Peter Moy, an international lecturer on dental implants. In 2005, Dr. Timm entered private practice as a prosthodontist. (Ex. 4; Tr., pp. 23-25)

23. In 2011, Dr. Timm was accepted into an oral and maxillofacial surgery training program at Gunderson Lutheran Hospital in La Crosse, Wisconsin, and spent four year studying oral and maxillofacial surgery. The surgery training program at Gunderson focused part of its curriculum on the utilization of titanium dental fixtures. The NDIs at issue are titanium dental fixtures. Dr. Timm became board certified by the American College of Prosthodontists in 2011. He has been active in the Implant Study Club in La Crosse since 2007 and has participated in teaching and lecturing opportunities. (Ex. 4; Tr., pp. 25-26, 30-34)

24. Dr. Timm is currently the owner of Coulee Region Implant & Oral Surgery Center in La Crosse, and is also a consultant for EON Dental clinics in Waukesha, Wisconsin, where he is tasked with removal of patients' teeth, preparing patients for placement of dental implants, and assisting the prosthodontist with the patients' transition into their implant-supported prosthetics. (Ex. 4; Tr., p. 32)

25. Dr. Timm was not compensated as an expert witness for these proceedings. (Tr., p. 21)

26. Dr. Timm places approximately 500 standard dental implants annually, which represents approximately 50% of his practice. (Tr., p. 107)

27. In Dr. Timm's experience, NDIs are not a frequent topic in formal dental education. He believes this to be the case because there is not enough evidence in scientific literature to support the widespread application of NDIs and the evidence shows higher failure rates for NDIs. (Tr., pp. 35-36)

28. Dr. Timm testified that NDIs are mainly used as temporary implants and may be used as an anchorage point to assist an orthodontist in moving teeth. Other applications for NDIs are limited to the anterior mandible for overdentures or very narrow spaces in the anterior maxilla for a non-load-bearing tooth. He stated that NDIs are not commonly used to replace a single tooth, and that they are most commonly used in his field for helping to retain and stabilize a mandibular complete denture. (Tr., pp 34-35, 37, 67)

29. Dr. Timm expressed concerns about NDIs and osseointegration, which is the process of the bone growing around the implant. He stated: "It is important that implants provide a certain amount of surface area for the bone to grow up to. Through the integration process the osteoblasts attach to the surface of the implant and start to gain that stability. . . . So mini implants, I think they're too narrow." (Tr. pp. 37, 134)

30. Dr. Timm has not taken any courses relating to NDIs. Dr. Timm has never placed an NDI and does not treat patients in his practice who have NDIs already in place. He has only seen two patients who have come to him for a second opinion after placement of NDIs. (Tr., pp. 108-110)

31. Dr. Timm testified that the usage of NDIs is limited because there are better results and substantiated success rates with larger implants. However, Dr. Timm does not know how many dentists in Wisconsin use NDIs in the posterior mandible. (Tr., pp. 37, 111-112)

32. Dr. Timm testified that he has not used NDIs in his practice because of the limited restorative capabilities when using an NDI. He testified that there is a higher risk of fracture of NDIs unless they are used in the anterior jaw where the teeth are not load-bearing, and there are additional issues with maintenance and hygiene when utilizing NDIs. He stated that scientific evidence and research does not support the use of NDIs in load-bearing areas of the jaw because NDIs cannot resist the bending, flexing and compression of chewing. (Tr., pp. 41-42, 57)

33. Dr. Timm reviewed all of the clinical records in this case and has reviewed medical literature related to NDIs. (Tr., pp.67, 71, 78-79)

34. Dr. Timm agreed that none of the studies indicate that 2 mm implants should be limited in any way. He testified: "There isn't a study that says that. There isn't." (Tr., p. 123)

35. Dr. Timm testified that standard diameter implants in the posterior region have a failure rate of 3-4% after 5 years. (Tr., p. 114)

36. Dr. Timm acknowledged that the Division's Exhibit 10 shows a mean survival rate of almost 95% for NDIs that are between 1.8 and 2.4 mm in diameter. He also agreed that Division Exhibit 11 showed a mean survival rate for NDIs less than 2.5 mm in diameter of 94.5%. He acknowledged that this percentage is close to the mean survival rate for standard dental implants. However, Dr. Timm also testified that in looking at survival rates, it is important to note where the tooth is located. (Tr., pp. 114-118)

37. Dr. Timm agreed that none of the exhibits introduced at hearing by the Division indicate that a 2 mm implant has a demonstrated mean survival rate of less than 95%. (Tr., pp. 125-126)

38. Dr. Timm testified that the overall (non-tooth-specific) success rate for endodontic therapy (root canal treatment) is only 70 to 80%. (Tr., pp. 127-128)

39. Dr. Timm testified that the only x-rays he was provided to review in this matter are contained in the Division's Exhibit 1 and that those paper copies were not diagnostic, *i.e.*, "the quality was poor." (Tr., p. 127)

40. Dr. Timm's opinion is that the use of 2 mm diameter NDIs to replace a single load-bearing tooth is controversial and should not be performed. He further opined that Dr. Lemke's use of 2 mm NDIs fell below the minimum standard of care for practicing dentistry in Wisconsin. (Tr., pp. 67, 71, 79-80)

41. Dr. Timm also authored a written report in this matter dated March 2, 2018, in which he listed eight specific "questions and concerns," presented as bullet points and a summation paragraph. The bullet points include concerns about food impaction, pain and bleeding in the area of tooth #29; no restorative abutment; no indication on the x-rays that the mini-implants were splinted to prevent micromotion; and the concave shape of the restoration which "contributed to food impaction and peri-implantitis which leads to pain." His report further stated that "the inherent design of the two 'mini-implants' do not provide the necessary resistance and retention form required for long-term restorative success." It also stated that "the lack of splinting the two 'mini-implants' with a restorative abutment" contributed to micromotion, premature failure of restorative cement and loss of restorative retention. (Ex. 5; Tr., pp. 82-83)

42. His report concluded that "most experienced, competent practitioners would have managed this case differently." (Ex. 5, p. 2; Tr., p. 83)

43. Dr. Timm testified that "it may be a cost savings to the patient to place that narrow-diameter implant because the shelf cost for the dentist is significantly lower, but in the long run the maintenance costs, the replacement costs are going to far outweigh utilizing a more conventional fixture that's of a larger size." (Tr., pp. 39-40)

Intra-Lock Instructions for Use (Ex. 7) and Report from Dr. Todd Shatkin, D.D.S. (Ex. 103)

44. The NDIs used in this case are Intra-Lock NDIs, distributed and possibly invented by Dr. Shatkin. The "Intra-Lock International Instructions for Use" contain the following "black

box" warning: "The use of small diameter implants and angled abutments in the posterior region of the mouth is not recommended due to possible failure of the implant." (Ex. 7, p. 4; Tr., pp. 76-78, 141)

45. In a report from Dr. Shatkin dated November 10, 2017, he states that he has been restoring dental implants for over 28 years and that he is a member of the International College of Implantology, the American Association of Osseointegration and past president of the International Academy of Mini Dental Implants. He states that he has placed and restored over 20,000 mini-implants over the last 18 years and that he "routinely" recommends two mini-implants for molar teeth. He reviewed the records, x-rays and CT scan for Dr. Lemke's treatment of K.W. and it was his professional opinion that Dr. Lemke provided proper care and treatment for K.W. (Ex. 103)

The Food and Drug Administration's 510(k) Summaries

46. The 510(k) Summaries introduced as exhibits in this matter are approvals by the federal Food and Drug Administration ("FDA") for Intra-Lock to market its dental implants. (Exs. 14 and 15; Tr., pp. 94-99)

47. Exhibit 16 is the 510(k) Summary Number K070601, issued by the FDA in 2007 regarding Intra-Lock Mini Drive-Lock Dental Implants ranging in diameter from 2 mm to 2.5 mm. The "Indications for Use" page states that these implants are "intended for use as a self-tapping titanium screw for transitional or intra-bony long-term applications" and "for long-term maxillary and mandibular tissue-supported denture stabilization." It also states: "The Intra-Lock Mini Drive Implant System has been shown to be safe and effective for its intended use." (Ex. 16, p. 5; Tr., p. 99)

48. Exhibit 14 is a 510(k) Summary Number K133613, issued by the FDA in 2014 regarding Intra-Lock International Dental Implants ranging in diameter from 3.75 mm to 5 mm. The "Indications for Use" page states that these implants are "designed to restore partially or fully edentulous patients" and "to be used in either the mandible or the maxilla and to support removable or fixed prostheses, from single tooth replacement to full arch reconstruction." (Ex. 14, p. 5; Tr., pp. 92-96)

Dr. Lemke's Testimony

49. Dr. Lemke is a general dentist licensed in Wisconsin, who has been practicing at the same location in Hartland, Wisconsin since 1979. He graduated from Marquette Dental School in 1979. (Complaint, ¶ 1 and Answer, ¶ 1; Tr., pp. 148-149)

50. At the time Dr. Lemke attended dental school, there were no courses offered in the placement of standard diameter implants. However, he took courses after dental school and then proceeded to place standard dental implants as a part of his practice beginning in 1989. General dentists may place dental implants. (Tr., pp. 159-151)

51. Dr. Lemke's education specific to standard diameter implants include a week-long course, and a yearly refresher course through the Chicago Dental Association. Dr. Lemke has taken five or six classes on NDIs, including courses hosted by Dr. Shatkin which covered the use of NDIs 2 mm in diameter in the posterior mandible. Dr. Shatkin taught Dr. Lemke many of the techniques he employs when utilizing NDIs. Dr. Lemke learned while taking these courses that 2 mm NDIs had been used in the posterior mandible thousands of times with success. Dr. Lemke purchased the NDIs and equipment he used on K.W. through Dr. Shatkin. (Tr., pp. 151, 153, 177, 203-204)

52. Dr. Lemke has placed over 800 NDIs in his practice. Of these NDIs, 149 have been lower (mandibular) molars, which are posterior teeth such as those at issue in this case. Approximately 30 to 40% of Dr. Lemke's procedures involving dental implants for first molar restoration use 2 mm diameter implants, the size used here. (Tr., pp. 162, 183, 206-207)

53. If Dr. Lemke was not allowed to use 2 mm diameter implants, he would "just switch to a larger size" because the jaw has a generous amount of bone. (Tr., pp. 206-207)

54. Dr. Lemke's primary reason for using 2 mm implants, as opposed to a larger size, is because they are less painful, less invasive, patients experience less problems, and they work. (Tr., p. 207)

55. Dr. Lemke did not consider the use of implants larger than 2 mm in diameter for K.W. because he believed that 2 mm NDIs were appropriate. He discussed K.W.'s restoration with her for 20 to 30 minutes before K.W. made a decision, and he did not present the option to use any other size or type of dental implants. (Tr., pp. 201-203)

56. When asked about Intra-Lock's instructions for these implants, which advise against the use of "small diameter implants and angled abutments" in the posterior region of the mouth due to possible failure of the implant, Dr. Lemke testified that he did not use a single small diameter implant but instead used two which were angled toward each other. He testified that he did so because the literature indicates it is best to splint implants together, and in doing the procedure for K.W., he splinted the two NDIs with a single crown which was a better option than creating two separate crowns. (Tr., pp. 205-206, 214-215)

57. Dr. Lemke believes that the NDIs he placed in K.W. had osseointegrated. He based this on the fact that they made the "right sound" when he tapped on them with the crown off and also on the radiograph identified as Exhibit 129. Dr. Lemke further stated that the radiograph showed no signs that the implants were fractured. However, Dr. Lemke also acknowledged during cross-examination that one would not be able to see microfractures on an x-ray, nor could he say for sure if an implant had fractures after it was placed. (Tr., pp. 187, 213-214)

58. The crown Dr. Lemke placed in the tooth #29/30 area of K.W.'s mouth was not impinging on the gums, and there was a space beneath the crown. Dr. Lemke explained that the use of 2 mm NDIs in this procedure created a concavity underneath the crown. Dr. Lemke testified that the space between the bottom of the crown he placed and K.W.'s gum tissues is the same type of space that is created every time a patient has a bridge which incorporates a pontic

tooth. Patients who have a bridge are recommended to use waterpiks beneath it and a thread flosser to keep the area clean, which is also true of the implants Dr. Lemke placed in this case. Dr. Lemke's Exhibit 113 is an x-ray which demonstrates a bridge that K.W. had with a pontic tooth showing the space beneath it and the gum tissue. (Ex. 113; Tr., pp. 214-216)

59. Dr. Lemke believes that placing NDIs such as those he placed in K.W. is not a "medically risky procedure." (Tr., p. 172)

60. Dr. Lemke believes he met the minimum standard of care in treating K.W. because he has had 149 prior instances of successful use of NDIs in similar circumstances. (Tr., p. 196)

61. Dr. Lemke believes there is resistance by specialists when general dentists do procedures over which specialists have a monopoly. (Tr., p. 197)

Dr. Lemke's Expert Witnesses

Testimony of Dr. Robert Heller, D.D.S.

62. Dr. Robert Heller is a general dentist who has been practicing in Kenosha since 1966. He graduated from Marquette University School of Dentistry in 1966 and received a certificate in periodontics in 1979, which was a two-year program. Periodontists specialize in treating gum diseases and the tissues around the teeth. Since 1970, Dr. Heller's practice has been limited to periodontics, which includes the placement of dental implants. (Tr., pp. 224-226)

63. Dr. Heller hs served as an adjunct clinical professor at Marquette Dental School for 18 years working one day a week in the clinic, teaching dental students how to do surgeries and to maintain a periodontal case. (Tr., pp. 228-229)

64. As a periodontist, Dr. Heller treats patients with peri-implantitis. He testified that 47% of standard implants result in some form of peri-implantitis and that it is a "big growing issue." (Tr., p. 226)

65. Upon review of this case, Dr. Heller found that K.W. did suffer from a form of peri-implantitis as shown on some of K.W.'s radiographs. It was Dr. Heller's opinion that K.W.'s peri-implantitis was caused by excess cementation of her crown. It is also his opinion that once Dr. Lemke removed that excess cement, the peri-implantitis was resolved. (Tr., pp. 227-228)

66. When Dr. Heller was in dental school, no courses were offered in how to perform standard dental implants. However, it is currently part of the residency program. In 1996, Dr. Heller attended a six-month program in Chicago regarding dental implants from The Center for Dental Implants. Dr. Heller testified that because the program was before the FDA approval for mini-implants, the smallest dental implant used in this program was a 3.2 mm diameter implant. He has also taken some one and two-day courses on 2 mm NDIs in Chicago, including at the Chicago Midwest Dental Meeting, that were co-hosted by Dr. Shatkin. Dr. Heller orders mini-implants from Shatkin Labs. (Ex. 101; Tr., pp. 230, 244-245)

67. Dr. Heller has placed thousands of standard dental implants in his career. (Tr., p. 230)

68. Dr. Heller began using NDIs as part of his practice in 2006. He began placing NDIs in the posterior mandible in 2012. More than 60% of his business is currently placing NDIs in patients. He has placed approximately 4,000 NDIs in his career. Of the 4,000 NDIs he has placed, approximately 1,000 were placed in the posterior mandible area. Since he began using NDIs, he has only placed 2 mm diameter implants in the posterior mandible. (Tr., pp. 231-234, 240, 245)

69. Dr. Heller began using NDIs because he realized that many of his patients in Kenosha did not have the resources for the kind of expenses that were being charged for standard dental implants. He testified that the more NDIs he placed, the more he observed that they worked for his patients. (Tr., pp. 231-232)

70. In Dr. Heller's experience, there have been more failures and more problems with standard diameter implants than with NDIs. (Tr., p. 234)

71. Dr. Heller's practice would be affected if there were an adverse ruling against Dr. Lemke in this matter. (Tr., pp. 241-242)

72. Dr. Heller was compensated as a witness. (Tr., p. 247, 305)

73. Dr. Heller reviewed the x-rays and chart from Dr. Lemke's patient file for K.W. as well as the records of K.W.'s subsequent treating dentists, Drs. Martin and Kimmel. Based on his review of the records, it was Dr. Heller's opinion that the implants at issue did osseointegrate. He testified that his review of Dr. Kimmel's notes regarding removal of the implants, in particular, Dr. Kimmel's "trough around implants" notes, indicate that the mini-implants had to be drilled out because they were "imbedded in bone." (Tr., pp. 235-238; Ex. 3, p. 3)

74. In Dr. Heller's opinion, the implants appeared stable on the oldest and the newest x-rays that were available and he saw no evidence that the implants themselves were loose or unstable. However, he also testified that movement would be seen clinically and there could be movement that would not show on an x-ray. (Tr., pp. 235-236, 242)

75. Dr. Heller believes manufacturer's instructions are often vague and he therefore does not view them as directives for specific procedures. He does believe it is important to follow FDA approvals. (Tr., p. 250-251)

76. Dr. Heller reviewed 106 journal articles in preparation for the hearing and in doing so, was struck not only by the high percentages of success rates for NDIs but also by the fact that there was no indication that the procedure should not be done or that they should not be used in the manner Dr. Lemke used them in the instant case. The articles referred to small-diameter implants of 3 mm and below. (Tr. pp. 247-248)

77. Based on his review of all the records and his own clinical experience, it is Dr. Heller's opinion, based on a reasonable degree of dental probability, that Dr. Lemke met the

standard of care when he placed two 2 mm NDIs in K.W.'s posterior mandible. (Tr., pp. 238-241)

Testimony of Dr. Gregory Harvey, D.D.S.[3]

78. Dr. Gregory Harvey is a general dentist who graduated from Marquette University School of Dentistry in 1979 and has practiced in Waupaca, Wisconsin since 1980. He has a fellowship in the Academy of General Dentistry which he received in 2010. He has accumulated between 750 to 1000 hours of continuing dental education since graduating from dental school. (Tr., pp. 252-253, 255)

79. Dr. Harvey was compensated for his hearing testimony. (Tr., p. 293)

80. Dr. Harvey places dental implants as part of his practice. He has placed both SDIs and NDIs as part of his practice, beginning with NDIs in 2013 and SDIs in 2017. (Tr., pp. 255, 257)

81. Dr. Harvey runs a dental practice that operates as a Mini Dental Implant Center of America, which is a comprehensive marketing and business system that he purchased from Dr. Shatkin. Dr. Harvey also orders and uses Intra-Lock dental implants from Dr. Shatkin. (Tr., pp. 285, 296)

82. Dr. Harvey's education related to NDIs consists of a two-day beginner course on NDIs offered by Dr. Shatkin, which he repeated once; a two-day advanced course on NDIs offered by Dr. Shatkin, which he repeated once; and two annual meetings offered by Dr. Shatkin. He is a member of the International Academy of Mini Dental Implants, founded by Dr. Shatkin, and has observed the techniques of Dr. Matt Lasorsa, a lecturer for Dr. Shatkin's courses. (Tr., pp. 257-258, 283-284)

83. In the courses he has taken from Dr. Shtakin, Dr. Harvey has learned about the utilization of 2 mm diameter implants in the mandibular area, the area involved in this case. (Tr., p. 258)

84. Dr. Harvey has placed approximately 200 mini-implants. He did not recall ever using a 2 mm diameter implant in the molar area but stated that if the situation called for it, he would do so. He testified that he chooses certain sized implants based upon the width and height of the bone that the implant is being placed into. (Tr., p. 259)

85. Dr. Harvey has placed crowns on NDIs approximately 46 times utilizing two NDIs in each instance. Of these procedures, 23 involved crowns on two NDIs in the mandible area. Of the 46 procedures that he has done, Dr. Harvey is not aware of any NDIs that he has placed which have failed. He stated that they have "held up very well," and that bone loss has not been an issue. (Tr. p. 259-269)

[3] The Division asks that Dr. Harvey not be recognized as an expert in this matter on grounds that Dr. Harvey's education and experience with NDIs is limited. I reject the Division's argument, particularly as its own expert, Dr. Timm, has had no education regarding NDIs or experience in placing them.

86. In Dr. Harvey's opinion, the benefits of placing NDIs instead of standard diameter implants include: simplicity of the procedure; no requirement of an incision with a scalpel into the gum tissue; a much smaller hole is created in the patient's jaw; there is no delay of several months awaiting integration of the implant; less post-operative pain; patients are usually symptom-free and pain-free after 24 hours; healing time is quicker; NDIs can be loaded with a crown the same day the NDI is placed; and the cost of the procedure is much less, in some cases, less than half of standard implants. (Tr., pp. 261-264)

87. Many of Dr. Harvey's patients could not afford standard implants or bridges and some of his patients who are farmers, foundry workers, waitresses and other modest income patients are able to afford NDIs, which allows them to chew in that area of the mouth. He called the placement of NDIs "real world dentistry." (Tr., pp. 264-265)

88. Based on his review of the records, it was Dr. Harvey's opinion that the NDIs placed by Dr. Lemke were well-integrated and showed very good bone level around the implants. He believed the implants were quite stable because the oral surgeon, Dr. Kimmel, had to cut them out of the bone. He believed the 2 mm implants placed by Dr. Lemke were "very strong and. . . were holding up quite well." He believed that the biggest mistake of this case involved the removal of Dr. Lemke's implants. (Tr., pp. 272-273, 275-276)

89. Dr. Harvey also testified that a radiograph cannot definitively demonstrate if an implant is fully integrated into a patient's bone and that a dentist may still need to partially drill out implants that are not fully integrated to remove them from a patient's jaw. (Tr. pp. 238, 279)

90. Based on his review of K.W.'s records, Dr. Harvey believed that K.W. had some gingival inflammation which was not related to a failure of the implants themselves. He believed K.W. was not following hygiene instructions, including with respect to daily flossing around the NDIs. (Tr., pp. 273-275)

91. It was Dr. Harvey's opinion, based on a reasonable degree of dental certainty, that Dr. Lemke "absolutely, no question" met the standard of care in this case. (Tr., p. 277)

Scientific Literature on NDIs

Exhibit 10

92. Exhibit 10 is a journal article entitled, "Narrow-diameter implants; A systematic review and meta-analysis," published in Clinical Oral Implants Research, a peer-reviewed journal that is a reputable and respected source in his field. Exhibit 10 was published in 2018, after the conduct at issue in this case. (Ex. 10; Tr., pp. 45-46)

93. The "objectives" section notes that NDIs "are claimed to be a reasonable alternative to bone augmentation procedures" and that "[t]he aim of this comprehensive literature review was to conduct a meta-analysis comparing the implant survival of NDI and standard diameter

implants (SDI) and to provide recommendations and guidelines for application of NDI." (Ex. 10, p. 1)

94. The article breaks NDIs into three categories. Category 1 involved NDIs smallest in diameter, less than 3 mm, which would include the size of NDIs used by Dr. Lemke in this case (2 mm). The article noted that with respect to all three categories, "numerous clinical studies have been published with promising survival and success rates (citation omitted). However, clinical evidence comparing NDI to SDI remains controversy [sic]." (*Id.*)

95. According to the results of the meta-analysis, the mean survival rates of NDI of Category 1 (less than 3 mm in diameter) "were promising, (94.7 ± 5%)." For those NDIs in Category 1 with a diameter of 1.8 mm to 2.4 mm (which includes the 2 mm size at issue here), the mean survival rate was 92.9 ± 5% (range 80% - 100%). (Ex. 10, pp. 25, 26)

96. Exhibit 10 noted: "[The NDI survival rates are] significantly lower than the survival rates of SDI. These results many not be surprising, as these mini-implants were generally inserted in highly atrophic edentulous jaws that represent surgically challenging situations. Studies comparing survival and success of NDI compared to SDI with augmentation procedures in high atrophic situations are missing so far." (Ex. 10, p. 25)

97. "Atrophic" means an area where there is bone loss and a lack of bone support.[4] "Edentulous" means toothless. (Tr., pp. 64-65, 299-300)

98. The study cautions that the results of the meta-data were driven mostly by one study, and that due to "the paucity of events and heterogeneity of study design and outcome measure," "drawing definite conclusions out of these data [from the meta-analysis] is not recommended." The study warned about the "high risk of bias" and "heterogeneity" in the studies. (Ex. 10, pp. 25, 35)

99. The study further states that "resilient long-term data and data on the possible risk of biological and technical complications with wide platform teeth on NDI are missing so far." (*Id.*)

100. Exhibit 10 also states: "The avoidance of augmentation or other invasive surgery using NDI may reduce morbidity of the patient. However, studies evaluating patient-reported outcomes (PRO) such as health-related quality of life. . . in patients receiving NDI vs. standard diameter implants (SDI) with augmentation procedures are missing so far." (Ex. 10, p. 22)

101. Within these limitations, Exhibit 10 concluded: "the included studies describe NDI as a possible treatment alternative with promising survival rates. Their clinical advantage might be in the extension of treatment options." (Ex. 10, p. 35)

102. With regard to bone loss, Exhibit 10 noted that mean marginal bone loss for Category 1 NDI (< 3mm diameter) was similar to that for standard diameter implants. (Ex. 10, p. 26)

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[4]There is nothing in the record to show that K.W. had bone loss in the area at issue. Dr. Harvey testified that based on his review of the records, K.W. had "very good bone." (Tr., p. 299-300)

103. With respect to Category 1, Exhibit 10 notes that the "most frequently described indications were the edentulous arch and single non-load-bearing teeth in the anterior region. Types of final restorations were mainly completed overdentures." In contrast, for the larger NDIs, Exhibit 10 notes that the leading indication for Category 2 (3-3.25 mm) was single tooth restoration in the anterior region while the indications for Category 3 (3.3-3.5 mm) included the load-bearing posterior region. (Ex. 10, p. 25)

104. The review concludes that "long-term data are rare and there is a lack of data on perio-implant tissue valued and prosthetic considerations, for example, the possible risk of biological and technical complications with wide-platform teeth on NDI." (Ex. 10, p. 35)

Exhibit 11

105. Exhibit 11 is an article entitled, "Group 1 ITI Consensus Report: The influence of implant length and design and medications on clinical patient-reported outcomes," published in Clinical Oral Implants Research, a peer-reviewed journal that is a reputable and respected source in its field. The ITI group is the International Team of Implantologists that meets every two years, where they explore advances in the fabrication and use of dental implants. Exhibit 11 is a systematic review looking at NDIs and how length, design and associated medications may affect the success of NDIs. Exhibit 11 was published in 2018, after the conduct at issue in this case. (Ex. 11; Tr., p. 51-52)

106. Exhibit 11 breaks NDIs into three categories, with Category 1 being less than 2.5 mm, which would include the size used by Dr. Lemke in this case (2 mm). (Ex. 11)

107. Exhibit 11's Consensus Statement 1 states that the mean survival rate of Category 1 NDIs was 94.5% ± 5% (Range 80% -100%) after observation periods of 12-78 months. However, the article notes that "[t]he most frequently described applications of these implants were for transitional restorations, overdentures, and single anterior tooth replacement." (Ex. 11, p. 73; Tr. pp. 57-58, 116-118, 139-140)

108. The article states: "Narrow diameter implants with diameters of 2.5 mm and more demonstrated no difference in implant survival rates compared to standard diameter implants. In contrast, it is concluded that narrow diameter implants with diameters of less than 2.5 mm exhibited lower survival rates compared to standard diameter implants." (Ex. 11, p. 70)

109. Exhibit 11 explains the following advantages of using NDIs:

- NDI should be considered when it is important to ensure maintenance of adequate tooth-implant and implant-implant distances in sites with reduced mesio-distal width.
- The use of NDI can be considered to reduce the need or complexity of lateral bone augmentation procedures to reduce morbidity.
- The use of NDI may allow simultaneous rather than staged bone augmentation procedures.

- The use of NDI may produce increased prosthetic flexibility in certain clinical situations.

(Ex. 11, pp. 73-74)

110. Potential disadvantages of NDIs were listed as:

Biological

- One-piece NDI with ball attachments might be difficult to manage at the onset of dependency.
- The use of NDI may compromise optimal prosthetic designs allowing the maintenance of peri-implant tissue health.

Mechanical

- Reducing implant diameter brings an increased risk of implant or component fracture.
- Caution is recommended for the use of NDI in patients with parafunctional habits[5] and malocclusions.

(Ex. 11, p. 74; Tr., pp. 56-57)

111. Exhibit 11 advises: "Given the reduced implant strength and bone contact offered by NDI, it may be advisable to use splinted restorations based on the individual clinical situations. (Ex. 11, p. 74)

112. Exhibit 11 lists "indications" for each classification of NDI. For those NDIs under 2.5 mm in diameter, the article states that they can be considered for "[s]upport of definitive complete mandibular overdentures," which means a lower denture on the bottom jaw going over the NDIs, and "[s]upport of interim prostheses, both fixed and removable." Included indications for Category 2 and 3 NDIs are "[s]upport of single tooth replacement in the anterior zone with narrow interdental width (maxillar lateral incisors and single mandibular incisors)" (Category 2), and "[s]upport of single tooth replacement in sites with reduced interdental and/or buccal-lingual width" (Category 3). (Ex. 11, p. 74; Tr., pp. 57-58)

113. Exhibit 11 further cautions: "There is insufficient evidence on the success rates for all NDIs. Clinical parameters and treatment protocols are often not sufficiently described and no controlled comparative long-term studies are available, resulting in a high risk of bias." (Ex. 11, p. 73; Tr., pp. 54-55)

Exhibit 12

114. Exhibit 12 is a journal article entitled, "Systematic Review on Success of Narrow-Diameter Dental Implants," published in the International Journal of Oral & Maxillofacial Implants, a peer-reviewed journal and one of the most reputable sources regarding dental

[5] Dr. Timm described patients with "para-functional habits" to include people who clench and grind or "bruxers." (Tr., p. 57) The record does not indicate that K.W. had para-functional habits.

implants. It was published in 2014, about the same time period as the conduct at issue in this case. (Ex. 12; Tr., p. 60)

115. The article states that "the quality of the studies was mostly low with a high risk of bias." (Ex. 12, p. 43)

116. The article states: "Until now, the use of NDI has been restricted to certain defined indications with comparable low occlusive loading like incisors or as retaining elements for overdentures. Before NDI can be recommended in a broader clinical setting, the analysis of available external evidence is necessary." (Ex. 12, p. 44)

117. Exhibit 12 breaks NDIs into three categories, with Category 1 implants being less than 3 mm in diameter. A meta-analysis of survival rates for Category 1 could not be conducted. (Ex. 12, p. 47)

118. Exhibit 12 states that survival rates for Category 1 (less than 3 mm) were between 90.9% and 100%. These Category 1 implants consisted mainly of one-piece implants which were 1.8, 2.4, or 2.5 mm in diameter. (Ex. 12, p. 47, Tr. pp. 63, 119, 121-122)

119. Exhibit 12 states that "[s]urvival rates of NDI appear to be similar compared to those of regular diameter implants (> 3.5 mm)." The study further states: "This might suggest reliable therapy option, but evaluation of the success of the employment of small diameter dental implants should not be carried out exclusively by determination of implant survival. The reported indications, implant success, and changes of the marginal bone level should also be considered." (Ex. 12, p. 47)

120. Exhibit 12 noted that NDIs with diameters of 3.3 mm to 3.5 mm were "well documented in all indications, including load-bearing posterior regions" but that NDIs less than 3 mm in diameter "were only documented for the edentulous jaw and single-tooth non-load-bearing regions," with long-term data and success rates not available for this category. Thus, "[d]ue to missing comparative studies, no conclusion can be drawn about the possibility of reducing the burden of care by using NDI." (Ex. 12, p. 52, Tr., pp. 63-64, 140)

121. The article listed potential advantages of NDIs as decreasing the rate of augmentations necessary for implant insertion; lower cost, with many elderly edentulous patients not able or willing to undergo expensive surgical procedures; potentially less complication and pain; and use in smaller spaces. (Ex. 12, p. 44)

122. Disadvantages of NDIs included "biochemical risk factors," such as more likelihood of fracture due to smaller diameter. (Ex. 12, p. 44)

Exhibit 18

123. Exhibit 18 is a journal article entitled, "Implant-Bone Interface Stress Distribution in Immediately Loaded Implants of Different Diameters: A Three-Dimensional Finite Element Analysis," published in 2009 in the Journal of Prosthodontics, a peer-reviewed journal that is a

respected and reputable source in his field. This study determined that as the diameter of an implant increases, the implant can withstand more force. (Ex. 18, p. 393; Tr., p. 66)

DISCUSSION

Burden of Proof

The burden of proof in disciplinary proceedings is on the Division to show by a preponderance of the evidence that the events constituting the alleged violations occurred. Wis. Stat. § 440.20(3); *see also* Wis. Admin. Code § HA 1.17(2). To prove by a preponderance of the evidence means that it is "more likely than not" that the examined action occurred. *See State v. Rodriguez*, 2007 WI App. 252, ¶ 18, 306 Wis. 2d. 129, 743 N.W.2d 460, citing *United States v. Saulter,* 60 F.3d 270, 280 (7th Cir. 1995).

Violation Alleged

If the Wisconsin Dentistry Examining Board ("Board") finds that a licensed dentist has engaged in unprofessional conduct or has violated the standard of conduct established by the Board under Wis. Stat. § 447.02(2)(g), it may reprimand the dentist or may deny, limit, suspend, or revoke his or her license Wis. Stat. § 447.07(3)(a). The Division alleges that Dr. Lemke violated Wis. Admin. Code § DE 5.02(5), which is a standard of conduct established by the Board pursuant to Wis. Stat. § 447.02(2)(g), and defines unprofessional conduct to include "[p]racticing in a manner which substantially departs from the standard of care ordinarily exercised by a dentist . . . which harms or could have harmed a patient." Specifically, the Division alleges that Dr. Lemke violated this provision by failing to place implants larger than 2 millimeters in diameter in place of Patient K.W.'s tooth #29. The Division asserts that NDIs of this size are not appropriate to replace a load-bearing tooth in the posterior mandible, as was done here.

The Division has not met its burden of proof in establishing that Dr. Lemke's conduct substantially departed from the standard of care ordinarily exercised by a dentist which harmed or could have harmed a patient. Most significantly, the Division did not adequately address the particular situation here – use of two NDIs with a single crown. The Division's evidence focused on the use of one NDI. To the extent the Division's scientific literature specifically addressed the use of two NDIs, it suggested that the technique was advisable. The Division's Exhibit 11 states: "Given the reduced implant strength and bone contact offered by NDI, it may be advisable to use splinted restorations based on the individual clinical situations." The record is not clear what such splinting entails. Dr. Lemke testified that in doing the procedure for K.W., he splinted the two NDIs with a single crown. Dr. Timm stated in his report that Dr. Lemke did not splint the two mini-implants with a restorative abutment. The Division, which has the burden of proof, failed to demonstrate that "splinting," as discussed in Exhibit 11, was something other than what Dr. Lemke did here.

Likewise, both the FDA approval and the Intra-Lock manufacturer's instructions contemplated the use of a single NDI, not the use of two NDIs with a single crown. Thus, to the extent that either the FDA approval or the manufacturer's instructions serve as any indication

that use of the Intra-Lock NDIs in the posterior mandible was not appropriate, that warning applied to the use of a single NDI, not to the use of two NDIs splinted with a single crown. The Division emphasizes that the manufacturer's instructions discuss implants in the plural form – *i.e.*, "the use of small diameter *implants* and angled abutments in the posterior region of the mouth is not recommended due to possible failure of the implant." This argument is not persuasive. A more reasonable interpretation is that the instructions pertain to a single implant supporting a single crown or other restoration. Nowhere in the instructions is there any reference to the type of procedure that was done here. Even if the instructions did pertain to the use of two NDIs with a single crown, the Division has not shown that the instructions prohibit the use of NDIs in the posterior mandible/molar area. First, as argued by Dr. Lemke, the instructions refer to "small diameter implants and angled abutments." It is clear from the instructions and from the record that abutments are used in combination with implants. Thus, I find reasonable Dr. Lemke's interpretation that the instructions pertain to implants used with abutments. Here, the NDIs used were one-piece implants without abutments. Moreover, Dr. Shatkin, a distributor (and likely the inventor) of Intra-Lock NDIs and an instructor on their use, stated that he recommends two mini-implants for the restoration of molar teeth on a routine basis. Dr. Lemke learned while taking courses from Dr. Shatkin that 2 mm NDIs had been used in the posterior mandible thousands of times with success. Thus, the Division's interpretation of Intra-lock instructions is undercut by Dr. Shatkin's view that using mini-implants to in the posterior mandible to replace molars is appropriate.

The FDA approval likewise does not address the use of two mini-implants splinted with a single, molar-sized crown. The FDA approval is also unavailing because the "Indications for Use" page states that the implants at issue here are "intended for use as a self-tapping titanium screw for transitional or intra-bony long-term applications." Dr. Lemke states that his use of the two NDIs at issue was an "intra-bony long-term application," and the Division, which has the burden of proof, presented no evidence or argument to the contrary.

The Division has not presented sufficient evidence demonstrating that the use of two 2 mm NDIs with a single crown substantially departed from the standard of care ordinarily exercised by a dentist and created harm or the risk of harm to patients. Moreover, the evidence presented by the Division, as a whole, was inadequate to establish that Dr. Lemke's conduct constituted a substantial departure from the standard of care, particularly in light of the evidence to the contrary, including from credible dentists who have successfully used the method Dr. Lemke used here. For example, both Dr. Lemke and Dr. Heller used 2 mm diameter NDIs in the posterior mandibular area with success on numerous occasions, and Drs. Lemke, Heller, Harvey and Shatkin, all of whom have extensive experience using NDIs, believed he had met the standard of care.

Dr. Lemke, a dentist since 1979, credibly testified that he has had 149 prior instances of successful use of NDIs in similar circumstances. Dr. Heller has been a practicing dentist since 1966, is a periodontist, and has served as an adjunct clinical professor at Marquette Dental School for 18 years. He has placed thousands of standard dental implants in his career. He began using NDIs as part of his practice in 2006 and began placing NDIs in the posterior mandible in 2012. He has placed approximately 4,000 NDIs in his career, and of those, approximately 1,000 were placed in the posterior mandible area, the same location at issue here. All of those placed in

the posterior mandible were 2 mm diameter implants, the same size as those used by Dr. Lemke. Dr. Heller testified that in his experience, there have been more failures and more problems with SDIs than with NDIs. Based on his review of all the records and his own clinical experience, Dr. Heller opined that Dr. Lemke met the standard of care when he placed two 2 mm NDIs in K.W.'s posterior mandible.

Dr. Harvey, a practicing dentist since 1979, stated that he has placed approximately 200 mini-implants. He did not recall ever using a 2 mm diameter implant in the molar area but stated that if the situation called for it, he would do so. He has placed crowns on NDIs approximately 46 times utilizing two NDIs in each instance. Of these procedures, 23 involved crowns on two NDIs in the mandible area. Of the 46 procedures that he has done, Dr. Harvey is not aware of any NDIs that he has placed which have failed. He stated that the NDIs he has placed have "held up very well," and that bone loss has not been an issue. His professional opinion was that Dr. Lemke met the standard of care. Dr. Harvey's testimony was credible.

Dr. Shatkin also stated in his report that it was his professional opinion that Dr. Lemke provided proper care and treatment for K.W. Dr. Shatkin has been restoring dental implants for over 28 years and that he is a member of the International College of Implantology, the American Association of Osseointegration and past president of the International Academy of Mini Dental Implants. He has placed and restored over 20,000 mini-implants over the last 18 years. He recommends two mini-implants for the restoration of molar teeth on a routine basis.

The Division makes much of the fact that Dr. Shatkin appears to be the primary, if not the sole source, of information regarding the use of mini-implants for Drs. Lemke, Harvey and Heller. While that may be the case, the Division has not produced any evidence indicating that Dr. Shatkin's views or instruction regarding these products have been deemed false or incorrect, much less that Dr. Shatkin is engaged in some nefarious operation.

The Division's strongest evidence was Dr. Timm's testimony. Dr. Timm is an impressive witness with stellar credentials in his field. However, the evidence on which he relied was insufficient to support the conclusions necessary for the Division to prevail and the conclusions were outweighed by other credible evidence. For example, Dr. Timm conceded that no study indicates that 2 mm implants should be limited in any way. He also agreed that none of the Division's exhibits indicate that a 2 mm implant has a demonstrated a mean survival rate of less than 95%. He also agreed that this was close to the mean survival rate for standard diameter implants in the posterior region.

With regard to the issue of bone loss, Dr. Timm testified that that Exhibit 10 stated that NDIs resulted in more flexing, which led to more bone loss than with standard diameter implants. (Tr., pp. 47-48) However, this testimony was directly contradicted by Exhibit 10 itself, which stated that marginal bone loss for NDIs less than 3 mm in diameter was similar to that resulting from standard diameter implants.

Nor did the evidence support the suggestion that K.W.'s problems in the tooth #29/30 area resulted from Dr. Lemke's placement of the NDIs at issue or that his actions risked harming her. Dr. Timm's suggestion that K.W.'s implants may not have osseointegrated was not proven

by the evidence, and was also undercut by other evidence. Dr. Lemke conducted a clinical evaluation and review of the x-rays and testified that osseointegration had occurred. In addition, the oral surgeons's notes reflect that he "trough[ed] around implants," which according to Drs. Harvey and Heller, indicates that the mini-implants had to be drilled out because they were imbedded in bone. With regard to K.W.'s pain and bleeding in the tooth #29/30 area, there was insufficient evidence that this was caused by failure of the implants versus inadequate hygiene or other causes. Although some weight is given to Dr. Martin's strong opinion that Dr. Lemke should not have used mini-implants on K.W., this opinion is not accorded much weight in light of the fact that he did not testify in this case and could not be cross-examined with regard to his views.

The Division's scientific articles (Exhibits 10-12, and 18) were likewise unavailing. First, as stated, they almost completely fail to address the procedure that occurred here – two 2 mm diameter NDIs "splinted" with a single crown. Moreover, to the extent this procedure is addressed by the articles, Exhibit 11 appears to advise in its favor.

The Division relies on its scientific literature to support its assertion that the smallest category of NDIs (under 3 mm or 2.5 mm in diameter), had lower survival rates than standard diameter implants. However, this assertion was contradicted not only by Dr. Timm, who conceded that the mean failure rate of 95% was similar to that of standard diameter implants in the posterior region, but also by one of the Division's exhibits itself. While Exhibits 10 and 11 state that the survival rates were statistically worse for the smallest category of NDIs (including 2 mm in diameter) than for standard diameter implants, Exhibit 12 states that "[s]urvival rates of NDI appear to be similar compared to those of regular diameter implants (> 3.5 mm)."

The Division also relies on its studies for the proposition that NDIs of the diameter used in this case are not indicated for load-bearing teeth in the posterior region/molar area. However, as conceded by Dr. Timm, none of the studies specifically limit the use of 2 mm diameter NDIs.

The Division's studies are also of limited use for the following reasons: (1) they involve use of NDIs in areas not at issue here, the highly atrophic edentulous jaws and single non-load-bearing teeth in the anterior region; (2) the studies showed a high risk of bias; (3) two of the main studies (Exhibits 10 and 11) are from 2018, years after the conduct at issue here; and (4) the studies contain various disclaimers regarding their reliability, such as Exhibit 11's caution that "[t]here is insufficient evidence on the success rates for all NDIs" and "[c]linical parameters and treatment protocols are often not sufficiently described and no controlled comparative long-term studies are available;" and Exhibit 10's disclaimer that "resilient long-term data . . . [is] missing so far."

At the end of the day, the question in this case is not whether placing two 2 mm NDIs in the posterior mandible region with a single crown is an acceptable practice. That question is left to the experts in the field of dentistry. Rather, the question here is whether the Division proved its case – *i.e.*, showed by a preponderance of the evidence that Dr. Lemke's placement of the NDIs in K.W.'s lower molar region substantially departed from the standard of care ordinarily exercised by a dentist which harmed or could have harmed K.W. Based on the facts established in this case, the Division did not meet this burden.

CONCLUSION OF LAW

The Division has not established by a preponderance of the evidence that Dr. Lemke engaged in unprofessional conduct pursuant to Wis. Admin. Code § DE 5.02(5) by practicing in a manner which substantially departs from the standard of care ordinarily exercised by a dentist which harms or could have harmed a patient.

ORDER

For the reasons set forth above, IT IS ORDERED that the Division's Complaint in this matter is dismissed, effective the date the Final Decision and Order is signed by the Board.

Dated at Madison, Wisconsin on April 15, 2019.

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By: _____
Jennifer E. Nashold
Administrative Law Judge