Author's response to reviews

Title: The International Documentation and Evaluation System IDES: a single center observational case series for development of an ankle prosthesis documentation questionnaire and study of its feasibility and face validity

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Author's response to reviews: see over
Bern, January 19th, 2010

Dear Dr. Borthwick, dear reviewers,

Thank you very much for the constructive suggestions and comments. We will answer them on a point by point basis. Changes in the document are highlighted in grey.

Dr. Borthwick: We would also request that you include "International Documentation and Evaluation System" in full in the title, rather than using the acronym IDES.

Our answer: we have changed the title to

The International Documentation and Evaluation System IDES: a single center observational case series for development of an ankle prosthesis documentation questionnaire and study of its feasibility and face validity

Reviewer Dr. Walther:

1) The paper would improve by using the system to analyze one or two items. E.g. by comparing two subgroups (Primary and Revision) of TAA the system can demonstrate that a difference can be really figured out.

Our answer: the primary purpose of the paper was really to introduce the content of the three documentation forms and demonstrate what can be done with them, respectively the collected data, not necessarily in form of a clinical question. We do, however, like the idea of introducing some comparisons and we did the following:

- Add a formal statistical comparison between pre- and postop AOFAS score in cases of primary THA

AOFAS score of primary TAA

At a mean followup time of 8.4 months (range 1.2 – 38 months) the AOFAS score improved from a mean 23.4 points preoperatively (range 10 - 49 points) to 76.1 points postoperatively (range 42 - 93) \( p<0.001 \). Figure 2 presents the regression function (with preoperative mean) of the AOFAS score of all patients without revision surgery.
- Add a formal statistical comparison between pre- and postop AOFAS score in cases of revision THA and compare that with the primary THAs

**AOFAS score before first revision TAA**

In order to see to what extent the AOFAS score deteriorates before a first revision surgery, we calculated the pre-primary and pre-revision scores for those 11 patients with a first revision where the information was present. The score increased from preoperative 24.3 points to pre-revision 43 points \((p=0.039)\). By that, it was preoperatively similar to patients without a revision \((23.4 \text{ points})\), still better before the first revision than before the primary TAA, but significantly worse than in patients without a revision procedure who scored an average 76.1 points at their last followup \((p<0.001)\).

2) Why has the author chosen the AOFAS Score for reporting?

Our answer: the AOFAS was proposed by the senior foot surgeon (MP) who had initiated the development of the IDES ankle module. As we stated in the paragraph Materials and Methods …

A surgeon-administered clinical rating system is an important part of the IDES forms. While the Harris Hip Score and the Knee Society Knee Score and Function Score are integrated into Clinical Evaluation subforms of the hip and knee modules, the AOFAS ankle score was chosen for the ankle module.[5] It’s validity and responsiveness were assessed by SooHoon.[6, 7] He found increased responsiveness compared to the SF-36 as general quality of life instrument and a moderate correlation in patients with ankle-hindfoot disorders. In addition, the users can optionally choose to use patient based disease-specific and general quality of life instruments such as the Foot Function Index (FFI).[8, 9]

… the IDES always offers a physician based clinical rating system integrated into the forms and patient based systems in addition, but as separate forms. We felt that the AOFAS was suitable to be integrated and had also been validated. We were not aware of any other disease specific physician based rating system that could have been used for our purposes.

Reviewer Dr. Fuhrmann:

Please add some comments on
- the financial aspect
- data pool: Will participants have only access to their own data or will they get access to all data?

We have added the following aspects in the discussion (highlighted in grey):

Thanks to numerous user tools every participating surgeon can export his raw data or monitor his proper outcomes and compare them to the cumulated data pool with online statistics. The online statistics do, however, not allow comparisons with other surgeons or access to their raw data.[10]

Use of IDES is free of charge since each user contributes his cases to the data pool owned by the University institute. Thanks to the exporting function, the users are in full control and ownership of all the cases they themselves stored in the database. User groups or specialist societies that want to make use of IDES ankle but also keep possession of the pooled data of their group will be charged based on participant number and case load.

Please add some comments on
- anonymization
We have added the following aspects in the discussion:

All information is sent in an encrypted fashion and in those cases where national filter modules are in place, the patient and user related information is stored in the national database and does not even leave the country, i.e. only anonymized clinical datasets reach the central database. [10]

Nevertheless, informed written consent by the patient is always recommended for the documentation.