To whom do the results of the multicenter, randomized, controlled INSECT trial (ISRCTN 24023541) apply?--assessment of external validity.

A response to Seiler et al: Interrupted or continuous slowly absorbable sutures for closure of primary elective midline abdominal incisions: a multicenter randomized trial (INSECT: ISRCTN24023541). Ann Surg 2009, 249(4):576-582. Existing evidence suggests that the transfer of results of randomized controlled trials into clinical practice may be limited. Potential reasons can be attributed to aspects of external validity. The aim of this study is to investigate issues related to the external validity of the INSECT trial. All participating surgical departments were categorized and the clinical and baseline characteristics of randomized patients were evaluated. In addition, demographic and clinical data of all screened and randomized patients at the Departments of Surgery in Heidelberg and Erlangen were analyzed. Twenty-five centers enrolled a total of 625 patients. These centers included eight primary, 11 secondary, and six tertiary care centers. The tertiary care centers enrolled the most patients (n = 237, 38%) followed by the primary care centers (n = 199, 32%) and the secondary care centers (n = 189 patients; 30%). The mean number and baseline data of randomized patients did not differ between the three types of care centers (p = 0.09). Overall, the treatment according to protocol was at least 92%. At the Department of Surgery, University of Heidelberg, 307
patients were screened and 60 out of 130 eligible patients were randomized. There were no differences in demographic and clinical baseline data between included and non-included patients. In Erlangen, 351 patients were screened and 57 out of 106 eligible patients randomized. Results of the INSECT trial are applicable to a broad spectrum of patients treated at different hospital levels.