A cross-sectional post marketing survey to evaluate real-life customer experience and satisfaction after using the B-Cure Laser device

Background:

Low level laser therapy (LLLT) is widely used for the treatment of a variety of inflammatory related conditions. The B-Cure laser is a home-use LLLT device that is sold in Europe and Asia for management of acute and chronic pain, as well as wound healing. To date, three small prospective double-blind randomized sham-controlled clinical trials were conducted with the device. Fornaini et al showed that daily self-treatment over the temporomandibular joint (TMJ) for 2 weeks significantly reduced pain typical to this disorder [1]. Moreover, in a separate study on the same indication, Del Vecchio et al showed that LLLT was comparable to the pain reducing effects of nonsteroidal anti-inflammatory drugs and both were superior to sham irradiation [2]. Adverse events related to the device were not reported in any of these studies. In view of these encouraging results from prospective controlled clinical trials, the company intended to evaluate the real-life experience and customer satisfaction with the device.

Methods:

To that end, a phone survey was conducted by Geocartography Knowledge Group that specializes in customer surveys. The company was given a database of 10,000 coded numbers representing patients that purchased the device at least 3 months prior to the survey, with the intention to survey a sample of 300. After collecting demographic information, the customers were asked about the indication for which they used the device, the frequency of use and its timing, perception of the pain before and after using the device, satisfaction with the device, duration of pain relief, and side effects/adverse events.

Results and Discussion:

1) **Accountability and response rate:**
   The survey includes answers of 300 customers. The response rate was 41%, which is considered exceptionally high suggesting that customers were interested in participating the survey.

2) **Customer demographic characteristics**:
   Two thirds (67%) of the customers that answered the survey were over 55 years old, which is 3 folds more than the percentage of this age group in the general population. The distribution by sex (56% males) was similar to the general population (49.5% males) (Israel central bureau of statistics, 2013). The customers were evenly distributed according to their income level.

3) **Overall treatment effectiveness**
   Overall, 138 of 300 (46%) of the customers reported that they were satisfied or very satisfied with the treatment. The %satisfied customers increased with the time of use, reaching 60% satisfied customers for those that had the device for a year of more (n=108) (Figure 1). The subjective pain reduction using the numerical rating scale (NRS) where 0 was “no pain” and 10 was “intolerable pain was 2.6±2.7 (mean±SD) and 3.0±2.5 respectively (Figure 2). Of the customers surveyed, 177 (59%) considered themselves as suffering intolerable pain (defined here as pain NRS=8-10). After treatment, 108 of these did not consider themselves in this category leaving only 24% in this category ($p<0.0001$ by chi square) (Figure 3).

Figure 1: Customer satisfaction level

Pie graphs by level of satisfaction for (left) entire survey population and (right) customers that used the device for 1 year or more. The proportion of satisfied or very satisfied customers was 46% and 60% respectively.

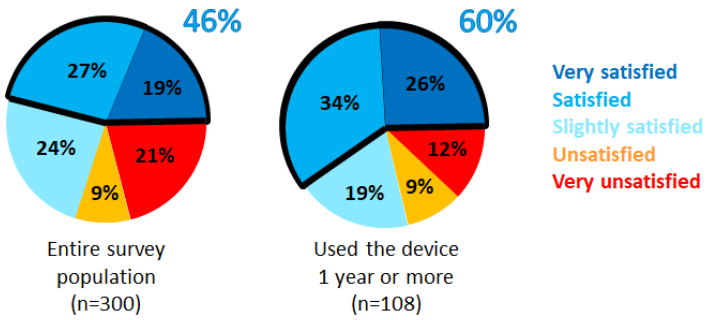


Figure 2: Subjective pain level before/after treatment

Subjective pain level was reported using the numerical rating scale (NRS) where 0 was "no pain" and 10 was "intolerable pain for (left) entire survey population and (right) customers that used the device for 1 year or more. *p<0.0001 by paired t-test

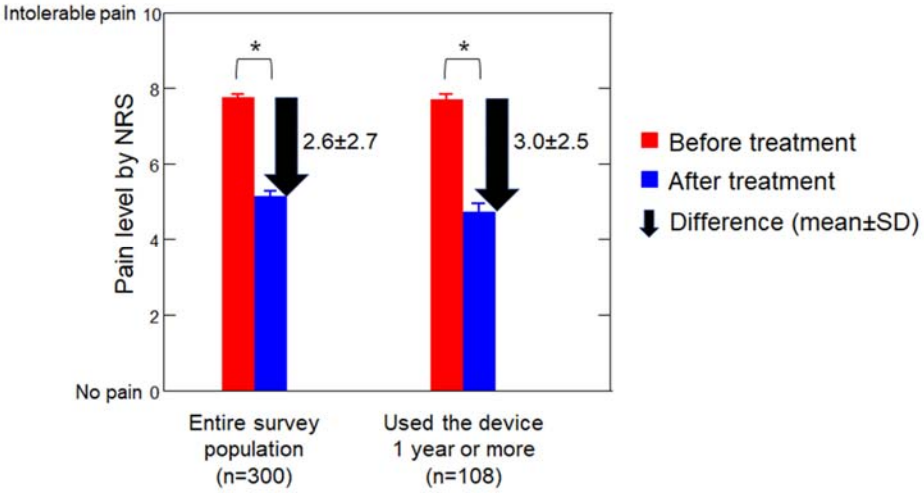
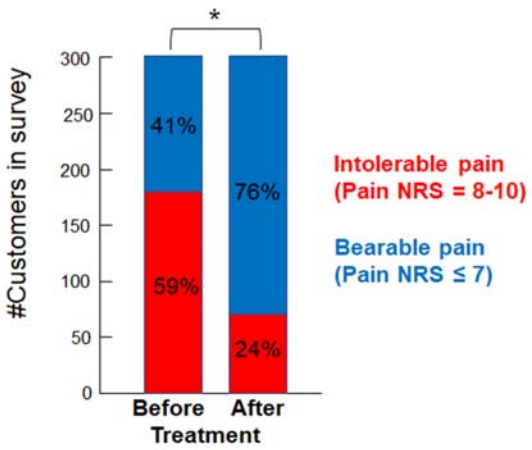


Figure 3: Proportion of customers with intolerable pain before vs after the treatment

Intolerable pain is defined here as pain by numerical rate scale (NRS) = 8-10 and depicted in the graph in red part of the bar, while bearable pain is defined here as pain NRS ≤ 7. Note the significant decrease in the proportion of the customers that initially reported suffering from intolerable pain (59%) vs after using the device (24%). *P<0.0001 by chi square.



Analysis by Dr. Lilach Gavish, PhD

4) **Treatment effectiveness by region**:
The major pain for which the customers reported using the device were knee pain (34%), low back pain (15%), and upper back and neck pain (11%). Using ANOVA adjusted for age, sex and initial pain level, it was demonstrated that there was no significant difference between the knees, lower back, upper back, or other regions regarding satisfaction level (p=0.69) or change in pain level (p=0.12).

Table 1: Effectiveness of treatment by pain level per region of treatment

Subset	n	No.(%) of satisfied or very satisfied customers	Pain before treatment*	Pain post treatment	Δ(before-after) pain, p-value**
Overall	300	138 (46%)	7.7 [7.5-7.9]	5.1 [4.8-5.4]	2.6 [2.3-2.9], p<.0001
Knees	101	42 (42%)	7.4 [7.1-7.7]	5.2 [4.6-5.8]	2.2 [1.7-2.7], p<.0001
Lower back	37	17 (46%)	7.9 [7.3-8.4]	5.1 [4.2-6.0]	2.8 [1.9-3.7], p<.0001
Upper back/neck	26	15 (58%)	8.1 [7.4-8.7]	4.5 [3.4-5.6]	3.6 [2.6-4.6], p<.0001

*mean[95%CI]; **by paired t-test

It can be summarized that the treatment with B-cure laser results in effective pain relief in 46% of the customers and that this effect is similar in all regions and is unrelated to either age or sex.

5) **Pain relief**
Customers that reported feeling pain relief up to 2 months after using the device also reported an average pain reduction of 3.0±2.8, 95%CI [2.4,3.5]. Of the customers that reported feeling pain relief, 43% experienced pain relief for at least 1 week after using the device and 25% reported several hours of relief. As expected, the level of satisfaction increased with the duration of pain relief.

6) **Manner of treatment**
Most customers (89%) used the device up to 15 minutes per session, of these, 24% used the device once a day, 46% twice a day, 23% three to four times a day, and 3% five to six times a day. As the number of uses per day increased, so did the percent of satisfied customers (38%, 46%, 47%, and 63% satisfied customers using the device for once, twice, 3-4 times, and 5-6 times a day). Superior effectivity was not found for a specific duration of treatment or frequency of use per period (p=0.9 and p=0.95 respectively by 1-way ANOVA for change in pain level). It can be summarized that increasing the number of treatments per day may increase the efficacy but in real life about half of the customers use the device up to 15 minutes twice a day.

7) **Time of use and compliance**

A quantitative relationship between satisfaction levels and contributing factors was found as follow: The model was [satisfaction level] = a1*[how long ago was the device purchased] +

a2*[when did you last use the device] + a3*[age] + additional factors [sex, frequency/duration of treatment, time of continuous use]. Using stepwise (backward) multiple regression the only contributing factors were the first three variables (coefficients, mean±SEM[p-value]: a1=0.35±0.06 [p<0.001]; a2=-0.22±0.03 [p<0.001]; a3=0.16±0.06 [p=0.005]). These three variables were uncorrelated (R<0.1 in all cases by Spearman correlation coefficient). The model explained 75% of the variance. The interpretation is that higher compliance, represented by more frequent use (last use in a shorter time) and / or long-term use predicts higher satisfaction rates. Indeed, compliant customers that had the device for over a year and used it in the past 2 weeks (n=60) were significantly more satisfied than less compliant customers (73.3% vs 39.2%, p<0.001 by chi square of satisfaction level) and reported higher pain relief (3.7±2.4 vs 2.3±2.7, p=0.001 by 2-sample t-test). Analyzing the data by region it was found that compliant customers as defined here were much more satisfied for all regions than less compliant customers (%satisfied customers – lower back 100% vs 33%; upper back/neck 71% vs 53%; knees 53% vs 39%). It is important to note that customers that had the device for a year or more were similarly more satisfied and reported higher pain relief than those that had the device for less than a year although to a lesser extent than those that also reported using the device for the last 2 weeks (%satisfaction: 60.2% vs 37.3%, p=0.001 by chi square of satisfaction level; pain difference by NRS: 3.0±2.5 vs 2.3±2.8, p=0.053 by 2-sample t-test).

8) Side effects/adverse events

When asked about the reasons to recommend the device, 80% related to the absence of side effects in addition to other reasons related to efficacy and ease of use. None of the customers reported experiencing adverse events.

Conclusions

The characteristic customer is over age 55, both men and women, from all levels of income. Customers used the device for a variety of pain indications but the most popular regions were knees, lower back, and upper back/neck. Overall, 46% of the customers were satisfied with the device and reported pain relief that was not significantly different for the different regions of treatment, nor for sex or age. The % of satisfied customers increased with the length of use reaching 60% for the customers that used the device for a year or more. These customers were significantly more satisfied compared to those that used the device less than a year. Of the customers surveyed, 177 (59%) considered themselves as suffering intolerable pain (defined here as pain NRS=8-10), but after treatment, only 69 (24%) considered themselves in this category. Of the customers that reported feeling pain relief, 43% experienced pain relief for at least 1 week after using the device. In real life, about half the customers used the device up to 15 minutes twice a day although increasing the number of treatments per day increased the efficacy of the device. Finally, none of the customers reported experiencing side effects or adverse events.

References

1. Fornaini, C., et al., *The "at-home LLLT" in temporo-mandibular disorders pain control: a pilot study.* Laser Ther, 2015. **24**(1): p. 47-52.
2. Del Vecchio, A., et al., *Abstract: A new home protocol of LLLT in patients affected by TMJD related pain: results of a randomized, double blind, placebo controlled clinical trial*, in *The 15th Congress of the World Federation for Laser Dentistry*. 2016: Nagoya, Japan.