

October 17, 2016

Dear Mr Gustavsson,

Thank you for inviting me to respond to Drs. Matthias Corbascio and Thomas Fux's allegations of scientific misconduct on the scientific poster publication "First in man synthetic nanofiber trachea transplantation" by Johnson J, Jungebluth P, Macchiarini P. (Poster publication "*First in Man Synthetic Nanofiber Trachea*", Aug 2, 2012) ([http://www.nanofibersolutions.com/Images/posters/First in man nanofiber trachea .pdf](http://www.nanofibersolutions.com/Images/posters/First_in_man_nanofiber_trachea.pdf)) and other posters and/or abstracts.

The accusers concluded that I, apparently having the overriding responsibility for the poster, present falsified data and am therefore guilty of research misconduct. It is also claimed that Dr. Jungebluth and myself have a close affiliation to commercial interest.

I am very glad to have this opportunity to address these false accusations of scientific misconduct and commercial interest:

Page 1: " This publication contains evidence of scientific misconduct, data manipulation and falsification on the part of Drs. Johnson (JJ), Jungebluth (PJ) and Macchiarini (PM). The publication is significant because not only does it present falsified data concerning a specific patient but also demonstrates the close affiliation to commercial interests with the ambition of generating investment (see reference list with comments, pages 13-17)"

The statement about the scientific misconduct is not only false but, represents, once again, a serious defamation. Neither Dr Jungebluth nor myself were aware that the (or indeed any) Nanofiber poster(s) was sent for possible publication to the different conferences presented by Dr Jed Johnson. Neither did we (directly or indirectly) participate in or approve the design and/or drafting of the final version of the Nanofiber abstract or poster(s). As demonstrated by the email correspondence made available here (<https://www.dropbox.com/s/qado3y7m8xo82u9/Re-%202012%20World%20Stem%20Cell%20Summit%20-%20POSTER%20ABSTRACT%20ACCEPTANCE.pdf?dl=0>), we indeed asked for immediate withdrawal of a poster once we were informed of its intended production by Dr Johnson, expressing in strong language our disappointment about Nanofiber's attitude, and concern about confidentiality and basic principles of scientific collaboration and respect. I believed after this correspondence that no poster had been submitted as neither Dr Jungebluth or myself had any further correspondence with Dr Johnson about it.

When I discovered a poster on Nanofiber Solution's website on October 29, 2012, I immediately asked for its withdrawal and clearly stated that I was, again, extremely upset with its presentation, authorship and scientific content, as the following email correspondence will also show (<https://www.dropbox.com/s/qc0lsn4fyj8z61n/Re-%20FW-.pdf?dl=0>).

There are clearly gross misrepresentations in the poster, due to it having been written

without the knowledge and input from anyone involved in the actual procedure.

With regard to the endoscopy picture shown in the poster/abstracts, it was taken by doctors from the Pneumology Department at the Thorax Clinic at the Solna Karolinska University Hospital seven days after transplantation. I cannot remember the name of the doctor who did the bronchoscopy herself but Dr. Jan Juto assisted to the best of my knowledge. Written and video records of the procedure should be available in that department. The cytology was technically processed at ACTREM and the samples were stored there and should be available for DNA verification, if necessary. It was read by an independent cytologist (Dr. A. Sotnichenko). The picture was forwarded to our scientific collaborators for acknowledgement but obviously should never have been used, without our approval, for an official publication. It is also, as the accusers point out, wrongly described in the poster, and obviously neither Dr Jungebluth or I would have sanctioned any of the descriptions in the poster (nor, as my emails show, the presentation of any such confidential patient information – something I take extremely seriously).

With regards to the commercial interest, this document (<https://www.dropbox.com/s/yjrjsb88g6iz2dy/FW-%20Please%20reconsider%21%20%28Answer%29.pdf?dl=0>) clearly shows that we never had any commercial interest with Nanofiber Solutions, or indeed any of the commercial companies that have collaborated with us during the transplantations. This is strongly against my ethics, as I have always stated. This was also previously recognised by an internal Karolinska audit, publicly released in April 2015 (<https://www.dropbox.com/s/0fiufm2m6ku1y3w/Secondary%20Occupations%20Audit%2024%20June%202015.pdf.pdf?dl=0>). Dr. Johnson also tells me that Nanofiber Solutions' lawyers have indeed publicly made a statement to confirm that to the Swedish press. To be accused now (again) of having commercial interests, and of having had anything to do with this poster which I had so vehemently disapproved of, had no part in, and requested withdrawal of in the strongest possible terms (as you will see in the email correspondence) is unjust and hurtful in the extreme.

The accusers also give detailed descriptions of the performance of the tracheal graft at 8 weeks, and appear keen to air their views on this case, as with the other two they have already discussed so publicly, although we note that Dr Grinnemo, who was the patient's primary clinician, has apparently declined to add his name to this particular complaint.

Although of no relevance in this particular instance since, as I have already demonstrated, I had absolutely no part in producing the poster in question, I feel it important to point out a few facts. Firstly, as per the protocol (<https://www.dropbox.com/s/joz6otwjvb6oyz9/Transplant%20Protocol%20%28CL%29.pdf?dl=0>), the cell counts on the transplanted scaffold were assessed before transplantation to ensure adequate cell coverage. These were carried out by Dr Emma Watz, Department of Laboratory Medicine, Karolinska Institutet, Karolinska University Hospital Huddinge, who would be able to provide the relevant data. In addition, we made microscopy images of the patient's cells on the remaining pieces of

scaffold not used during the transplant. These left-over pieces of scaffold were delivered to the laboratory in Huddinge by Dr K-H Grinnemo after the operation, and the images are viewable here: <https://www.dropbox.com/sh/8hax9p0xnwqjga0/AACYyg8AvX3FiXgGQjrNvNvha?dl=0>. There can thus be no doubt that the cells were indeed correctly seeded onto the scaffold prior to transplant.

Secondly, the complainants are, once again, citing extremely selectively from the patient's medical records. I will not discuss confidential medical records in such a public document as this, and (as I have stated before) I do not have access to the full records in order to enter a war of words with them over this, but the important fact is that none of us on the clinical team had any doubts about the health or future prospects of the patient when he was discharged from the hospital. His initial discharge papers (this is my own translated copy in English – the medical records would need to be consulted for the original Swedish version <https://www.dropbox.com/s/skjrkc0mcs53y/discharge-letter.doc?dl=0>) listed everything that had occurred, and not one of us on his clinical team thought anything other than that we had done our very best for a young man with a terminal diagnosis. His subsequent death was unrelated to the graft, as everyone accepts, and he had suffered no complications from it.

Thirdly, the materials used for the subsequent transplants in Russia were different – we were seeking materials with an increased flexibility in order to overcome the biomechanical issues that we were encountering during the operation procedures with the first scaffolds.

In summary, in this unusual case I concur with the accusers that the poster was inaccurate and should never have been made public, but it should be clear from my email correspondence made available to you now that neither I nor Dr Jungebluth sanctioned the poster, had any input into it, and in fact we forbade its production – and when we discovered that it had indeed been published on Nanofiber Solutions' website, requested its immediate withdrawal. We were never aware that it had been presented in public in any other context. I therefore deny any scientific misconduct: as the accusers themselves note, I would never have made such claims as are made in the poster in question. I also strenuously deny any claims of commercial interests in any of my research work, and to make such claims in public I take as defamatory in the extreme. It should be clear from all my work, and correspondence, that I have never sought to profit from healthcare - I have always sought only to do the very best for all patients, to give them every opportunity possible for life and health.

Best,

Prof. Paolo Macchiarini