Advanced Bionics European Clinical Research Department uses *STATISTICA* to assess results of clinical studies

About Advanced Bionics and cochlear implants

Founded in 1993 and partnered with Phonak under the Sonova Group in 2009, Advanced Bionics® is a global leader in the development and manufacturing of cochlear implant systems. Cochlear implants are active implantable medical devices designed to restore hearing to profoundly deaf people. Cochlear implant devices are made up of two parts: One is the implant itself that comes with an electrode array inserted surgically in the cochlea; the other part is an external processor that transforms the sounds captured by the microphone into electrical currents which are sent by the electrode to the auditory nerve. The sound processor is running specialized software called *SoundWave*. The parameters for "tuning" this software are refined by audiologists in cochlear implant centers, and can be uploaded to patients' processors.

1 Background

Advanced Bionics is regularly conducting clinical studies, and results need to be updated frequently in order to achieve continuous improvements and scientific progress which is presented at scientific meetings and conferences worldwide. Before *STATISTICA* was adopted, we were searching for an easy-to-use analytics solution that can seamlessly resume analyses, share the results among the team members, and with « nice » and « customizable » graphs (so they can be included in PowerPoint presentations and reports). Some members of the research staff had been using various software packages, including SPSS and Excel, and to a lesser extent SPAD, XlStat, SAS and Matlab. *STATISTICA*'s graphs are indeed of a higher quality and generally nicer than in any other software I've been using. A training course helped us to quickly learn the program and identify the possibilities for our future uses and needs; as a result we are now fully independent in our use of the *STATISTICA* platform. I really appreciated how quick and easy it was to learn the program, to address our needs.

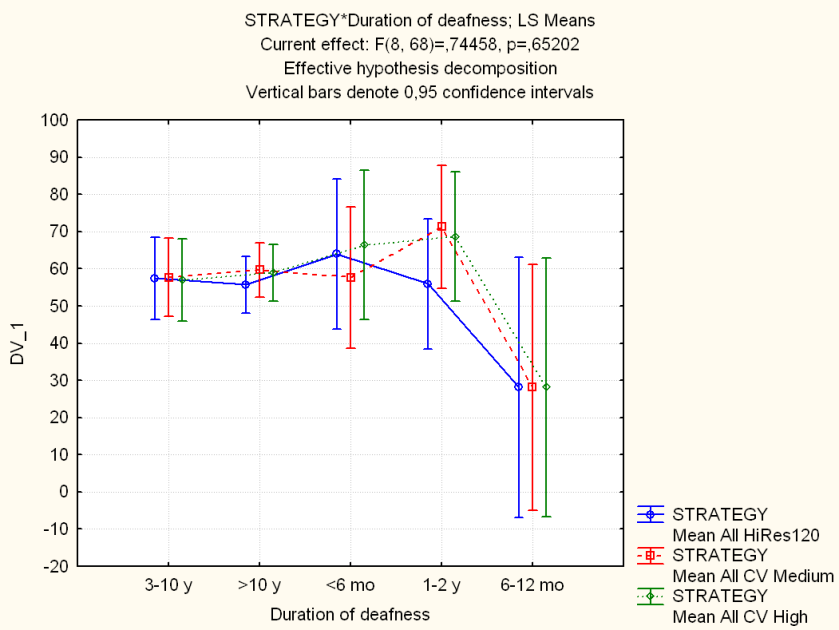
2 Case Study : Clinical Research

While cochlear implant users successfully understand speech in quiet situations, there is still room for improvement in more challenging listening conditions, namely in the presence of background noise and music. Advanced Bionics also develops special products designed to help with the fitting of the software, to assist clinicians to optimize the parameter settings for their patients. The European Clinical Research Department of Advanced Bionics aims at assessing the performance of cochlear implanted subjects in various situations, in so-called post-market studies. We chose *STATISTICA* to perform the critical statistical analyses for those studies, as illustrated in the two examples below.

2.1 ClearVoice™ feature evaluation

One specific software feature that was developed by Advanced Bionics in order to improve performance in noisy situations is a product called HiRes 120®. It comes with three strategy options for fitting the software: Standard, ClearVoice High, ClearVoice Medium. A multicentre clinical study was conducted where patients were randomly assigned to one of the three fitting options, and their subsequent subjective experiences recorded for one week. Subjects were asked to complete the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire, designed to assess their subjective benefit in various listening situations. Figure 1 shows the results graph created with *STATISTICA* as a result of a repeated measures ANOVA, comparing the *Strategy* effect on the mean APHAB score.

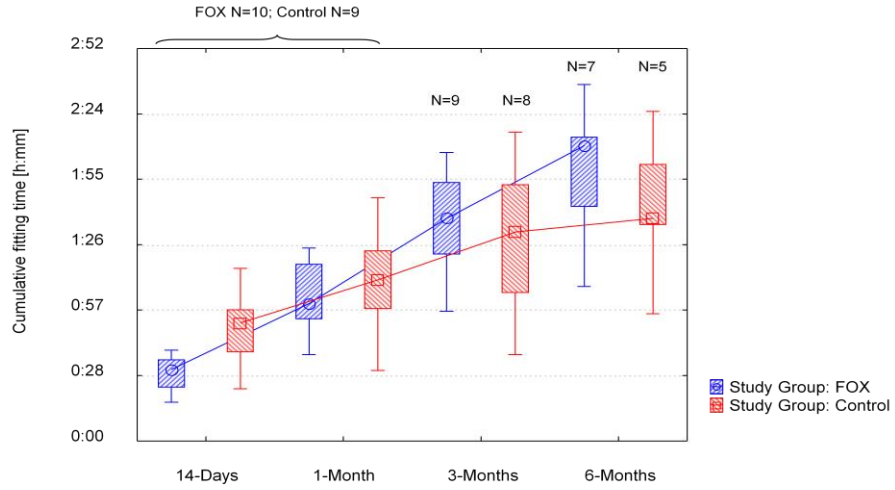
Figure 1 : Strategy effect on the mean of the APHAB score



2.2 FOX™ clinical study

Another area of research is assistance with expert systems, to help clinicians set optimal parameters when programming the cochlear implant device. In this area, Advanced Bionics is proud to present the FOX™ expert system, which is being evaluated in a multicentre European study looking into the effects of fitting time in standard and FOX™ assisted fittings. This variable is measured at predefined fitting sessions post activation: 14 days, one month, three months and six months.

Figure 2: box plots of the cumulative fitting time for the 2 groups of subjects: FOX™ and control at successive fitting sessions



3 Conclusion

STATISTICA provides a powerful tool for our needs within our clinical research department. In particular, the high quality and easily customizable graphs are universally praised in our poster presentations and summary reports and communications delivered at international conferences. Additionally, we want to highlight the quality of the relationship with StatSoft's French headquarters, and thank them for the support they provide to us.

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