Response to Letter to the Editor: ‘Assessing the quality of randomization and allocation concealment’

First of all we want to thank Dr Berger for his letter and his kind words concerning our paper. Dr Berger makes a valid point in questioning the validity of randomization and allocation concealment in the trials included in Vavken and Samartzis1.

Dr Berger is absolutely right to point out that even computer-generated randomization sequences can be predicted, especially when patient allocation is randomized in blocks, and are thus just as predictable as alternating allocation. However, we granted the included studies the benefit of the doubt since decryption of computer-generated block sequences requires a willful act of transgression against the rules of scientific conduct. Alternating allocation or allocation by date is obvious to everyone without code breaking and invites selection bias.

Another related problem is to maintain allocation concealment. The experimental treatment, autologous chondrocyte implantation, requires two operations, one being a (mini) open procedure, as opposed to the control treatments (both single, arthroscopic procedures). Theoretically, blinding of patients and assessor could be achieved if all patients underwent two “procedures” with a sham operation and/or equally big skin incisions for the control groups. Such methods have been used in other studies before (e.g., Refs. 2, 3), but are reluctantly employed by many surgeons and are associated with ethical questions due to the perioperative risk even of sham procedures.

In summary, there are two interconnected problems, establishment and maintenance of allocation concealment, that deserve more attention4. Obviously there are “mitigating circumstances” in some cases, but for most studies it is possible to allocate and assess patients blindly and both investigators and journal editors should try to identify and point out such possibilities.

Conflict of interest
None.

References

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