

MILLER
SCHOOL OF MEDICINE
UNIVERSITY OF MIAMI

November 8, 2005

Mr. James C. Crumlish, III
Elliott, Greenleaf & Siedzikowski
925 Harvest Drive
Blue Bell, PA 19422

Re: Cavitat Medical Technologies, Inc. vs. Aetna, Inc.

Dear Mr. Crumlish:

I have been asked to review nine patient files from the office of Dr. Wesley Shankland related to the use of the Cavitat device, its appropriateness as a diagnostic tool, the diagnoses of so-called "Neuralgia Inducing Cavitation Osteonecrosis" ("NICO"), and the appropriateness of surgeries related to the interpretation of Cavitat device ("cavitat") data and the diagnoses of NICO. The patient files I have been given to review are those of 1) SD, 2) MH, 3) LI, 4) PK 5) RL, 6) EL, 7) LMCK, 8) MR, and 9) JT.

I will first provide an overview of consistent patterns found between these nine cases and then a detailed analysis of each case, followed by a summary.

I have reviewed in detail the charts of SD (Shankland 2639 - 2790), MH (Shankland 1745 - 1856), LI (Shankland 2448 - 2546), PK (Shankland 1857 - 1950), RL (Shankland 1951 - 1970), EL (Shankland 3225 - 3302), LMCK (Shankland 3303 - 3424), MR (Shankland 3069 - 3224), and JT (Shankland 0899 - 1007) from Dr. Wesley E. Shankland's practice that you sent to me. While there are numerous specific problems with Dr. Shankland's care related to incorrect diagnoses, false claims concerning the diagnostic ability of the cavitat device, inappropriate and unnecessary surgeries, and unsuccessful outcomes, there are some general patterns of significance I would like to point out first. They are:

1. Dr. Shankland consistently takes desperate patients often with another established diagnosis that readily explains their pain and then relates it to cavitations that he diagnoses with the cavitat. He then uses it to remove teeth unnecessarily and to justify unneeded surgeries.
2. Few of his patients really got better. One notable exception happened to have a real cyst proved by the histopathology. In fact, most of his patients experienced complications or a return of symptoms.

Daughtry Family Department of Surgery
Division of Oral/Maxillofacial Surgery
Deering Medical Plaza
9380 SW 150 Street, #190
Miami, FL 33157
(305) 256-5293

1

EXHIBIT

4

tabbies

3. Dr. Shankland has a very defensive boiler plate consent form and stresses over and over again that he cannot guarantee results and that the patient has been offered his standard two other options. Nevertheless, he uses the cavitat to imply that the other options are inappropriate.
4. He repeatedly justifies his surgery in the face of unsupported radiographs and histopathology as being an "early case" of NICO and that it would have become worse.
5. Dr. Shankland frequently telephones, e-mails, and writes his patients most always to reinforce his diagnosis and treatment. He frequently uses religious phraseology to gain the patients' trust.
6. He repeatedly described finding "oil cysts" during his surgeries as to document for the record that pathologic cavitations were present. Actually, the oil cysts are normal fatty marrow degenerations and the cavitations are normal marrow spaces.
7. Seven of the nine patients are women. Women are known to have more fatty marrow spaces than men particularly as they age. Eight of the nine patients had their "cavitations" in the posterior mandible or maxilla where normal fatty marrow spaces are more prominent. The one exception was the lone man who coincidentally had the real cyst as proven by the pathology report.
8. Many of the cavitat positive findings were of previously made surgical defects, i.e. extraction sites, previous cavitation surgeries, previous biopsy sites, apicoectomy sites, etc.
9. Dr. Shankland repeatedly claimed that the cavitat could discern ischemic bone blood flow, and marrow edema which, of course, it cannot.
10. Dr. Shankland's operative findings are frequently at odds with the MRI reports and with histopathology reports.

Analysis of Cases:

Case 1:

SD, DOB [REDACTED], has a known history of migraine headaches and temporomandibular joint pain. She has been treated by Dr. Shankland since 3/19/96 at first for "TMD" with bite splints and muscle relaxants, but continued with headache pain 1996-1999. She saw a chiropractor five times for a diagnosis of "ribs out of place". Chiropractic care did not improve her headaches. On 5/11/00 Dr. Shankland noted a "shadow" in the edentulous area where tooth #18 once was. On the same day, Dr. Shankland prescribed amoxicillin and scheduled her for "removal of tooth #19 and NICO surgery". No other diagnostic methods were employed. Dr. Shankland accomplished "NICO" surgery 5/30/00 and confirmed NICO by the observation of "yellow adipose droplets within the blood indicating NICO". On 6/8/00 Ms. D complained of occipital headaches and on 6/27/00 jaw pain now around tooth #20. On 8/31/00, Dr. Shankland removed

tooth #20 due to persistent pain. Ms. D continued to have pain now more focused at the surgical site in the left mandible through 9/13/01. Dr. Shankland performed a cavitat testing and diagnosed an "ischemic region" from tooth area #17 to #20. This is actually the area of his past surgery which was registering his own surgical defect. Dr. Shankland re-operated the area on 9/14/01 and noted "characteristic oil bone cysts". Ms. D's pain continued unabated through 2002 and 2003. Dr. Shankland decided on a third surgery on 3/02/04 based on an MRI. Dr. Shankland accomplished a third surgery in the same location on 3/19/04. Once again he noted "a lot of oil cysts were encountered".

Ms. D's chart entries ended on 3/19/04. Cavitat graphs taken on 9/13/01 and 2/19/04 were available in the chart. Pathology reports by Dr. J. E. Bouguot on 6/13/00 diagnosed "partially non-viable and denuded osteoporotic bone, consistent with regional ischemic osteoporosis, variant of ischemic osteonecrosis/avascular necrosis, left molar region" and one on 3/25/04 diagnosed "necrotic marrow and viable bone (ischemic damaged)".

Opinion Summary:

This is a case of a vulnerable patient with migraine headaches being taken advantage of. She underwent three unnecessary surgeries and two cavitat tests at what ever cost and never improved because her pain was not originating in the jaws. Dr. Shankland diagnosed NICO on 5/30/00 without a cavitat or any other imaging beyond a plain radiograph. The "oil cysts" that reinforced Dr. Shankland's impressions represent the normal fatty marrow in the posterior mandible which is even more prominent in a post menopausal woman in her 60's. The cavitat testing each time recorded a previous surgical site misinterpreted by Dr. Shankland as NICO. Dr. Bouquot's microscopic diagnoses are series of gibberish used to justify a wrong diagnosis. He is merely looking at surgically damaged bone, not intrinsic pathology.

Case 2:

MH DOB, [REDACTED], is a woman with diagnosed systemic osteoporosis on Actonel (a bisphosphonate). She also has a complex dental history of extractions, orthodontics, headaches, and several root canal treatments with complications of pain and infection, dental implant placement with bone substitute grafts, nerve damage with sensory nerve loss and pain before seeing Dr. Shankland.

The patient presented to Dr. Shankland on 5/24/01 referred by Dr. Bouquot and Dr. Wahib [REDACTED] with complaints of severe pain lower right posterior mandible (the area of all her previous root canal treatments, infections, and implant surgery) and "transient numbness lower right". Dr. Shankland performed a cavitat on the initial examination and diagnosed "an avascular region". Dr. Shankland preformed NICO surgery on the very same day. He noted profuse bleeding "bled profusely" and "mushy unhealthy bone" with "brittle" "chalk-like marrow". He noted that "I came directly involved with the inferior alveolar nerve". One 6/4/01 MH called to report "a lot of pain". Dr. Shankland sees Ms. H on 10/10/01 and cavitat scans all four quadrants and diagnoses "ischemic regions" in the mandibular left quadrant (MH stated that she was having problems there) and also ischemic regions in the maxillary left quadrant. Then, Dr. Shankland himself reversed his cavitat interpretation upon reviewing a panoramic radiograph and realizing that the area was actually a portion of the normal maxillary sinus. On 10/31/01 Ms.

H reports continued pain in the lower right and now pain in the lower left jaw. On 11/07/01 Dr. Shankland performs yet another cavitat scan and diagnoses "ischemia in the mandible". The chart ends with the 11/07/01 entry.

Of note is a pathology report dated 5/02/01. It is from oral pathology associates Dr. Edward P. Rossi concerning a specimen taken from the posterior mandible. His diagnosis is "vital compact bone and adipose tissue". He notes "the adipose tissue was suggestive of fatty marrow". "Enlarged marrow spaces can appear as focal radiolucencies on x-ray". This was about one month before seeing Dr. Shankland. Yet, Dr. Bouquot who referred Ms. H diagnosed Dr. Shankland's biopsy specimen of 5/24/01 from the same area as "partially nonviable and denuded bone, consistent with ischemic osteonecrosis (bone marrow edema?) mandibular right third molar area".

Opinion Summary

Ms. H is another patient who did not improve with NICO surgery. She is also a patient with pain from another cause, namely root canal complications and obvious nerve damage as evidenced by her reports of numbness. Dr. Shankland begs the question by diagnosing NICO and accomplishing cavitat testing and surgery on the very first visit when this lady has strong evidence of neuropathic pain. The referral by Dr. Bouquot and his supporting microscopic diagnosis is suggestive of collusion. Dr. Bouquot's stated a diagnosis is once again gibberish with the use of partially nonviable and denuded bone. One would have to ask; is not then the bone partially viable, and what is the bone denuded of? Denuded bone is a clinical description not a microscopic one. No less than three cavitat testings were done. All three on the right side once again recorded a previous surgical site; the one on the maxillary left recorded an admitted normal maxillary sinus and the one on the left probable osteoporosis consistent with her systemic diagnosis.

Case 3

LI DOB [REDACTED], has a history of multiple sclerosis, clinical depression, on lithium for a time, pemphigoid, and chronic fatigue syndrome. Undergoing active psychiatric care by MD psychiatrist, she saw Dr. Shankland on 5/10/04 with complaints of focal numbness (has noted upper and lower extremity numbness due to multiple sclerosis), discomfort left face upon chewing, and sensitive teeth. Dr. Shankland performed cavitat testing of all four quadrants on initial visit and diagnosed NICO in each quadrant. No other testing was done or diagnostic tools used except MRI scan. He scheduled NICO surgery for next day 5/11/04. The MRI scans of 5/10/04 talks about "early cavitations" and "bone marrow edema". Dr. Shankland notes its correlation to the ultrasound. During cavitation surgery of 5/11/04 Dr. Shankland takes specimens for bone toxicology and notes "numerous oil cysts" in all areas. Chart entries conclude on 5/12/04. Patient returned to New York.

Pathology reports from Dr. J. F. Bouquot report two sites; #19 site "viable and partially denuded bone (from chronic ischemia?)" and "viable pulp with congestion and with attached osteoporotic bone", site #31 "viable bone with small focus of apparent subcortical marrow necrosis with aggregated PMN's (periodontal abscess?) and viable pulp".

Opinion Summary

Ms. I is another vulnerable patient with pain due to more obvious medical reasons that Dr. Shankland either consciously used to justify a NICO diagnosis or is very naive as to not recognize the connection. He jumps right into a cavitat test and surgery. The supportive MRI seems to have been led to that conclusion as the MRI report hedges its statement by reporting "early cavitations" and following the written clinical impression of "bone marrow edema" when an MRI cannot make that judgment alone. Dr. Shankland's self serving clinical conclusions are exposed by Dr. Bouquot's microscopic report that the pulps of teeth #'s 19 and 31 were both "viable". Yet Dr. Shankland's operative observations noted that the pulps were "necrotic". In addition, although Dr. Bouquot reports "viable bone" he supports an "ischemic osteonecrosis" diagnoses.

Case 4

Mr. PK DOB [REDACTED], was self referred to Dr. Shankland via the internet. He chiefly complains of right temporal headaches, right infraorbital pain, and right ear pain. Initial examination is on 10/08/01. The patient complains of "feeling of something" that he believes to be an infection because antibiotics partially relieve it. He has a history of frontal and temporal headaches as well as anterior maxillary teeth #'s 6 and 7 removed within the past month after failed root canal treatments and failed apical surgeries. Dr. Shankland performed cavitat testing which he interpreted as showing ischemia in five separate areas; areas #'s 1-3, 4-6, apices of 7-8, 15-16, and 9-13. During the examination Dr. Shankland finds that he "changed the angulation of the transducer as was able to demonstrate that the area was not as bad as I originally thought", referring to the #11-13 area only. He ended the examination by noting three areas of ischemia and scheduled surgery for the next day. Dr. Shankland performed cavitation surgery on 10/09/01 entering each maxillary tuberosity and noting "oil cysts". He also enters the anterior maxillary areas where the previous apical surgeries were accomplished a month ago and noted granulation tissue, brown bone, and exquisite tenderness for the patient requiring additional anesthesia. The chart entries end the next day 10/10/01. A strange letter from Mr. K to Dr. Shankland dated 7/22/01 talks about "my surgery 10/09/02 when the surgery was actually on 10/9/01. This letter is in printed form rather than cursive and pre-dates the surgery by three weeks yet it talks about the surgery in the past tense as well as describes the insurance denial. The letter lauds Dr. Shankland and identifies great relief. It also requests Dr. Shankland contact "Jackie" in Human Resources. Treatment plan cost estimate by Dr. Shankland for the 10/08/01 surgery is listed as \$8,022.00. Dr. J. E. Bouquot's microscopic diagnoses are "inflamed residual cyst" in the specimen from the anterior maxilla and "regional ischemic osteoporosis in the right maxillary tuberosity and partially dunned osteoporotic bone without inflammation from the left maxillary tuberosity".

Opinion Summary

This patient improved not because of NICO surgery but because of the removal on an inflamed cyst in the maxilla. The two surgeries in the right and left maxillary tuberosities were unnecessary as was the testing related to them. Once again, Dr. Bouquot's pathology description of the tuberosity specimens is inventive terminology suggesting pathology of a normal area. The letter purportedly written by Mr. K is inconsistent in its dates.

Daughtry Family Department of Surgery
Division of Oral/Maxillofacial Surgery
Deering Medical Plaza
9380 SW 150 Street, #190
Miami, FL 33157
(305) 256-5293

5

REDACTED

Case 5

Mr. RL, DOB not recorded, initially visits on 9/27/01 self referred via the internet with complaints of "right sided temporal headaches", "right infra orbital pain", and "right ear pain". Dr. Shankland finds muscle tenderness and obtains a panoramic radiograph which he interprets as "normal". He also performs a cavitat examination which he interprets as "possible ischemic osteonecrosis" in the maxillary right posterior and mandibular right posterior quadrants. Dr. Shankland fabricates an "NTI" (presumably a bite splint) and relates possible NICO surgery if the pain does not abate. Mr. L returns 10/29/01 and reports significant pain relief. No surgery is performed and Mr. L returns to Maryland.

Opinion Summary

Mr. L had classic symptoms of what is called myofascial pain dysfunction (MPD) which is essentially muscle tenderness due to overworking jaw muscles from teeth clenching or grinding habits. Here, cavitat testing was not indicated and consideration for an unnecessary surgery was inappropriate. Fortunately, Mr. L gained relief from the bite splint proving the cavitat identification of possible ischemic areas incorrect.

Case 6

EL, DOB [REDACTED], initial examination on 1/17/05. Chief complaint of "my gums swell up" "always tired" and "ear infections". She was referred by Dr. Brown of Versailles Indiana who accomplished a surgery in the #32 area on March 17, 2004. He noted "periosteal perforations" and "tunnels in the medullary bone". Dr. Bouquot's diagnosis was ambivalent between "chronic low grade infection" or "ischemic bone disease". Dr. Shankland notes that teeth #'s 1, 16, 17, and 32 were missing and feels #32 never developed. A soft tissue biopsy specimen had been accomplished in the #32 area on 2/18/03 and reported as "fibrous hyperplasia with ulceration". A panoramic radiograph of 10/10/04 is read out as "normal study" by an independent provider. Cultures taken on 11/17/04 identify staphylococcus, alpha streptococcus, and lactobacillus.

Dr. Shankland's examination identifies chronic periodontitis and the cavitat identifies ischemic areas #'s 30-32 and #29. He also schedules a MRI study in which Dr. Kukula identifies "minimal marrow edema/ischemic areas at #17 to #20 sites" and early cavitary osteonecrosis at #17 and #32 extracted sites". Dr. Kukula further identifies that his findings are more clear on the left than the right despite the patient's symptoms on the right. He also reports "mild marrow edema/ischemia with possible early cavitation at #1 and #16 extraction sites". The chart of this patient contains the report from a Tc 99m MDP bone scan of 11/20/03 as normal in all these areas. This chart also contains numerous coagulation studies all of which are normal.

Dr. Shankland removes tooth #31 and performs NICO surgery on 1/18/05 in the #'s 30-32 area and reports a "huge cavernous area with oily cysts". The chart entries conclude on the next day 1/19/05. Dr. J. E. Bouquot pathology report diagnoses "focal osteoporotic marrow defect".

Opinion Summary

There is no real pathology identified here other than perhaps chronic periodontitis. Even Dr. Bouquot's pathology report fails to identify anything more than an osteoporotic bone marrow defect. Dr. Kukula's MRI report is at odds with an outside radiology report of a panoramic film, a Tc 99m MDP scan, the patient's symptoms and Dr. Shankland's surgical findings. Once again the surgical findings are consistent with a normal marrow space in this region of the mandible. In all likelihood this woman's complaints arose only from chronic soft tissue infection (gingivitis).

Case 7

LMcK, DOB [REDACTED]. Initial examination with Dr. Shankland on 3/17/04 with a chief complaint of "pain and swelling in left jaw". Referred via the internet. Pain began after dental work on the maxillary left first molar (tooth #14). Dr. Shankland's examination includes a cavitat examination and diagnoses her maxillary left (#14 area) pain as "ischemic osteonecrosis". From 4/29/04 to 7/06/04 Dr. Shankland refilled prescriptions for Ultram. Dr. Kukula's MRI report supports Dr. Shankland's contentions of "ischemic necrosis" but was inconsistent with Dr. Shankland's cavitat findings and the patient's symptoms. That is, Dr. Kukula's MRI report of 7/08/04 also identified a "cavitary osteonecrosis with osteomyelitis" in the left anterior maxilla, and "extensive marrow edema of the left mandibular body and angle and to a lesser degree on the right", none of which were identified by the cavitat that is supposedly specific for these diagnoses. Dr. Shankland uses this report and his cavitat data to justify his 7/09/04 surgery in which he removes #14 and accomplishes a NICO surgery. Once again, Dr. Shankland's operative report identifies oil cysts. Dr. Shankland followed her for one month then the chart entries were concluded.

Opinion Summary

This patient simply has a "bad tooth". That is, a pulpitis from her previous dental caries, a recent crown preparation, or a cracked tooth. Her pain and swelling could have been eradicated with a simple tooth extraction. Yet, Dr. Shankland incorporated the extra costs of the cavitat and an MRI to make her complaints seem so much more than they were and to justify a more invasive and unnecessary surgery. The inconsistency of Dr. Kukula's MRI report and Dr. Shankland's cavitat is most revealing. Throughout several other patients Dr. Shankland uses Dr. Kukula's MRI report and leads him to diagnose findings that support his own. Here their communication must have broken down as Dr. Kukula describes several areas of extensive marrow edema and disease in which the cavitat did not and in areas where the patient had no complaints. This is highly suspicious.

Case 8

MR, DOB [REDACTED]. Initial examination by Dr. Shankland on 4/30/02 was labeled as "NICO exam". Patient is a forty four year old woman with a biopsy and culture established diagnosis of chronic sclerosing osteomyelitis of the right mandible. Ms. R been recommended for a segmental jaw resection for cure or a maintenance schedule of antibiotics for control. Ms. R is looking for alternatives. Her pain was under control at the time with significant relief and only

infrequent episodes of flare-ups. She was referred by Dr. Green but had e-mailed Dr. Shankland on 3/12/02 (six weeks before her visit). Dr. Shankland sent her via mail an "anodyne infrared unit" for her pain. Dr. Shankland's examination included a cavitat examination which diagnosed ischemia in the right mandible (Note! Chronic sclerosing osteomyelitis is a known true ischemia of bone and has a distinctive radiographic and CT pattern). Despite minimal pain at this point, Ms. R agrees to surgery for 5/01/02. Dr. Shankland reports falling into a "cavernous region" during the surgery. Ms. R leaves after the 5/02/02 with continued use of the infrared anodyne unit. She returns about one year later now with "deep aching pain" in the right side of the mandible and swollen lymph nodes". Dr. Shankland diagnoses ischemic osteonecrosis of the right posterior mandible and "periosteal osteosarcoma of the right mandible". Telephone calls persisted back and forth from 6/19/03 to 7/29/03 about ruling out osteosarcoma in Miami. Dr. Shankland speaks with Ms. R on 9/08/04 and criticizes others for not accomplishing a biopsy to rule out osteosarcoma. Yet, he had the opportunity to do the biopsy himself during his 5/01/02 surgery. Biopsies by Dr. Marx prior to her visits with Dr. Shankland on 7/16/01 also diagnosed osteomyelitis, not osteosarcoma. However, Dr. Shankland accomplishes an exploration biopsy on 9/09/04 and reported that he "did not encounter any oil cysts". The biopsy report identified the same "chronic osteomyelitis" she originally came to Dr. Shankland for.

Opinion Summary

Ms. R is a patient of mine and one with whom I am very familiar. She is another vulnerable patient that Dr. Shankland exploits. She does not want to undergo curative surgeries and is looking for short cuts and alternative medicine approaches. Dr. Shankland supplies hope, invokes new diagnoses to her, uses new machines, and then uses a similar surgery to that which diagnosed her condition originally. He fails to take cultures and fails to biopsy the area then criticizes others for not accomplishing a biopsy. In the final analysis Ms. R leaves Dr. Shankland's practice after undergoing two more surgeries with the same condition that she entered. It is also interesting to note another Dr. Kukula MRI report that identifies areas of "marrow edema" (here the maxillary right and left as well as the mandibular left) where there are absolutely no signs or symptoms.

Case 9

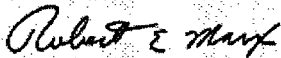
JT, DOB [REDACTED]. She is initially examined 5/21/02 with a chief complaint of pain in the left mandible, some pain in left ear, and sometimes burning sensations left face and tongue. She was referred by Dr. Shankland's website. She has a history of a deep filling in mandibular left second molar, crown restoration, and root canal therapy. After root canal therapy she experienced burning in lip and tongue as well as a "cold feeling". Re-treatments of the root canal did not help. Dr. Shankland diagnoses ischemic necrosis and bone marrow edema via clinical examination, a panoramic radiograph, and a cavitat examination. Dr. Shankland performs surgery on 6/7/02. He reports "oil cysts" and "fibrous marrow". He also encounters "brown marrow" and diagnoses from this "chronic non-suppurative osteomyelitis. On 8/07/03 Ms. T reports more pain. Another cavitat is done and Dr. Shankland once again diagnoses "ischemic osteonecrosis" in the same area of his surgery on 6/07/02. Dr. Shankland re-operates the area on 8/27/03 and reports "a few oil cysts and a large cavernous region". Ms T continues with pain and now reports a sour taste in her mouth. Dr. Shankland now diagnoses "chronic non-suppurative osteomyelitis". Dr. Shankland performs a third surgery in the same area on

12/04/03, a debridement of "granulation tissue". However, no culture is taken (Note Dr. Shankland's letter to Ms. T on 6/18/02 incorrectly states that chronic non-suppurative osteomyelitis is a "sterile type of infection"). Ms. T continues with jaw pain and a sour taste to 2/09/04 when Dr. Shankland re-examines her and now diagnoses ischemic osteonecrosis. He performs a fourth "clean out" surgery on 2/13/04. Ms. T is no better after this surgery. Continued pain, sour taste and now a draining fistula are the constellation of signs and symptoms. Another cavitation is performed. Dr. Shankland diagnoses ischemic osteonecrosis, myofascial pain dysfunction, and temporal tendonitis. Dr. Shankland sees her on 9/20/04 for the last time. She still has the sour taste and pain.

Opinion Summary

~~Dr. Shankland incorrectly diagnosed this patient's condition and accomplished unnecessary surgeries that created a new and worse condition. This patient had the classic history and symptoms of a nerve damage neuropathy (deafferentation neuropathy). Yet, Dr. Shankland via the cavitation and extreme tunnel vision focused in on his usual diagnosis of ischemia. Ms. T did not improve because her pain was of nerve origin. In fact, she worsened and developed a chronic osteomyelitis by repeated surgical entries. Dr. Shankland's cavitation examinations after the first were identifying his own surgical defects. Dr. Shankland also demonstrates a manipulative or ignorant approach by his letter to Ms. T of 6/18/02 stating that her obvious infection is a "sterile type of infection". No it is not. Non-suppurative merely means non-pus forming. Bacteria are still part of the process. This entire case was misdiagnosed, misunderstood, and mismanaged by Dr. Shankland. It seems to me that Dr. Shankland is embarking on diagnoses and treatment he is not sufficiently trained to manage.~~

Sincerely,



Robert E. Marx, DDS
Professor of Surgery and Chief

REM/mr

NICO AND CAVITAT

Throughout Dr. Shankland's cases he used the diagnosis of ischemic necrosis (Neuralgia Inducing Cavitation Osteonecrosis or NICO) as determined by the cavitat ultrasound device to justify significantly invasive surgeries. In nearly every case he gave the patient a reference list of six textbooks and articles that purportedly gave credence to the NICO concept. Four of the cited publications were either by Dr. Shankland himself or by Dr. Bouquot.^{1,3,4,6} The other two mention NICO related to other entities.^{2,5} In my literature review even today there remains no valid scientific literature that documents the reality of NICO or any diagnostic value to the cavitat. Nearly every publication that purports NICO to be a real disease or that the cavitat is a legitimate diagnostic tool is either written by Dr. Shankland or Dr. Bouquot. Neither NICO nor the cavitat device are taught in any dental school or residency training program and no discussion of either as a legitimate entity are included any textbook except the one where Dr. Bouquot is one of the editors'. In fact, one textbook and two scientific journal publications point out the fallacies of NICO.^{15,16,17}

Neuralgia inducing cavitation osteonecrosis suggests that sterile cavitations in the jaws produce pain and therefore should be debrided (cleaned out). This is actually a concept that was discredited and abandoned in the 1980's and known as "Ratner's bone cavities".¹⁸ The reality is that these so-called cavities merely represent the normal marrow spaces in the jaws and can be seen on nearly every CT scan in an adult. They actually represent normal anatomy misinterpreted as a disease. The bones of the jaws contain bone marrow as does every bone of the skeleton. As we age the hematopoietic elements (cells that produce red blood cells and white blood cells) are slowly replaced by fatty deposits. This is even more prominent in women over forty years of age due to menopause and particularly osteoporosis. Therefore, it is not a coincidence that Dr. Shankland's patient population is over 75% women as are those of the few other NICO doctors. Of the nine cases from Dr. Shankland that I reviewed, seven were women. The two men in his group actually had other real diseases. In addition, the major deposits of fibro-fatty marrow are in the posterior regions of the jaws. Nearly all NICO cases are reported in these regions and of the nine cases I received from Dr. Shankland's records, eight were in these posterior regions. The only one exception was a man who had an actual cyst in the anterior maxilla. The very fact that adult bone marrow particularly that in the posterior regions of the jaws, is nearly all fibro-fatty explains the observation of "oil cysts". These are not actual cyst but the chemical products of normal fat. They are seen in most all surgeries in this area and only represent part of the biochemical makeup of bone marrow. In essence, these so called cavitations represent the normal marrow space anatomy in the region, not disease.

The cavitat device is an ultrasound device that essentially tests only bone and/or soft tissue density. Ultrasound devices are used in several areas of medicine today including obstetrics, vascular surgery, and osteoporosis management. In these situations the ultrasound device is a calibrated device for the area tested and is conducted by trained technicians using standard protocols. The cavitat device is not standardized, it is conducted by a clinically biased dentist, and there are no standard protocols for its use. Therefore, readings from the cavitat can be intentionally manipulated or unintentionally changed to show positive findings in normal tissue or even normal findings in diseased tissue. This was well illustrated by Dr. Shankland's own mistake when he caught himself registering an ischemic area that was actually the air space of the normal maxillary sinus.

The cavitat machine boasts a 510 K clearance by the FDA which should be understood that it only indicates equivalency to already marketed devices as I noted above. It does not mean that the cavitat device has shown efficacy for the diagnosis of NICO. In fact, the cavitat brochure indicates that the green to yellow to red escalating color changes on the screen have not been FDA tested related to normal or pathologic bone.

As an ultrasound device the cavitat can only ascertain tissue density. It cannot ascertain blood flow or ischemia in bone. Dr. Shankland may be misinterpreting the use of other ultrasound devices in determining "blood flow" in large blood vessels. As an example, in the area of the carotid artery blood flow is determined not as blood flow but as the percent constriction of the artery. In determining blood flow in the leg related to blood clots, it is the tissue density of the blood clot and the size of the vein that these ultrasound devices determine. The cavitat cannot determine the nutrient blood flow to bone. It therefore, cannot diagnose ischemia and the cavitary lesions it registers as yellow or red merely represent areas of less dense tissue i.e. normal marrow spaces, surgical defects, nerve canals, and in some cases real cysts or even the normal maxillary sinus all of which were illustrated in the cases of Dr. Shankland.

In summary NICO is not a scientifically proven nor accepted pathology and surgeries to address this condition represent unnecessary invasions that in many cases worsen the patient's condition. The cavitat is a limited ultrasound device that is not calibrated or standardized and has insufficient independent testing to validate its efficacy. Both are subject to misuse and abuse. I understand that discovery is still ongoing and I reserve the right to supplement this opinion as additional materials become available.

References:

1. Facial pain and neuromuscular diseases. In: Neville B, Damm D, Allen C, Bouquet J. Oral & maxillofacial pathology, 2nd ed. Philadelphia: W. B. Saunders; 2001:746-748.
2. Glueck O, Freiberg R, Gruppo R, et al: Thrombophilia and hypofibrinolysis: reversible pathogenetic etiologies of osteonecrosis. In: Urbaniak JR, Jones, JP Jr (eds). *Osteonecrosis etiology, diagnosis, and treatment*. Chicago: American Academy of Orthopaedic Surgeons; 1997:105-110.
3. Gruppo R, Glueck CJ, McMahon RE, Bouquet J, Rabinovich BA, Becker A, Tracy T, Wang P. The pathophysiology of osteonecrosis of the jaw: anticardiolipin antibodies, thrombophilia, and hypofibrinolysis. *J Lab Clin Med* 1996; 127:481-488.
4. Bouquet JE, Roberts AM, Person P, Christian J. NICO (neuralgia-inducing cavitation osteonecrosis): osteomyelitis in 224 jawbones samples from patients with facial neuralgia. *Oral Surg Oral Med Oral Pathol* 1992; 73:307-319.
5. Simon JHS: Periapical pathology. In, *Pathways of the pulp*, 6th ed. Cohen S, Burns RC (eds). St. Louis: CV Mosby Co;1994:337-362.
6. Shankland WE: Osteocavitation lesions (Ratner bone cavities): frequently misdiagnosed as trigeminal neuralgia - a case report. *J Craniomand Pract* 1993;11:232-234.
7. Bouquet JE, Roberts AM, Person P. Neuralgia-inducing cavitation osteonecrosis (NICO): osteomyelitis in 224 jawbone samples from patients with facial neuralgias. *Oral Surg Oral Med Oral Pathol Oral Radiol*. 1992. 73:307-319.
8. Bouquet JE, LaMarche MG: Ischemic osteonecrosis under fixed partial denture poetics: radiographic and microscopic features in 38 patients with chronic pain. *J Prosthe Dent*, 1999. 81:148-158.
9. Bouquet JE, McMahon RE. Ischemic osteonecrosis in facial pain syndromes. Part 1: A review of NICO (neuralgia-inducing cavitation osteonecrosis) based on experience with more than 2000 patients. 5-3 ed. Morgantown (WV). The Maxillofacial Center. 1996, p. 1-19.
10. Bouquet JE, McMahon RE. Ischemic osteonecrosis of the jaw in 2023 patients with facial pain (abstract). *J Oral Pathol Med*. 1996. 25:271..

11. Bouquot JE, McMahon RE. Neuropathic pain maxillofacial osteonecrosis. *J Oral Maxillofac Surg.* 2000. 58:1003-1020.
12. Bouquot J, Martin W, Wroblewski G. Computer-based thru-transmission sonography (CTS) imaging of ischemic osteonecrosis of the jaws - a preliminary investigation of 6 cadaver jaws and 15 pain patients (abstract). *Oral Surg Oral Med Oral Pathol Oral Radiol Endod.* 2001;92:550.
13. Bouquot JE, Margolis M, Shankland WE II. Through-transmission alveolar sonography (TTAS) - a new technology for evaluation of medullary diseases. Correlation with histopathology of 285 scanned alveolar sites (abstract). Proceedings, annual meeting. *American Academy of Oral & Maxillofacial Pathology*, New Orleans, April 2002.
14. Bouquot JE, Shankland WE II, Margolis M, Glaros W. Through-transmission alveolar ultrasonography (TAU) - new technology for detection of low bone density of the jaws. Comparison with radiology for 92 osteoporotic alveolar sites with histopathologic confirmation. Proceedings, annual meeting, American Academy of Oral & Maxillofacial Pathology, New Orleans, LA, April 2002.
15. Marx R, Stern D. Oral and maxillofacial pathology: a rationale for diagnoses and treatment. Quintessence Publishing Co., Inc. Chicago. P 885, 2002.
16. Goldstein BH. Unconventional dentistry: Part III. Legal and regulatory issues. *J Can Dent Assoc.* 2000. 66(10):503-506.
17. Goldstein BH, Epstein JB. Unconventional dentistry: Part IV. Unconventional dental practices and products. *J Can Dent Assoc.* 2000. 66(10):564-568.
18. Ratner EJ, Person P, Kleinman DJ, et al. Jawbone cavities and trigeminal neuralgia and atypical facial neuralgias. *Oral Surg Oral Med Oral Pathol.* 1979. 48:3-20.