

INOS 2008: Ethical Science or Something Else?

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For almost two decades, I have supported and attended many INOS meetings all over the world. In each of them, invited speakers were recognized authorities on the topics of their presentations. However, in the program for INOS 2008 there has been a radical departure that raises many questions and concerns both about the qualifications and objectivity of one invited speaker and a possible political agenda behind the invitation. These questions and concerns were communicated to the person responsible for the invitation and were ignored; I was summarily informed that the invitation was a *fait accompli*. In order to evaluate this presentation, the members of INOS and others in the audience deserve disclosure about the qualifications and possible lack of objectivity of the invited “expert” they are listening to. In the interests of such disclosure, I will address both in this editorial.

Qualifications

There are many respected scientists whose research in the field of Infantile Nystagmus Syndrome (INS, aka CN) and its treatments is known to most members of INOS; some have decades of experience and numerous publications of their results. Other, younger scientists have also made significant contributions to this field. The person chosen to speak on “Does tenotomy work for CN and for acquired nystagmus?” does not appear on this list by any objective criteria. According to his CV, he only has two minor publications involving the actual recording and analyzing of INS patients; they were both “case-report” types of papers on a few atypical patients with vestibular symptoms and oscillopsia that were studied in the lab of David Zee. Their publication dates were 1985 and 1989; there have been no publications of any INS studies conducted by him in the past 18 years. Why then, was Lance Optican invited to give an address at the INOS meeting on a topic in which he has no expertise and no apparent direct experience in recording INS patients’ eye movements? It appears that he was chosen solely on the basis of two papers published in Vision Research in 2003 (1,2). These papers are the crux of the matter. There are two issues involved: 1) their scientific merit and 2) their history, detailing the methods used by the responsible authors to acquire and use the data of others during an ongoing masked-data NEI clinical trial (i.e., the possibility of deception and bias). The first falls under “Qualifications” and the latter under “Objectivity”

Scientific Merit

The major conclusions in the respective abstracts of the above two papers were: 1) “tenotomy surgery has no effect, or only a quite small effect, on the waveform structure of CN” and 2) “tenotomy has no effect, or only a quite small effect, on the underlying mechanism of the CN beats.” To many who read the abstracts, these carefully worded (“only a quite small effect”) but unsupported conclusions cast doubt on the positive findings of the masked-data NEI clinical trial of the effectiveness of the tenotomy procedure. Most readers did not have the background to understand the complex mathematics underlying both methods. First, neither of the two methods (wavelets or dynamical systems analysis) was demonstrated to be *sensitive* enough to detect the NAFX-measurable foveation improvements produced by tenotomy; not in those papers nor in any to be found in the literature, before or since. Second, analysis of the papers revealed serious methodological errors in the application of the analysis methods and in the data handling;

the responsible authors had limited experience in both. Third, additional errors remained undetected until after publication of my letter to the editor of Vision Research outlining the problems detected from the papers alone and concluding that their poor methodology effectively precluded and made moot the conclusions of the papers (3). Optican's response letter (4) failed to persuasively address the methodological errors but rather contained personal attacks not only related to the NEI clinical trial but also, all of the prior work by my colleagues and me, including the canines with achiasma and INS. None of these were the subject of my letter. Specific rebuttal to the issues brought up in the response letter may be found elsewhere (5). With no foundation, he also questioned the objectivity of the NAFX and its application.

The NAFX has been used in the Daroff-Dell'Osso Ocular Motility Laboratory for over a decade and its sensitivity to waveform changes directly affecting visual acuity had been repeatedly demonstrated and published for all waveforms in patients with and without afferent visual deficits. It is applied to the fixating eye during intervals free of recording artifact (e.g., blinks, switch of fixation to the other eye, loss of attention/fixation, switch in fixation elsewhere, etc.). This is common practice (indeed, essential) in eye-movement research and is easily done by any one after some training and experience. The NAFX does require that the data be accurately *calibrated* so eye position is known. The efficacy of the NAFX has also been demonstrated by other researchers applying it and obtaining results equivalent to ours; they used the NAFX to predict visual acuities because it *exceeded all other measures* in correlating with visual acuity (6). Because of its accuracy in predicting visual acuity, the NAFX has also been used to estimate post-therapy improvements in INS and acquired nystagmus patients independently of any afferent deficits (7-9). To specifically ensure that the method was both *repeatable* and *objective*, not only was the NAFX analysis in the NEI clinical trial conducted on *masked* data but also on *redundant masked data files* that were sent to me for analysis. Optican failed to report this critical information in either his papers or response. Significantly, there was no such protection in Optican's "playing" (see below) with our data; he also failed to report that he drew his conclusions from unmasked data files whose only purpose was to uncover asymmetric aperiodic alternating nystagmus.

Optican's response letter seemed to reveal ignorance of basic concepts involved in the calibration and analysis of INS data; it is necessary to accurately calibrate data if one is to analyze it properly. The additional errors revealed in the response further invalidated both studies and, in response to a reviewer's *specific* request, were addressed in a subsequent publication on the beneficial "small-signal" effects of tenotomy (10). Optican and Miura indicated in their response that they found it *difficult* to calibrate the cleanly recorded search-coil data from our NEI clinical trial, data that I easily calibrated despite being masked! It is not surprising that such inexperience needed the shield of coauthors with some expertise in recording and analyzing INS data; it is unfortunate that their expertise was not evident in the papers. Hertle's verbal warning that Optican and Miura should not choose long, uncontrolled and artifact-filled files for analysis, was ignored; he, and I, assumed that Optican and Miura accurately calibrated the data they analyzed. Even if all of the methodological errors were corrected and the same failure to find a difference occurred, the only supportable conclusion that could be drawn from the wavelet paper would be that the method *did not detect* the tenotomy-produced waveform changes that were measured by the NAFX and resulted in improved visual function. The authors could not conclude there were no changes. Unlike the NAFX, wavelet analysis has never been proven to be a definitive measure of the specific waveform changes in question; it has not been proven to be a measure at all. From the dynamical systems analysis paper, The authors' conclusion that tenotomy does not appear to affect the underlying mechanism of INS applies only if INS was caused by one mechanism; our data suggest that is not the case. However, tenotomy was never claimed to have affected INS mechanisms but rather, that it improved the resulting INS waveforms, a *critical* difference that also was omitted.

The bottom line is, those two papers cannot even support the null conclusions of their authors because of the apparently insensitive methods, applied in violation of their underlying mathematical principals, coupled with improper data choices and failure to accurately calibrate the data. I found them devoid of scientific value; they should have been rejected on merit alone. Perhaps an analogy will help clarify the scientific fallacy of the two papers. Consider if one used a Gieger counter to measure the pre- and post-tenotomy radiation given off by the patients' eyes and found no difference. This is also a sensitive method designed for other tasks. No careful scientist would conclude from such a null finding that tenotomy did not affect the eye movements. In both my letter to Vision Research and the "small-signal" paper, my harsh (and, in the letter, intense) criticism of the two papers in question concentrated solely on the obviously bad science and did not expose the ethical problems raised by the surreptitious data mining that enabled them (see below). Apparently, my expectation that demonstrating their lack of scientific merit would suffice was misplaced.

Objectivity

We all presume an invited speaker to a prestigious meeting is both presenting his data objectively and that he followed the normally accepted protocols associated with ethical science in acquiring and analyzing it. Unlike evaluating one's qualifications and publications, which are a matter of public record, detecting possible bias is more difficult and proving it, almost impossible. However, deviations from the norm, or actions that raise ethical concerns, are red flags that should warn of the possible absence of objectivity, the foundation of scientific inquiry. Knowledge of them requires responsible scientists to at least, disclose them allowing more objective evaluation of the presentation.

History

After Rich Hertle and I demonstrated (1998) and published (1999) the positive effects of tenotomy on the nystagmus waveforms of a canine, we began to study the INS waveform changes produced by tenotomy in humans. We recruited Bob Burnstine to provide another clinical site and source of patients. It was during that time that the NEI recruited Hertle from Philadelphia and, after he arrived there, we submitted our protocol for a clinical trial of tenotomy. I provided the ocular motility protocol and was the investigator in charge of performing all the motility analyses; the NAFX evaluation of INS waveform changes was the *primary outcome measure*, visual function measures were *secondary*. It was decided that the data would be masked. I was given assurances that the masking would be carefully controlled to avoid any mislabeling of data. I was also assured that during the time I would be masked from the data and we published our results, no one outside of our research team would have access to our data. That assurance was to be violated by Optican from early on in our clinical trial and continue throughout its course.

At some point before the protocol was approved (August 16, 1999), the NEI head (Carl Kupfer) attempted to exclude me from the project, despite the fact that this project was based on my prediction and subsequent demonstration of the beneficial effects of tenotomy, was initiated before the NEI was involved, and required my expertise in nystagmus analysis to provide the primary outcome results. Hertle prevented this blatant attempt to hijack our joint work and place it entirely within the NEI.

On April 19, 2001, while in the middle of my masked-data analysis, Hertle sent me a SFN abstract prepared by "K. Miura" and "L.M. Optican" at the NEI; they had accessed our unmasked data and used it for a study of the dynamical systems analysis of nystagmus waveforms pre- and post-tenotomy. The abstract was sent to Hertle and Ed FitzGibbon with two extra places allotted for authors filled with "?????," prompting them to add their names as co-authors; this, despite the fact that the work was done by Optican and Miura. Earlier, Optican had assured Hertle that his interest was not in the effects of tenotomy on INS (the subject of the NEI clinical trial) but in underlying mechanisms of INS. I immediately protested this violation of the data- and patient-protection agreements that ensured my participation in the clinical trial. I was assured: 1) Optican had violated the NEI DSMC guidelines; 2) the improper behavior would be stopped; and 3) Optican would not be allowed to submit the abstract. Indeed,

he was prevented from doing so. Optican claimed he was only “playing with” our data (documented by email). I was then reassured that the data would not be shared with any one until our publication of the results of the clinical trial. Thus, during the three years I attended to the mind-numbing task of analyzing a mountain of masked data, I was under the illusion that our data were being protected by the NEI from unauthorized eyes, and use, until publication of our results.

That illusion was shattered when, about the *same time* as our first publication demonstrating unequivocally the beneficial effects of tenotomy on INS waveforms (11), the two companion papers discussed above appeared in *Vision Research* authored by Optican and Miura plus both of their NEI colleagues; the papers claimed that tenotomy had no effects on INS waveforms (1,2). Needless to say, I was shocked to learn that our unmasked data had continued to be accessed by Optican during our NEI clinical trial allowing choices of the data to be analyzed and to prepare these papers to be submitted at about the same time as our first submission (his papers on September 23, 2002 and ours on September 3, 2002). Thus, unknown to me and despite his initial reprimand, Optican had access to the 880 records unmasked, whose masked analysis took over 550 hours. Optican and Miura should have been prevented from accessing and using our data. This, and his failure to wait until publication of our results, was in direct violation of the NEI DSMC guidelines and of their agreements with me. I believe that no one had the right to give permission to access data in an ongoing study without the knowledge and permission of all the scientists conducting the study. Furthermore, it is my contention that no ethical scientist would either seek or accept access to another's unmasked data without their knowledge and permission. Unlike the above evaluation of the scientific merit of the papers, I cannot definitively assign specific motive for these extraordinary actions; I do consider them an attack on the integrity of all those who collaborated with me on the careful INS research we have done for 40 years. I remain confident that the careful work of those who actually study INS and tenotomy will survive this unprovoked and baseless attack.

Conclusions

Bad science (that also was the fruit of secretive and deceptive data mining) and questionable motives are all that support this invitation; any underlying agenda remains only speculation. The members of INOS deserve better. These objections, based solely on the speaker's qualifications and abnormal behavior suggesting bias, should be sufficient to preclude his speaking on the subject, the final content of the presentation, notwithstanding. INOS should not reward either poor science or questionable behavior and certainly not both. Each of us must decide personally what, if any, action to take; I cannot support this violation of our trust. The members of the audience at INOS 2008 now have access to the information necessary to properly evaluate both the presentation (should they choose to listen to it) and its source. The real victims of this unjustified invitation are the conduct of ethical science and those patients whose physicians withhold effective treatment under the mistaken impression that there is a scientifically valid controversy about whether tenotomy really improves INS or acquired nystagmus waveforms and, with them, visual function. There is abundant proof already in the literature that it does both.

Acknowledgements

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Citation

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Comment (added 7/23/07)

On July 16, 2007, a link to this Editorial was posted on the NANOSNET list (prompted by the posting of the INOS 2008 link on the same list). As a result of that posting, the facts contained in this Editorial are now known to over 300 (and counting) potential attendees at INOS 2008. My obligation to provide full disclosure to the members of NANOS was accomplished in two days (relying on Google alone may not have accomplished that much in a year). Despite the fact that most of the information in this Editorial is a

matter of public record, the organizers of INOS 2008 would not disclose it. Fortunately, what was to be disguised as an objective scientific presentation from an "expert" will have neither "controversy" nor "drama" (does INOS 2008 really need a hawk?). I do not plan to dignify Optican's presentation with my presence. If Optican's two papers or his Response are any indication, the person responsible for that ill-advised invitation will have to be satisfied with misinformation and possibly worse; that is what his decision will bring to those INOS attendees who choose to attend that talk. My advice is, visit a winery or have a big breakfast instead.

To my surprise as well as that of others, my simple posting of links to an Editorial and a Report on another site was construed as a "personal attack" by the NANOSNET list maven, Preston Calvert, who proceeded to remove my ability to post further information on the list. In contrast, my posting has appeared on other similar professional lists with no negative reaction by the responsible list managers. Apparently, Calvert wishes to censor any controversy, not only on NANOSNET but also on other sites on the web. My Editorial and Report only present the relevant facts and several of my opinions (clearly identified as such) and contain no personal attacks. Despite this, he continues to mischaracterize both and refused to reverse his decision (a decision that may be supported by others on the NANOSNET committee).

My monitoring the NANOSNET list was for educational (i.e., NANOS members') purposes only; that too, was halted, since I no longer receive it. However, as a Fellow of NANOS, I shall continue to monitor the list using other means and respond directly to NANOSNET members who need accurate information on those subjects where I can provide it, especially when a posting is in error. I regard this as my obligation to the membership. Calvert also refused to post my side of this matter, claiming that to do so would somehow "reiterate" my attack. It might also have revealed the weakness of his position. He may disagree with my opinion regarding to Optican's lack of credibility on this subject (unlike Optican's Response, my Editorial does not contain comments on his other work) but Calvert is clearly overreaching in trying to apply his rules to another site and is wrong to claim "personal attack" where none exists.

Censorship hasn't worked in the past and is no longer viable. We all appreciate the effort put in by those who monitor web sites or organize meetings. However, we do not expect them to abuse their positions or act with personal agendas to the detriment of their organizations or membership. We certainly do not surrender our rights to hold or express our data-based opinions, the essence of scientific discourse.

LF Dell'Osso, PhD 7/23/07

Comment (added on 8/31/07)

Recently, Dr. Lance Optican posted a letter to INOS members in which he denied the veracity of the historical record detailed in OMLAB Editorial #071107 and in OMLAB Report #071107. In response to his blanket denials, I can only reiterate that the above-mentioned record is both accurate and well documented, as attested to by Dr. Rich Hertle. The OMLAB documents stand as the only description exposing the extraordinary measures taken by Dr. Optican to prematurely access data from an ongoing masked-data, clinical trial to which he was not a participating party (*which he did not deny*) and to use that data, unmasked, (*which he did not deny*) to undermine the trial. In my opinion, his own "inappropriately aggressive" and unethical actions violated the DSMC rules under which the trial was conducted and the assurances made to me by the NEI in return for my participation. Those assurance were in accordance with NIH Policy [NIH Data Sharing Policy], that states no one outside the study would have access to or use data until publication of the results by the investigators conducting the trial (i.e., guaranteeing the right of "first use" to those conducting a study). *He did not deny* accessing our data and publishing his papers before our results were in press, as required by the above policy.

In his letter, Dr. Optican continued to rely on the cunning sentence structure exhibited in his unprofessional Response to my Letter to the Editor of VR; neither that nor "neutrality" is an acceptable substitute for truthfulness. His denials are aimed at whether or not his actions (*which he did not deny*), as documented in the Editorial and Report, actually violated existing regulations. That is not for him to determine but for objective committees that exist expressly for that purpose. Because of Dr. Optican, the literature now contains two extraordinarily flawed papers on INS and a personal attack on the integrity of the pioneering INS research performed in our Laboratory, the Laboratory of Dr. Robert Williams, and on all of the scientists who conducted that research. He squandered his opportunity for a "productive scientific discourse" when he failed to respond to the scientific criticisms contained in my Letter and instead, attacked my integrity and that of my work. I urge any who wish to read his disrespectful Response to have an open copy of OMLAB REPORT #071107 which provides a paragraph-by-paragraph exposure of the many statements based on false premises or made without citing the relevant conflicting information.

If Dr. Optican wishes to identify specific statements in either the Editorial or Report that are "factually in error" (*his letter failed to identify any*), he is welcome to submit them to me along with any documentation he might have. I will then append them and my response to the appropriate posted document. The OMLAB Editorial and Report are the only retrievable documentation of both his extraordinary behavior and the fallacies contained in his papers; they will remain so to prevent the misperception that Optican's two papers were the product of an unbiased and properly conducted study into the effects of tenotomy; the latter was accomplished by the NEI-sponsored Clinical Trial conducted and reported on by Hertle et al. The flawed attempts by Optican's two papers to deny the demonstrated positive effects on nystagmus waveforms cannot be compared to the results of our carefully designed and strictly supervised, masked-data analysis of INS waveforms. During the past few years, I have been appalled by members of both the research and clinical communities who cite this supposedly negative evidence of tenotomy's effectiveness yet could not tell a wavelet from a ringlet. Those that cite these papers after merely reading their overreaching abstracts do a disservice to the careful research that has established tenotomy as both viable and beneficial for nystagmus and, more importantly, to the patients who may benefit from this revolutionary therapy. One needs only to read the many publications that followed those in question to realize that new experiments documenting the progress of the tenotomy procedure in both INS and acquired nystagmus have already been conducted and reported.

Dr. Optican states that he knows of no reason to accuse Dr. Carl Kupfer of attempting to hijack my work. Dr. Optican was not a party to our Clinical Trial and would not have had reason to be at the meeting where this took place. Dr. Hertle was and reported it directly to me at the time it occurred; as a senior member of the research team, I did have a right to know. Several years earlier, when discussing my work with Dr. Williams on the achiasmatic Belgian sheep dogs, Dr. Kupfer stated, "Nothing clinically useful will come from studying the eye movements of dogs;" I believe history has proved him wrong.

Whether Dr. Optican's actions violated any data- or patient-protection agreement or NEI Data and Safety Monitoring Committee (DSMC) guidelines (or severely bent them), is something for others to determine. However, if the NEI's rules protecting a researcher's or patients' data were not violated by Dr. Optican's accessing and using them without obtaining my permission, especially after I specifically forbade further access, a chilling message will have been sent to all researchers considering collaboration with NEI employees. Such a result of Optican's actions would be a disservice to the many ethical scientists at the NEI. *Despite his protestations to the contrary* in his letter to INOS members, Dr. Optican was reprimanded by Dr. Hertle at my insistence and was told to cease and desist or the matter would be brought before the DSMC; he elected to forgo that experience but only pretended to comply. *He was told specifically not to submit his Neuroscience abstract and he did not submit it.* Had he ignored that directive, his actions would have immediately prompted a formal charge of misconduct.

As pointed out in the Editorial, Dr. Optican's own CV demonstrates his dearth of experience in studying either INS or the effects of tenotomy. He should never have accepted this ill-advised invitation to speak at INOS 2008 on a topic for which he has a demonstrable lack of experience, expertise, and objectivity. There are at least a dozen well-qualified scientists who could make a more well-informed presentation and who will not carry the baggage Dr. Optican has inflicted on himself.

As an Italian-American, I was taught at an early age that respect was not a verb to bandy about but something you demonstrate by your actions. For someone who, over the past six years, has shown both disrespect and disdain not only for my and my colleagues' reputations for integrity, but also for ethical scientific behavior, data- and patient-protection and the NEI institutional policy governing them, and full disclosure to Journal reviewers (and ultimately to the readers of the published material), his "respectfully" submitted self-serving request is pure chutzpah. If Optican truly wishes to demonstrate his respect for ethical science, the INOS membership, and for the INS research he has so unprofessionally maligned, he should decline the invitation. As a Fellow of NANOS and an INOS member, I urge him to do so.

LF Dell'Osso, PhD 8/31/07

Epilog (added on 8/6/08)

To express my opposition to the heedless action of the INOS "committee" responsible for an indefensible invitation to a speaker with no expertise in the either INS recording, calibration, analysis, or therapy, I chose to spend the month of June in Sardinia (attending a wedding and lecturing on eye-movements) and southern Italy (visiting friends and relatives while continuing my genealogical research in Calabria, Basilicata, and Puglia).

Several objective scientists who did attend the talk in question (instead of sampling the wines of the Napa Valley, as I recommended) reported their impressions to me. They expressed their disappointment at both the "unimpressive" and "unbalanced" content of Optican's talk, the lack of alternatives to proven analysis methods, at least one false statement about tenotomy, and his inability to satisfactorily address the concerns and questions raised after the talk.

Hopefully, I can now close this ugly chapter chronicling what the evidence suggests were politically driven actions of some in our community of scientists with the satisfaction that comes from the knowledge that I did what was necessary to educate the INOS membership both to the insult to them embodied in the Optican invitation and the unethical behavior that caused this problem in the first place.

The professional skeptics and their minions have failed miserably to either: 1) demonstrate scientifically that the tenotomy procedure does not benefit nystagmus patients or 2) provide a viable alternative mechanism to the proprioceptive-control hypothesis. Perhaps now objective and unbiased evaluation can continue of the data that has thus far demonstrated the multiple beneficial clinical effects of the tenotomy procedure and supported the proprioceptive-control hypothesis. I remain confident that both the resulting paradigm shift in nystagmus surgery and the renewed appreciation of the role of proprioception in eye-movement control will emerge as driving forces in future contributions to both basic and clinical ocular motor research. That is, and must be, the reward for scientific study, as the search for "ultimate truth" is an endless one.

LF Dell'Osso, PhD 8/6/08