



A new study design?

One of my main activities is to evaluate clinical trials. I have been evaluating thousands of studies over many years and seldom do I find something that triggers my curiosity. Recently, I read a randomised controlled trial (RCT) comparing 6 mm-long implants with 11 to 15 mm-long implants in augmented sinuses. A very interesting topic so I read it eagerly. A very nice article I must say, well written and very clear. It included 64 patients, not easy for a single centre, but what really captured my attention was the length of the follow-up: 3 years post-loading. This means that the study started quite a while ago. In fact, the authors described in detail that the patients were recruited and treated in the period between January 2007 and March 2008. OsseoSpeed Astra Tech 4 × 6 mm implants were placed in the short implant group.

In June 2008, I attended the Astra Tech World Congress 2008 in Washington and I remember that the main event was the launch of the new 4 × 6 mm-long implant. This means that all patients of the trial were treated with short implants even before they were launched. Of course, this is possible since often companies supply products for testing before their official launch. So I disturbed my Astra Tech colleagues to find out when their short implants started to be supplied in Italy. I was told that the very best Astra Tech intimates received very small quantities of the new short implants in February 2008 at the earliest. Surprised by this finding, I wrote to the trial authors asking how they could manage to treat patients between January 2007 and March 2008 if the first short implants reached Italy in February 2008. The answer was that patients were recruited from January 2007 and treated with short implants starting from the third day of January 2008, and Astra Tech kindly sent them the implants for that day. Suffice it to say, I was

sceptical about the answer and I wanted independent verification so I decided to contact the ethical committee to ask to see the original study protocol. After a brief check, it was soon discovered that no ethical committee approval existed, in contrast to what was reported into the article. Then, skipping the formalities of the ethical approval and going to the 'heart' of the trial, namely the patients, I discovered that none of these patients was ever treated at the department reported in the trial (Astra Tech implants were not placed in the department either).

In the end I finally managed to get information about the putative 6 mm implants received by the main authors: 15 4 × 6 mm Astra Tech short implants purchased in 2010. In 2011, 60 implants were received through a protocol contract with Sweden and 5 short additional implants were purchased. So, when and where has this trial been conducted? And if it was ever conducted, how long is the real follow-up? I don't know, if anyone actually knows, ... it suggests the coinage of a new term such as 'ghost' randomised controlled trial (GRCT). I am pretty sure that there are a few more around.

As in every field, oral implantology is not free of academic fraud in different forms. Plagiarism, duplicated publications, fabrication of data and 'ghost' studies can be explained by competitive pressure, defects in the peer review system, financial benefits (grants), 'big ego' personalities, etc. The real issue is that it is better to have no data than fabricated data. The role of the editors of *EJOI* is to detect and prevent ghost trials from getting published.

In addition, *EJOI* shall reject by default manuscripts from authors involved in manipulating scientific data.

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