The relationship between wound healing and pain relief after the treatment with BRH-A2 system

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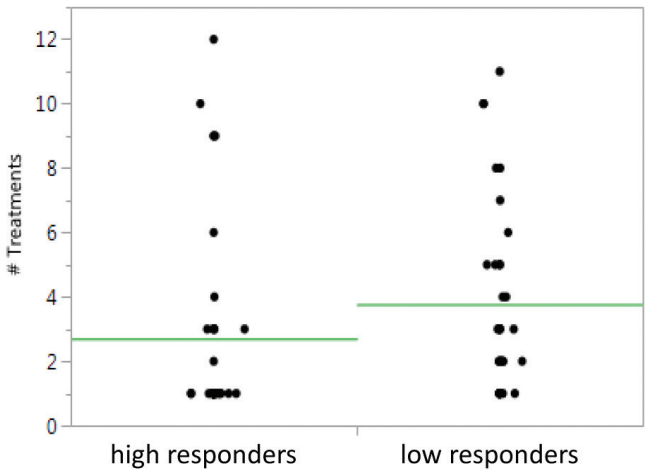
The sample size consists of patients of various etiologies that received treatment with BRH-A2 system for the wound healing.

The main study group consists of Israeli patients (N=71; 30 females; mean age 78.8±11.5 years). The clinical characteristics of the patients group is presented in Table 1.

Parameter	Value ± SD
Number of wounds	2.5±1.6
Wounds duration (months)	5.4±8.1
Number of treatments to pain relief	3.2±3.0
Pain prior to the treatment (0-10 VAS)	6.6±2.5
Pain after the treatment (0-10 VAS)	2.1±1.9
Pain reduction (in %)	67±22

Correlation analysis did not find a significant relationship between pain reduction and any of the demographic or clinical parameters. However, dividing the patients into high or low treatment responders (based on the median value of 75% of pain reduction) indicated that the patients that responded with ≥75% of pain reduction (high responders, N=37) needed a significantly smaller number of treatments (3.8) in order to achieve pain relief than those with <75% pain reduction (low responders, N=34), (2.7); Wilcoxon non-parametric P=0.007.

Figure 1

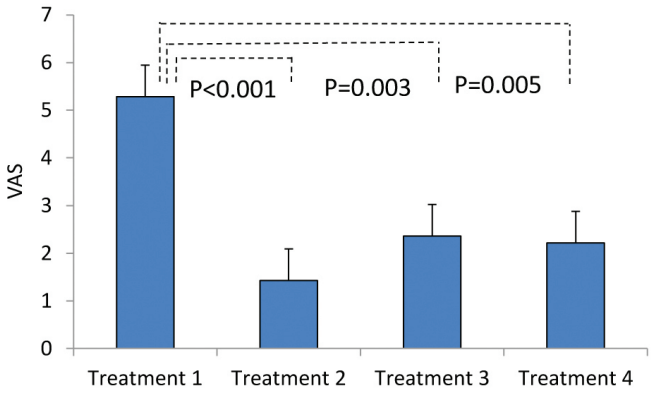


In addition, data concerning pain scores and the wound size per each treatment for patients who had at least 4 sequential treatment sessions were provided for 11 patients from the Italy site, and for 3 patients from the Israeli site. No demographic or clinical data were provided in addition to this.

Based on this, a repeated measures ANOVA (rmANOVA) was applied in order to understand the dynamics of pain relief vs. the dynamics of wound size decrease in 14 patients along 4 treatment sessions, and in 12 patients along 6 treatment sessions.

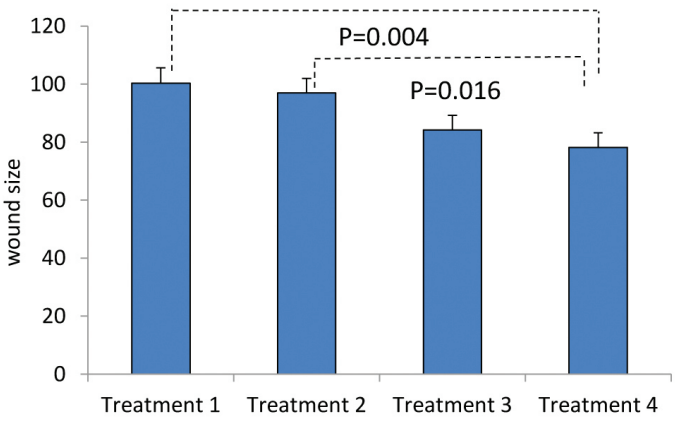
Pain relief and wound size decrease along 4 treatment sessions:

Figure 2



Significant effect of the treatment sessions on pain scores was observed (P<0.001). Pain decreased significantly after the 1st treatment session (P<0.001) with no further decrease along sessions 2nd - 4th.

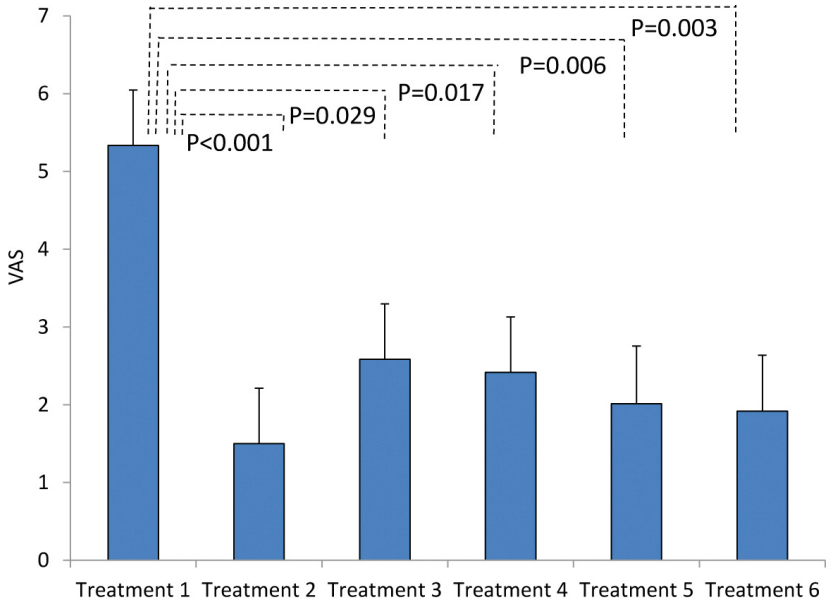
Figure 3



Similar to the pain scores, significant effect of the treatment session on the wound size was found (P=0.002). However, the decrease in the wound size was observed only after 3rd treatment session; the wound size at the 4th treatment session was significant different from the wound size at 1st (post hoc P=0.004) and from the 2nd session (post-hoc P=0.016).

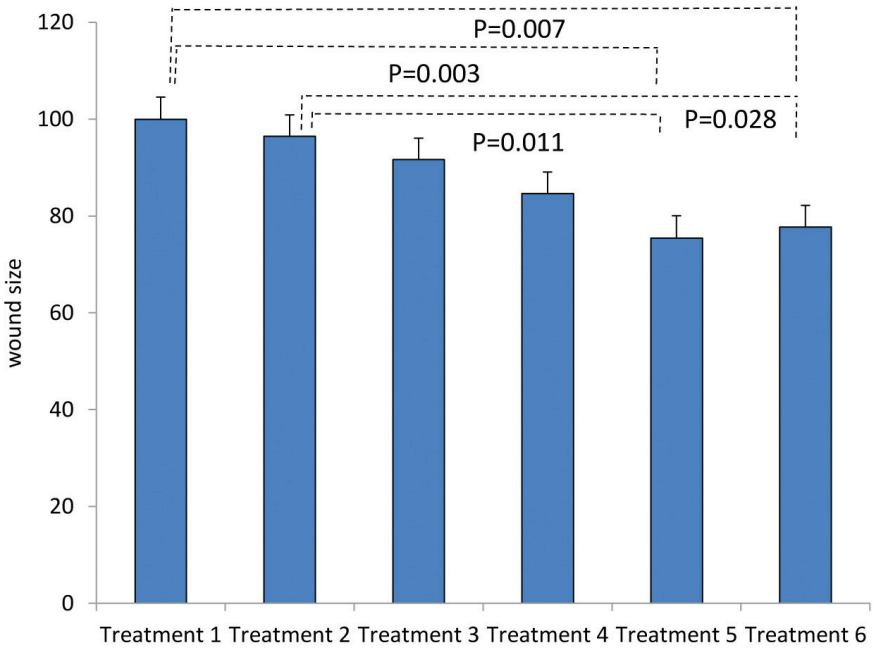
Pain relief and wound size decrease along 6 treatment sessions:

Figure 4



Significant effect of the treatment sessions on pain scores was observed (P<0.001). Pain decreased significantly after the 1st treatment session (P<0.001) with no further decrease along sessions 2nd - 6th.

Figure 5



Similar to the pain scores, significant effect of the treatment session on the wound size was found (P=0.002). However, the decrease in the wound size was observed only after 4th treatment; the wound size at the 5th and 6th treatment was significant different from the wound size at 1st (post hoc P=0.003 and P=0.007, respectively) and from the 2nd session (post-hoc P=0.011 and P=0.028, respectively).

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