BMC2012 Phase IIa

experimental data
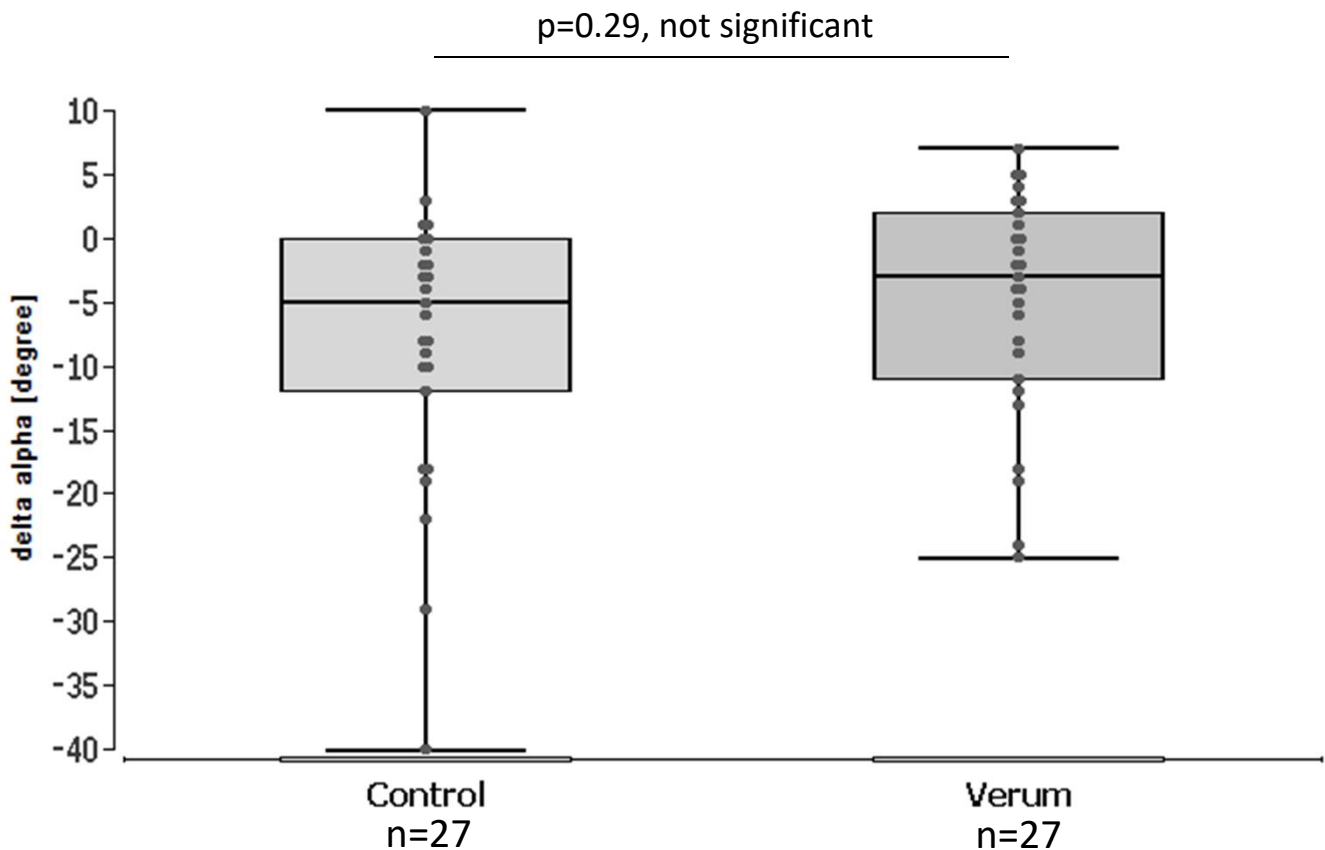
Primary endpoint: Frequency of angular difference delta alpha > 20°.

The hypothesis was that the frequency of the angular difference delta alpha > 20° would be significantly increased in the verum group. Neither in the control group nor in the verum group an angular difference >20° could be observed. The hypothesis must therefore be rejected.
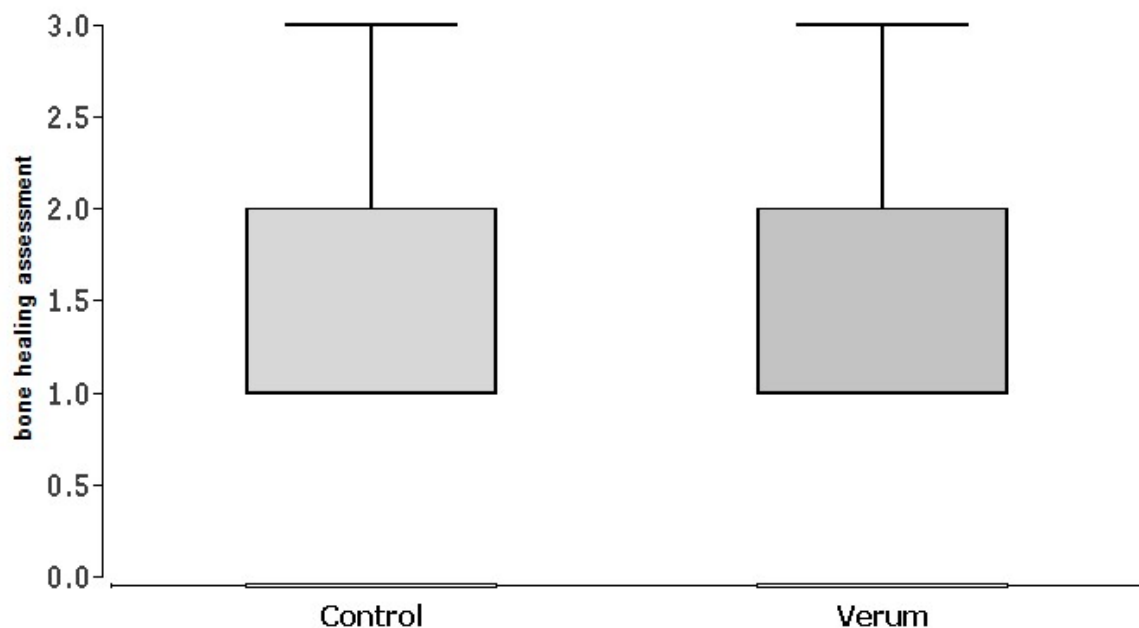
The following diagram shows the angle differences of the study patients.

p=0.29, not significant

Boxplot diagram of the median are presented. The borders of the box represent interquartiles, whisker show minimum and maximum. All measurements used for generation of boxplots are additionally shown as dots. No significant difference was detected between the groups.

Secondary outcome: radiological assessment of bone healing

The original plan was to measure the angle difference alpha as an objective and quantifiable indicator of bone defect healing. Due to the reproducibility of the positioning of the respective study patient during the conventional X-ray procedure at visits V3 and V5, which cannot be achieved in everyday clinical practice, the measurement of the angle alpha was not possible with sufficient accuracy. Therefore, an alternative strategy was chosen to achieve an estimation of the bone healing outcome. For this purpose, the blinded radiographs of the study participants from V3 and the corresponding size-adjusted radiographs from V5 were directly compared. Eleven orthopedic and trauma surgeons and physicians in training individually assessed bone healing using a scale of 1=poor to 3=good.
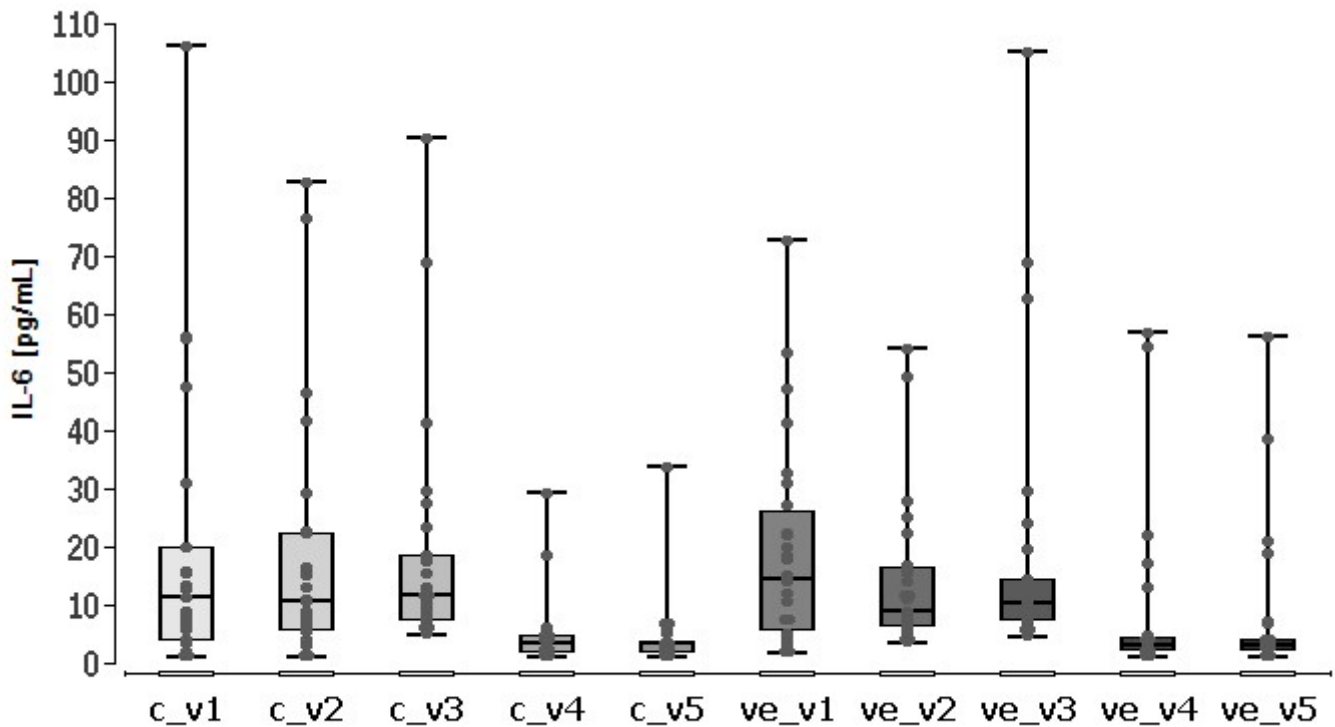

The assessment of bone healing did not differ significantly between the control and verum groups with comparable scatter of results. Furthermore, a high correlation (r=0.83, p<0.05) was observed between residents (n=4) and specialists (n=7).
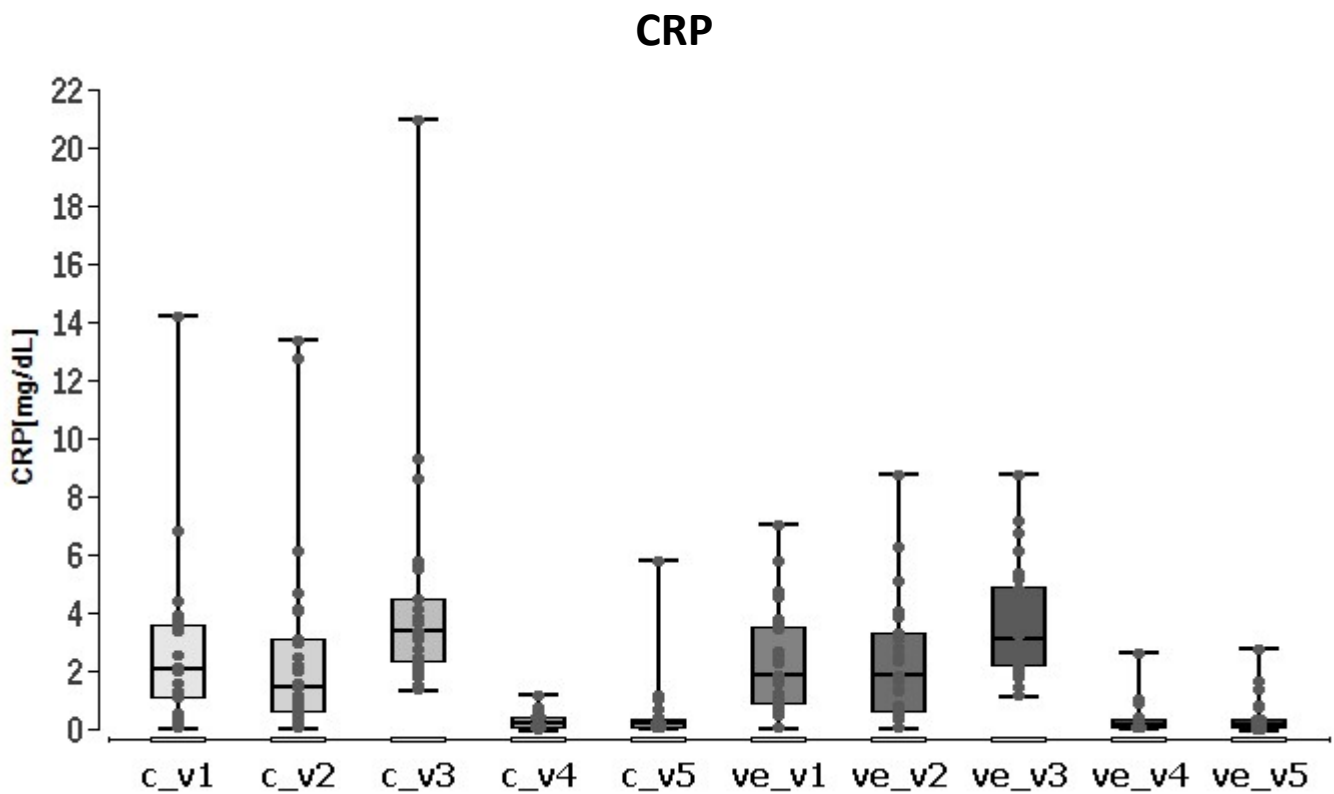
Secondary outcome: systemic inflammation

Relevant secondary endpoint were inflammation as measured by serum values of IL-6, C-reactive protein (CRP), procalcitonin (PCT).
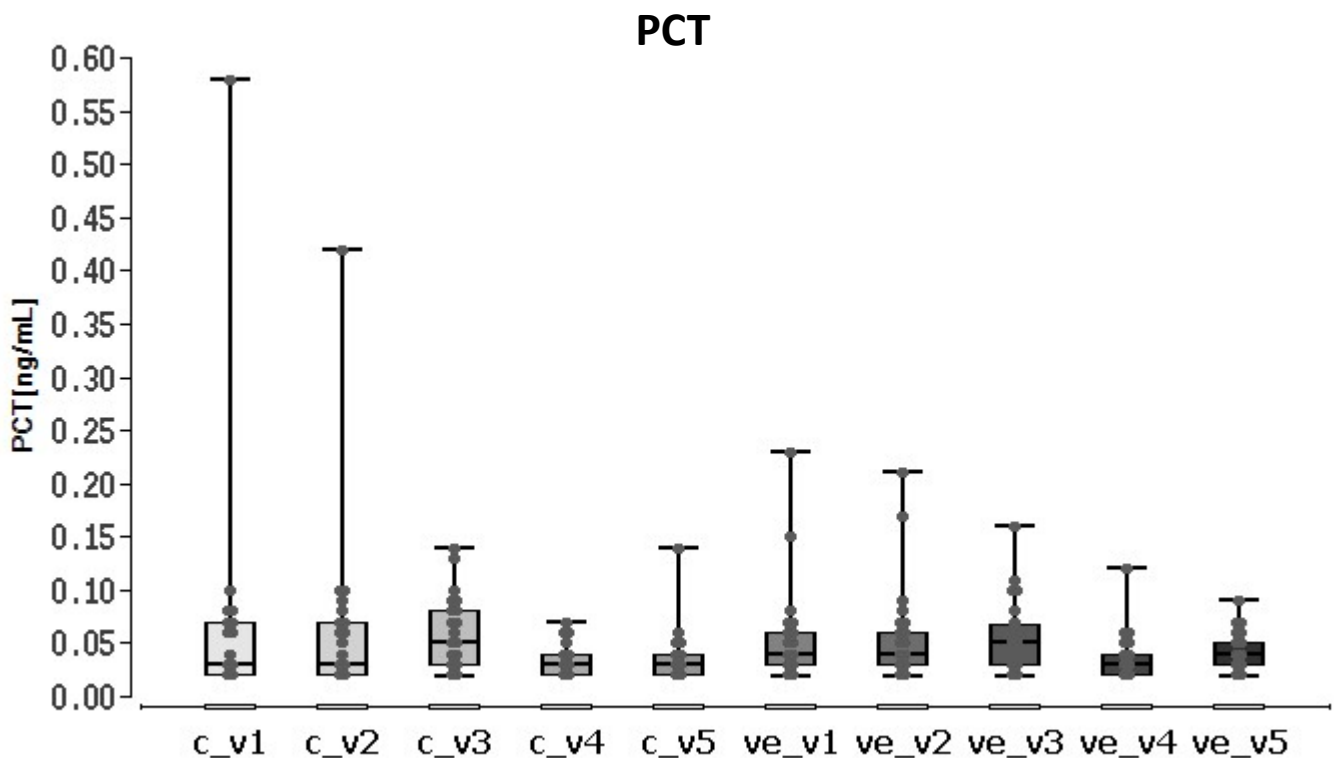
IL-6

Systemic IL-6 concentration in controls (c) and verum (ve) at visits (v) 1 to 5. Boxplot diagram of the median are presented. The borders of the box represent interquartiles, whisker show minimum and maximum. All measurements used for generation of boxplots are additionally shown as dots. No significant differences between controls and verum were observed for all visits (Wilcoxon-Mann-Whitney-U-Test). The course of IL-6 levels was very similar in both groups, initial high levels can be attributed to the initial trauma as well as the surgical trauma. At the later time points (v4, v5), a significant decrease in values was recorded for both groups compared to v1-v3. (Kruskal-Wallis-Test with Bonferroni-Holm adjusted posthoc analysis (Dunn-Test).

Secondary outcome: systemic inflammation

CRP

Systemic CRP-concentration in controls (c) and verum (ve) at visits (v) 1 to 5. Boxplot diagram of the median are presented. The borders of the box represent interquartiles, whisker show minimum and maximum. All measurements used for generation of boxplots are additionally shown as dots. No significant differences between controls and verum were observed for all visits (Wilcoxon-Mann-Whitney-U-Test). The course of CRP levels was very similar in both groups, initial high levels can be attributed to the initial trauma as well as the surgical trauma. At the later time points (v4, v5), a significant decrease in values was recorded for control group compared to v1-v3. This reduction was also seen in verum group (Kruskal-Wallis-Test with Bonferroni-Holm adjusted posthoc analysis (Dunn-Test).
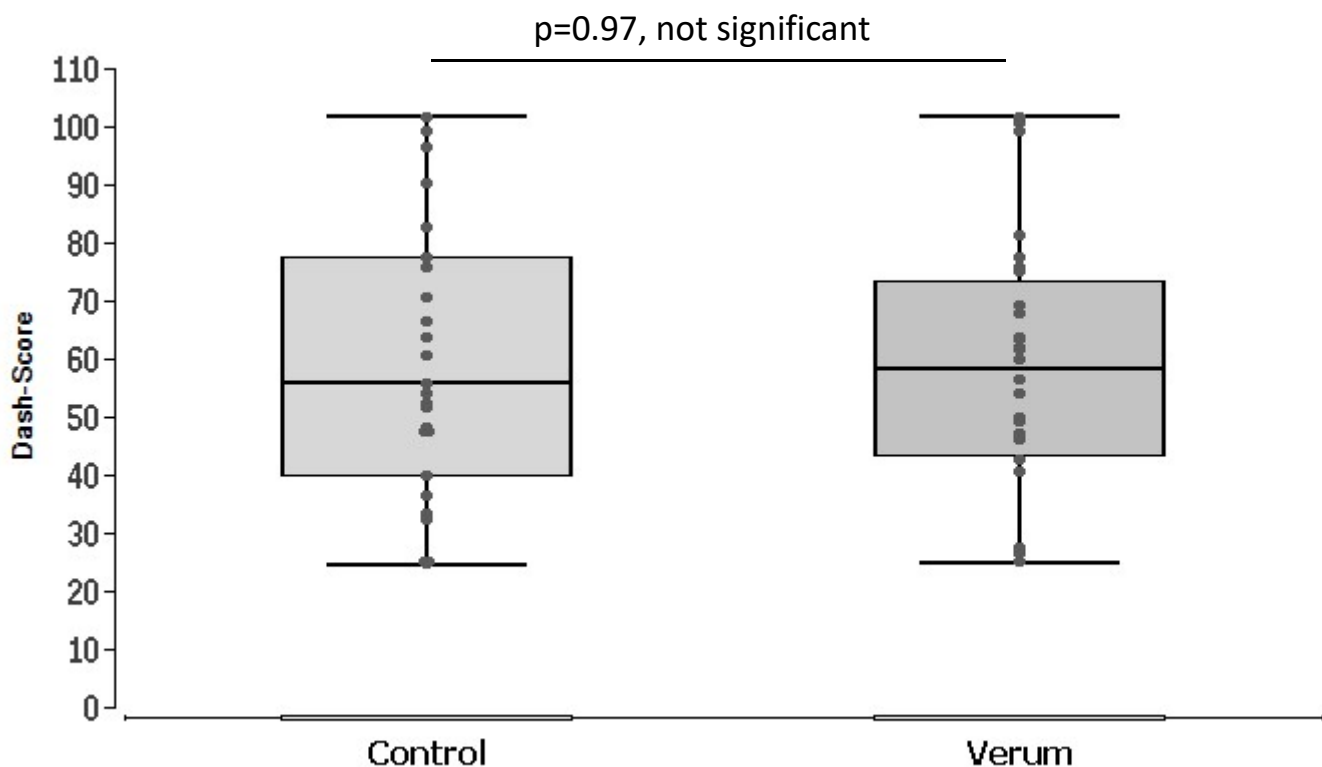
Secondary outcome: systemic inflammation

PCT

Systemic PCT-concentration in controls (c) and verum (ve) at visits (v) 1 to 5. Boxplot diagram of the median are presented. The borders of the box represent interquartiles, whisker show minimum and maximum. All measurements used for generation of boxplots are additionally shown as dots. No significant differences between controls and verum were observed for all visits with exception of v5(p=0.049, Wilcoxon-Mann-Whitney-U-Test). The course of PCT levels was very similar in both groups, initial high levels can be attributed to the initial trauma as well as the surgical trauma. At the later time point (v5), a significant decrease in values was recorded for control group compared to v3. This reduction was also seen in verum group but level of significance was not reached (p=0.06, v3 vs. vs. v4) (Kruskal-Wallis-Test with Bonferroni-Holm adjusted posthoc analysis (Dunn-Test).

Secondary outcome: Shoulder function

Shoulder function was assessed by the Dash-score. Lower values indicate better function.

Boxplot diagram of the median are presented. The borders of the box represent interquartiles, whisker show minimum and maximum. All measurements used for generation of boxplots are additionally shown as dots. Non parametric Wilcoxon-Mann-Whitney-U-Test was used for comparison. No significant difference was detected between the groups.