Date: 21 June 2023
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Decision regarding research misconduct

Decision

The National Board for Assessment of Research Misconduct ("the Board" or "NPOF") finds [redacted] and [redacted] not guilty of research misconduct.

Background

On 22 September 2022, Chalmers University of Technology submitted a case of alleged research misconduct to the Board. On 17 October 2022, the University of Gothenburg submitted a case of alleged research misconduct to the Board concerning the same suspicions and the same article as the previous submission. The submissions took place pursuant to Section 6 of the Swedish Act (2019:504) on responsibility for good research practice and the examination of research misconduct.

The research concerns arm prostheses with tactile sensory feedback. The article in question presents follow-up of four patients who each received an osseointegrated arm prosthesis. They can voluntarily move the prosthesis by means of electrodes in the muscles to which the prosthesis is attached and — in three cases out of four — the prosthesis provides sensory feedback.

The submissions relate to allegations of falsification in the following article:

1. [redacted] (2020). Self-Contained Neuromusculoskeletal Arm Prostheses. *The New England Journal of Medicine*, 382(18), 1732–1738. https://doi.org/10.1056/NEJMoa1917537

The allegations relate to falsification through unwarranted omission of the complications suffered by one of the four people described in the article.

The authors whose names are underlined conducted the research at a Swedish entity responsible for research. [redacted] did his research at a responsible entity abroad.

Respondents' statement

The respondents have submitted a joint statement to the Board. They contest the allegation of falsification. They state that the purpose of the article reported was to follow up the individuals provided with equipment for sensory feedback connected with their prosthetic arms. Since Patient 4, the one who suffered complications, did not receive a prosthetic arm with enhanced functionality, the intention was not in any case to include a description of this patient in the article reported. They state that their intention throughout was to present the follow-up of Patient 4 in a separate article. They explain the fact that Patient 4 is nonetheless mentioned in the published article by adducing that this addition was made at a late stage. This was after discussions with the Journal's editor, who wanted Patient 4 to be included in a comprehensive account. The

respondents further state that they never intended to conceal the complications suffered by the patient in question. To support this claim, the respondents have sent the Board two presentations from international conferences where the patient's complications are mentioned. These conferences were held in 2022, before the unclear points regarding Patient 4 were noticed.

Expert statement

The Board obtained an expert witness's opinion on the matter. This expert[1] had the task of assessing whether there are grounds for the suspicions of fabrication or falsification in the reported article and, if so, whether they are to be regarded as a serious breach of good research practice.

The expert's assessment is that evidence of fabrication or falsification is lacking. In his view, however, potentially vital information has been withheld. The expert explains that when new surgical methods are developed, especially when the methods are of an experimental nature, thorough scrutiny is vital to detect unforeseen adverse effects. He states that the complications suffered by Patient 4 were clearly related to the treatment described in the article, and should therefore have been reported.

Respondents' comments on expert statement

After getting access to the expert witness's statement, the respondents submitted a joint commentary to the Board. They argue that there are several misunderstandings in the statement, particularly regarding the timeline of the study in question, the complications that affected Patient 4 and the article's publication. The commentary clarifies that:

1. The complications affecting Patient 4 arose during what may be considered an established treatment, not while the research study in question was under way.
2. The complications occurred after Patient 4 had left the study preceding the one in question.
3. Patient 4 never had sensory feedback in his prosthetic arm. This was because of gaps in his completion of the study he was included in, not because of the complications that arose later. That was why he was not initially included in the article.

Legal regulation

Under the Act (2019:504) on responsibility for good research practice and the examination of research misconduct ("the Act"), the Board is tasked to investigate issues of research misconduct.

Section 2 of the Act defines research misconduct as a serious breach of good research practice in the form of fabrication, falsification or plagiarism, committed with intent or through gross negligence, in the planning, conduct or reporting of research.

The Board's assessment takes place in stages, pursuant to the above provision.

[1] Professor Lars Adolfsson, Division of Surgery, Orthopedics and Oncology, Department of Biomedical and Clinical Sciences, Linköping University.

Grounds for decision

Research covered

Section 3 of the Act covers research conducted by higher education institutions that have the Swedish state as the entity responsible for their research, and that are subject to the Swedish Higher Education Act (1992:1434), other government agencies, municipalities and regions and certain other specified activities.

The co-author [redacted] conducted the research as part of his employment abroad at an entity responsible for research. The Board therefore considers that he should not be subject to its investigation. At the time when the research was being conducted, the other co-authors were employed at Chalmers University of Technology or affiliated with the University of Gothenburg ([redacted]) and are thus subject to assessment by the Board.

Planning, conduct or reporting of research

As defined in Section 2 of the Act, breaches of good research practice that may constitute research misconduct must have been committed during the planning, conduct or reporting of research. This means that the term "misconduct" refers to breaches throughout the research process.[2] "Reporting" refers both to publication and to other types of disclosure.[3]

The Board considers that the article constitutes reporting of research because it is published in a scientific journal.

Fabrication, falsification or plagiarism

The Board's remit is to investigate three forms of research misconduct: fabrication, falsification and plagiarism. These terms are not defined by law, but the preparatory work for the Act refers to the fact that they are described in codes (codices) and guidelines on research ethics, such as *The European Code of Conduct for Research Integrity*.[4,5]

Fabrication means that the researcher invents results and documents them as if they were genuine.

Falsification refers to manipulation of research material, equipment or processes or unjustified alteration, omission or suppression of data or results.

[2] Government Bill 2018/19:58, p. 100.
[3] Government Bill 2018/19:58, p. 49.
[4] *The European Code of Conduct for Research Integrity*, revised edition. Berlin: All European Academies (ALLEA); 2018, section 3.1.
[5] Government Bill 2018/19:58, pp. 45, 100.

According to the submissions, one research participant in the study forming the basis of the article reported suffered complications before the functionality of the prosthetic arm was enhanced in terms of sensory feedback. This person is referred to as Patient 4 in the article, but the complications (s)he incurred are not described.

The respondents state that Patient 4 should not have been included in the article from the start, since it was intended to report on the people whose prostheses had been given enhanced functionality, but that text about Patient 4 was added at a late stage, at the request of the Journal's editor. To support their claim that they had no intention of hiding the fact that a fourth person had initially been included in the study or that complications had occurred, the respondents have sent the Board documentation for presentations made at international conferences.

The expert believes that key information was omitted from the article.

The Board's assessment is that Patient 4 was included in the published version of the article. It is not always clear in the article which assertions refer to the three patients whose prosthetic arms were given enhanced functionality and which relate to all four. For example, it is stated on page 6 of the article that:

> "No serious adverse events, infections, bleeding, or discontinuation of use of the prothesis due to adverse events occurred as a result of the implants (Table S2). The neuromusculoskeletal interface remained functional after 3 to 7 years of use in all three patients who could be followed."

The second sentence clearly refers to three patients, while the first does not. A ready interpretation is that the first sentence refers to all four individuals the article addresses, although only three are listed in Table S2, part of the "supplementary material".

Since the complications that affected Patient 4 are mentioned nowhere in the article, although the patient is described in detail at the beginning of the article, the Board's assessment is that unwarranted omission or withholding of data took place. This constitutes falsification as defined above.

Serious breach of good research practice

Only serious breaches of good research practice can constitute research misconduct.

In principle, fabrication and falsification are always serious breaches of good research practice.

The premise of the Board's assessment is that falsification is, in principle, always a serious breach of good research practice. No reason to deviate from this premise has emerged in this case. Accordingly, the Board's conclusion is that the falsification constitutes a serious breach of good research practice.

Intent or gross negligence

Since 1 January 2020, researchers' responsibility to comply with good research practice in their work has been subject to statutory regulation under Section 4. The

potential or required extent of such responsibility must be examined and assessed in each individual case.

Under Section 2 of the Act, for research misconduct to be found, the serious breach of good research practice must have been committed with intent or through gross negligence.

"Intent" means that the researcher understood what (s)he was doing, while "negligence" means that the researcher, in any case, should have understood this.

Gross negligence requires the conduct to stand out as particularly serious or reprehensible. According to the preparatory work, oversights, carelessness or misunderstandings should not, as a rule, be regarded as gross negligence.[6]

Since 1 January 2020, researchers' responsibility to comply with good research practice in their work has been subject to statutory regulation under Section 4. The potential or required extent of such responsibility must be examined and assessed in each individual case. According to international guidelines,[7,8] all parties in a collaboration must take responsibility for the integrity of the research. The guidelines also say that, unless otherwise stated, all authors bear full responsibility for the content of the publication.

The authors have explained that the complications affecting Patient 4 occurred during established treatment and not in the research study that the article in question is about. They claim that their intention from the start was not to include Patient 4, but that this was done in the final versions of the article in question at the request of the *Journal*'s editor. They have provided material to the Board that supports this assertion. The reason for excluding Patient 4 was not the subsequent complications that arose, but the fact that not all the checks on this patient had been completed in a previous study. This was despite the fact that the preconditions existed, in the form of implanted electrodes, to attain the functionality that the study and the article were intended to monitor. They further state that they it was not their intention to omit the complications that affected Patient 4 and, as support for this, they had attached presentation documentation that covered these complications and was presented at international conferences.

It is already clear from the article's title and introduction that the intention is to describe the development of a new method, not a clinical study. The focus of the article is on innovation in medical technology-device innovation and procedure, and some case studies are presented. The authors have stated that they intend to write a separate article on Patient 4 and an additional article describing the clinical trial, which includes more patients.

The article makes it clear that Patient 4 did not participate in the follow-up after the initial surgical attachment of the arm prosthesis. Possible complications are listed in a table relating to the three research participants who had received prosthetic arms with enhanced functionality, and here too it is clear that the table excludes Patient 4.

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[6] Government Bill 2018/19:58, pp. 50–51, 100.

[7] *The European Code of Conduct for Research Integrity*, revised edition. Berlin: All European Academies (ALLEA); 2018, section 2.6.

[8] *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Records*. Updated May 2023, International Committee of Medical Journal Editors. http://www.icmje.org/recommendations.

Together, this is convincing evidence that the author of the article did not intend to give a complete description of all the patients who were originally included in the study.

The authors have stated that the complications were unrelated to the surgery that provides the functionality that the article addresses. Nevertheless, it would have been appropriate to state more clearly the reasons why Patient 4 was excluded from the study, since the description of this patient in the article is relatively detailed. The Board considers that the authors' procedure may be regarded as negligent, but not grossly negligent.

Summary of the decision

Summing up, the Board finds [redacted] and [redacted] not guilty of research misconduct.

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The Board has made a decision on this matter, following a presentation by Sofia Bergström, case officer. The Board is not unanimous; see the Appendix.

Catarina Barketorp
Chair
Dissenting

Sofia Bergstrom
Case officer

Appendix 1

Dissenting opinion by the Chair, Catarina Barketorp, and the board members Karin Sporre and Susanne Tornhamre

We consider that [redacted] and [redacted] have been guilty of research misconduct and that the text under the heading 'Intent or gross negligence' should read as follows.

Since 1 January 2020, researchers' responsibility to comply with good research practice in their work has been subject to statutory regulation under Section 4 of the Act. The potential or required extent of such responsibility must be examined and assessed in each individual case. According to international guidelines,[9,10] all parties in a collaboration must take responsibility for the integrity of the research. The guidelines also say that, unless otherwise stated, all authors bear full responsibility for the content of the publication.

The article addresses a new method in which the meeting between human and technology is central, and the study is in the nature of a clinical study in a medical context. It is published in a highly well-established medical journal. For medical studies in general, the rule is that both inclusion and exclusion criteria must be stated since it is important for the reader to see the whole picture. This also applies to complications that have arisen in patients who were excluded after a study has commenced. Inclusion and exclusion criteria should therefore have been specified in this case as well.

When the article was ready for publication, the authors knew about the complications that affected Patient 4. However, the reasons why Patient 4, who is mentioned in several places in the article, was excluded are not made clear and the context in which complications arose is not knowable either.

To provide reliable knowledge both about the potential of the new method and about problems it may possibly entail, a reliable overall picture should have been presented, in accordance with good research practice. We consider it was gross negligence not to report the complications that arose in one of the few research participants included in the study described in the article.

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[9] *The European Code of Conduct for Research Integrity*, revised edition. Berlin: All European Academies (ALLEA); 2018, section 2.6.

[10] *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Records*. Updated May 2023, International Committee of Medical Journal Editors. http://www.icmje.org/recommendations.

Npof.

Appendix

How to appeal

A decision pursuant to an investigation of research misconduct may be appealed to a general administrative court. An appeal must be in writing and must reach the Board for Assessment of Research Misconduct (NPOF) no later than three (3) weeks after you were notified of the decision. If the appeal is received by NPOF within the prescribed period, the matter is referred to the Administrative Court in Uppsala.

The appeal should preferably be sent by email or letter post.

Email
registrator@npof.se

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