Development and validation of a new instrument for the assessment of patient-defined benefit in the treatment of acne

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- acne
- patient reported outcome
- benefit assessment
- Patient Benefit Index
- Individualized weighted outcome assessment
- quality of life

Summary
Background: Benefit assessment of drugs and medical products has become a legally established feature of medical research. A standardized assessment of benefits using scientifically sound and valid methods is essential.
Objective: Development, validation and practical evaluation of an instrument to record patient benefit in treatment of acne.
Patients and Methods: In open interviews with n = 50 patients, possible benefits of the therapy from the patients' point of view were recorded. The item pool thus generated was reviewed by a panel of dermatologists, psychologists and patients and transferred to a 23-item questionnaire. This is used prior to therapy to assess patients' desired benefits and after therapy to record the perceived benefits. The therapy goals and the resulting benefits are then used to generate a weighted 'Patient Benefit Index' (PBI). The procedure has been tested for its validity and feasibility in n = 923 patients with acne.
Results: Patients accepted the instrument and deemed it to be easily understandable. Additionally, the method proved itself to be internally consistent, constructively valid and sensitive to changes.
Conclusions: The Patient Benefit Index (PBI) is a valid and highly accepted practical instrument for recording patient benefit. The PBI permits an individualized, patient-weighted assessment of the benefits of acne therapy.

Introduction
Numerous studies have shown that patients with acne can experience a dramatic reduction in quality of life (LQ) [1, 2, 3, 4, 5, 6]. The most important factors for the handicap are the stigmatization experienced or anticipated by the patient, disturbing subjective symptoms as well as the chronic, oftentimes therapy-refractory course. Even treatment itself can constitute a burden. The assessment of treatment benefit of drugs has become a central legislative and administrative procedure [7].
In many western nations, the benefit of drug treatment to the patient is one criterion for the reimbursement of treatment [8]. In Germany, the Statutory Health Insurance Modernization Act (GMG) 2004 and the Act to Strengthen Competition in Statutory Health Insurance (GKV-WSG) 2007serve as the legal basis for a central benefit evaluation in medicine. The Federal Joint Committee (Gemeinsamer Bundesausschuss, GBA) is responsible for benefit evaluation; it can commission the Institute for Quality and Economic Efficiency (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG) to perform scientific benefit evaluation.
Windeler (2006) defines "therapeutic benefit" as "all effects of an intervention that result in an improvement of prognosis and/or symptoms/quality of life of patients in

more than an insignificant degree" [9]. In the law itself as well as in the regulations of the GBA and IQWiG, therapeutic benefit is defined as primarily "patient-relevant benefit" [10, 11, 12]. Primary features of patient-relevant benefit in the regulations and in SGB V (Book V of the Social Code) are reduction of mortality and morbidity, improvement in quality of life, patient satisfaction as well as a reduction of burdens of treatment. Recent studies on skin diseases show that patient-relevant benefit can only reliably be assessed by the patient [13]. In acne, clinical findings (lesions, severity) as well as disease-specific quality of life are important parameters in evaluating benefit. In practice, instruments used up to now to evaluate benefit often have not reflected the broad and individual spectrum of benefit to patients. Beyond a multitude of possible benefits, conventional instruments failed to include a patients-weighted assessment.

Against this backdrop the Patient Benefit Index (PBI) was developed as a system for benefit assessment from the patient's perspective, where the patient chooses treatment goals which are relevant for him before starting from a standardized list of possible benefits in a weighted fashion and evaluates the achievement of these self-chosen goals after treatment. The first clinical trial of this novel concept was performed in patients with chronic wounds [14]. In the present study this instrument was applied to acne therapy and subsequently validated in clinical use.

Goals

1. Development and validation of an instrument to assess patient-defined benefit in acne therapy.
2. Testing the suitability of the instrument under clinical conditions.

Methods

Creating a pool of items of potential benefits on the basis of open patient and physician interviews

According to usual international standards in developing psychometric and biometric tests an item pool of personally relevant treatment benefits was generated first in an open patient interview (n = 50) and supplemented with additional items of individual burdens caused by the disease.

Development of a questionnaire by a board of experts with participation of patients

The resulting item pool was reduced by an expert board (two dermatologists, two psychologists and two patients) to 23 benefits of acne therapy particularly relevant to patients. The selected items were transferred to a questionnaire. To answer the items a five grade Likert scale was expanded by the possible answer "does not apply to me".

Development of Patient Benefit Index (PBI)

Arriving at parameters of patient-defined benefits was by way of further development of goal-oriented measurement of results taking criticism into consideration [15, 16]. First, this method allows the patient to choose individual personal benefit preferences out of a standardized list of items ("Patient Needs Questionnaire" – PNQ, see Figure 1). This results from rating the 23 items according to their individual importance (0 = "not at all important", "does not apply to me" up to 4 = "very important").

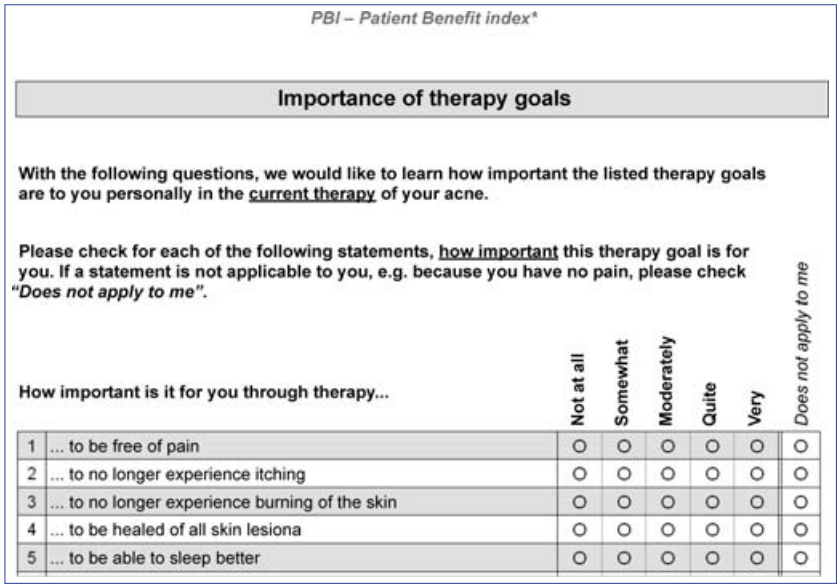
The "Patient Benefit Index" derives from the sum of the benefit items weighted by their respective relevance divided by the number of relevant items. Values between 0 = no benefit and 4 = maximal patient-defined benefit are possible. Analogously the achievement of the individually selected benefits ("Patient Benefit Questionnaire – BPQ, see Figure 2) is measured during the course of therapy (0 = therapy did not help at all" up to 4 = "therapy helped very much") are measured.

Finally, the preferences before therapy (PNQ) and the achieved benefit after therapy (PBQ) are converted into a weighted index value, the "Patient Benefit Index" (PBI). This is calculated by taking the individually determined importance for each item (PNQ) divided by the sum of all individual importances and multiplied by the respective benefit achieved (PBQ). The sum of these products is the PBI (Figure 3). This can have a value between 0 (no benefit) up to 4 (maximal benefit). On the basis of our own pilot studies, a minimum PBI value of 1 can be viewed as "relevant benefit". The goal criterion "response" is the percentage of patients achieving a PBI 1.

Validation and test under clinical conditions

To validated the method and test its suitability under clinical conditions it was employed in a prospective observational study on 925 patients with acne. The patients were treated with a topical combination product containing 5 % benzoyl peroxide and 1 % clindamycin. The clinical results of this study are not subject of the present publication.

(1) Study design: Prospective, open, uncontrolled, multicenter cohort study in line with the recommendations of the Federal Institute for Drugs and Medical Devices as well as the German Society for Medical



*PBI – Patient Benefit index**

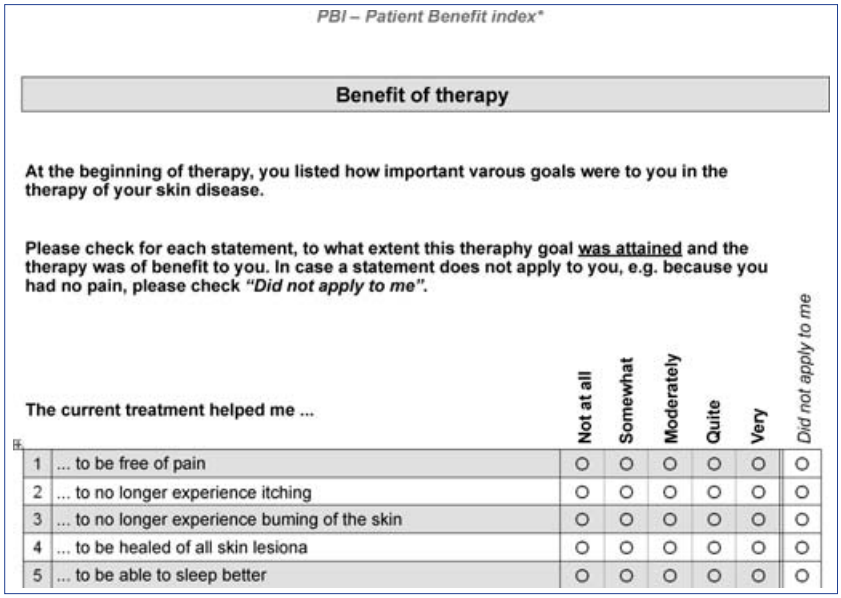
Importance of therapy goals

With the following questions, we would like to learn how important the listed therapy goals are to you personally in the current therapy of your acne.

Please check for each of the following statements, how important this therapy goal is for you. If a statement is not applicable to you, e.g. because you have no pain, please check *"Does not apply to me".*

	How important is it for you through therapy...	Not at all	Somewhat	Moderately	Quite	Very	Does not apply to me
1	... to be free of pain	○	○	○	○	○	○
2	... to no longer experience itching	○	○	○	○	○	○
3	... to no longer experience burning of the skin	○	○	○	○	○	○
4	... to be healed of all skin lesiona	○	○	○	○	○	○
5	... to be able to sleep better	○	○	○	○	○	○

Figure 1: Excerpt from the Patient Needs Questionnaire (PNQ), instructions and items 1–5.



PBI – Patient Benefit index*

Benefit of therapy

At the beginning of therapy, you listed how important varous goals were to you in the therapy of your skin disease.

Please check for each statement, to what extent this theraphy goal was attained and the therapy was of benefit to you. In case a statement does not apply to you, e.g. because you had no pain, please check *"Did not apply to me".*

	The current treatment helped me ...	Not at all	Somewhat	Moderately	Quite	Very	Did not apply to me
1	... to be free of pain	O	O	O	O	O	O
2	... to no longer experience itching	O	O	O	O	O	O
3	... to no longer experience burning of the skin	O	O	O	O	O	O
4	... to be healed of all skin lesiona	O	O	O	O	O	O
5	... to be able to sleep better	O	O	O	O	O	O

Figure 2: Excerpt from the Patient Benefit Questionnaire (PBQ), introductory instructions and items 1–5.

$$PBI = \sum_{i=1}^{k} \frac{PNQ_i}{\sum_{i=1}^{k} PNQ_i} PBQ_i$$

Figure 3: Formula of Patient Benefit Index (PBI) with k need-items (w, range 0–4) and benefit-items (b, range 0–4).

Informatics [17] for performing post-marketing surveillance studies.

(2) *Patients and study centers:* Questionnaires for up to 1,025 patients were distributed to n = 205 dermatology offices in Germany. Data from n = 925 patients were collected between September 2005 and March 2006.

Patients of both genders aged 12–30 years with mild to moderate acne (physician's global assessment) were included.

(3) *Collection of data:* Data were collected from the physician and patient respectively at three time points: at the beginning of the study (V1), after 4–6 weeks (V2) and at the end of the study after 10–12 weeks (V3). In addition to measuring patient-defined benefit and PBI, the quality of life was assessed in accordance with the appropriate AWMF guideline [18]. As an instrument to assess disease-specific quality of life in acne, the ADI (Acne Disability Index [19]) was employed, an internationally widely used instrument with 5 items which assess social and mental aspects of quality of life.

Methods to test validity of PBI

In accordance with the AWMF guideline 2004 of the German Society of Dermatology [18], the following criteria for validation were considered:

(1) Clinical use („feasibility")
(2) Item characteristics (distribution, distinction, internal consistency)
(3) Constructive validity with respect to patient satisfaction, to self and foreign assessment of treatment success as well as to the Acne Disability Index [2, 19]
(4) Sensitivity to change during topical therapy

Results

Feasibility

The good practicability of the method in clinical use is especially reflected in the low rate of missing responses to the items (missing values per item 1.7 %, median = 5, range: 2–14 missing values). In a sample of n = 50 patients 95 % of patients responded that the questionnaire was principally well understandable and easy to complete and from its content took benefit needs of acne patients well into consideration.

Patient-defined benefit preferences

From the response to the importance of treatment goals of the patients at time point V1 (begin of therapy) a broad spectrum of patient-defined benefit preferences is seen (n = 832, see Table 1). The distribution shows that acne patients formulate treatment goals of varying relevance which should not be neglected when assessing benefit relevant for the patient.

Internal consistency of PNQ

In the validation study the internal consistency of PNQ showed good characteristics. With respect to all cases, Cronbachs alpha was in a very good range with α = 0.96. The distinction between items when building sum in the PNQ was satisfactory (Table 2), which again underscores the variability of individual treatment goals and confirms the inventory-like nature of the method as well as the need for individual weighting in determining the PBI.

Constructive validity of PNQ

At time point V1 (begin of the study) the sum of importances in the PNQ correlates to r = 0.59 ($p \leq 0.01$, n = 764) with the LQ score of ADI which suggests a convergent validity. The PNQ does display test-specific variance, pointing to a discriminant validity of the PNQ.

Patient-defined Benefit Index

Distribution characteristics of the PBI: At the time point V2 (after 4–6 weeks) 90.2 % of patients achieved a PBI $\geq$ 1; at time point V3 (after 10–12 weeks) 92 % of patients did so (Figures 4, 5). The corresponding mean PBI was 2.45 (SD 1.02, n = 780) and 2.79 (SD 1.04, n = 731) at time point V3. Thus, a majority of patients achieved a high patient-defined benefit.

Constructive validity of the PBI: Table 3 summarizes the results with convergent validity of the PBI at time point V2 (after 4–6 weeks of therapy) and V3 (after 10–12 weeks of therapy). In general middle to high degrees of correlation between the PBI and relevant parameters of patient satisfaction, efficacy of therapy out of the physician's and patient's perspective as well as quality of life were observed. This suggests convergent validity of the PBI, as it correlates to relevant validation constructs as well discriminant validity of the PBI, as other variances are obviously also included.

Sensitivity to change: In the course of therapy the PBI displayed parallel to further clinical improvement between time points V2 and V3 good sensitivity to change (Figures 4, 5).

Discussion

The goal of the present study was the development, validation and testing of

Table 1: Results on the importance of therapy goals in the patients' view at time point V1 (beginning of the treatment, descending order, n = 832).

Therapy goal	Mean	SD	Applies to me	Does not apply to me	Missing	Portion important/ very important (%)
To be healed of all skin lesions	3.62	0.77	788	20	24	88.5
To have faith in the treatment	3.22	1.04	751	61	20	74.6
To find a clear diagnosis and treatment	2.99	1.22	718	92	22	62.8
To want to show oneself more	2.96	1.21	712	96	24	61.1
To have no fear of disease progression	2.84	1.32	680	129	23	55.5
To be more cheerful	2.81	1.28	640	165	27	51.9
To lead a normal daily life	2.74	1.30	577	229	26	45.3
To be less burdened in a partnership	2.68	1.35	465	345	22	35.9
To have more contacts to other people	2.64	1.33	590	218	24	42.9
To spend less time on daily therapy	2.62	1.27	746	61	25	53.1
To be able to pursue normal recreational activities	2.56	1.37	531	281	20	37.6
To be less depressed	2.56	1.35	633	177	22	44.9
To no longer experience burning of the skin	2.51	1.34	521	279	32	35.2
To have less side effects	2.49	1.39	623	185	24	41.5
To need less physician or hospital consultations	2.46	1.30	680	130	22	44.5
To lead a normal sex life	2.44	1.47	413	392	27	27.9
To have less therapy costs	2.43	1.42	632	175	25	41.2
To no longer experience itching	2.35	1.41	513	297	22	32.9
To lead a normal professional life	2.32	1.45	392	418	22	23.9
To be free of pain	2.27	1.42	509	302	21	30.3
To be more productive in daily life	2.26	1.36	464	344	24	26.7
To be less of a burden on family and friends	2.06	1.40	489	320	23	25.5
To be able to sleep better	1.88	1.47	358	452	22	16.5

0 = not at all, 1 = somewhat, 2 = moderately, 3 = quite, 4 = very important.

the clinical suitability of an instrument to assess patient-defined benefit in acne therapy.

The development of the method was in accordance with internationals standards for developing psychometric and biometric instruments [20, 21, 22, 23, 24, 25, 26, 27], the AWMF guidelines of the DDG (German Society for Dermatology) to assess quality of life in dermatology [18] and already takes benchmarks of IQWiG and the GBA on measuring patient benefit into consideration. Development of the questionnaire which can be applied to other skin diseases was done by an interdisciplinary team that included patients.

The results of the PNQ show that acne patients expect a broad spectrum of possible benefits from therapy. Determining the PBI originally was modeled on the not well-standardized methods of "goal attainment scaling" used in rehabilitative medicine [28, 29, 30, 31, 32] and psychiatry [33, 34] to verbally formulate treatment goals and to check their attainment at intervals. This method has also been applied in nursing [35, 36]. The limitations of "goal attainment scaling" are, among others, the low-degree of standardization of the method and the lack of external validation [37]. As a further, more structured method goal-oriented result measurement (ZOE = zielorientierte Ergebnismessung) was introduced [15] also termed goal attainment scaling by other authors [16]. Here patient goal selection is done in a systematic and prestructured form. The PBI is a further modification of this method including a dimensionally scaled assessment of individual patient-defined therapy goals and benefits which are weighted and summarized by a single benefit index. The PBI allows for the depiction of benefit functions over the course of time or in the comparison of cohorts. With the PBI it is possible to avoid major criticism of ZOE [16]; by, for example, assessing two differing constructs (importance and benefit) a regression to the middle is blocked and a positive distortion of effects is minimized by the dimensional conception of weighting.

The questionnaire PBI for acne was shown to be valid and reliable in the validation study. Is practicability in terms of patient acceptance and understandability was good. In a clinical study on

Table 2: Item characteristics at time point V1 and with the respective item distinction Cronbachs alpha.

Therapy goal	Corrected item-scale correlation	Cronbachs alpha, when item is excluded
To be free of pain	0.612	0.960
To no longer experience itching	0.660	0.960
To no longer experience burning on the skin	0.716	0.959
To be healed of all skin lesions	0.370	0.962
To be able to sleep better	0.669	0.960
To be less depressed	0.796	0.958
To be more cheerful	0.763	0.959
To have no fear of disease progression	0.712	0.959
To lead a normal daily life	0.802	0.958
To be more productive in daily life	0.799	0.958
To be less of a burden on family and friends	0.729	0.959
To be able to pursue normal recreational activities	0.763	0.959
To lead a normal professional life	0.796	0.958
To have more contacts to other people	0.756	0.959
To want to show oneself more	0.679	0.960
To be less burdened in a partnership	0.746	0.959
To lead a normal sex life	0.753	0.959
To need less physician or hospital consultations	0.748	0.959
To spend less time on daily therapy	0.650	0.960
To have less therapy costs	0.694	0.959
To have less side effects	0.745	0.959
To find a clear diagnosis and treatment	0.636	0.960
To have faith in the treatment	0.573	0.961

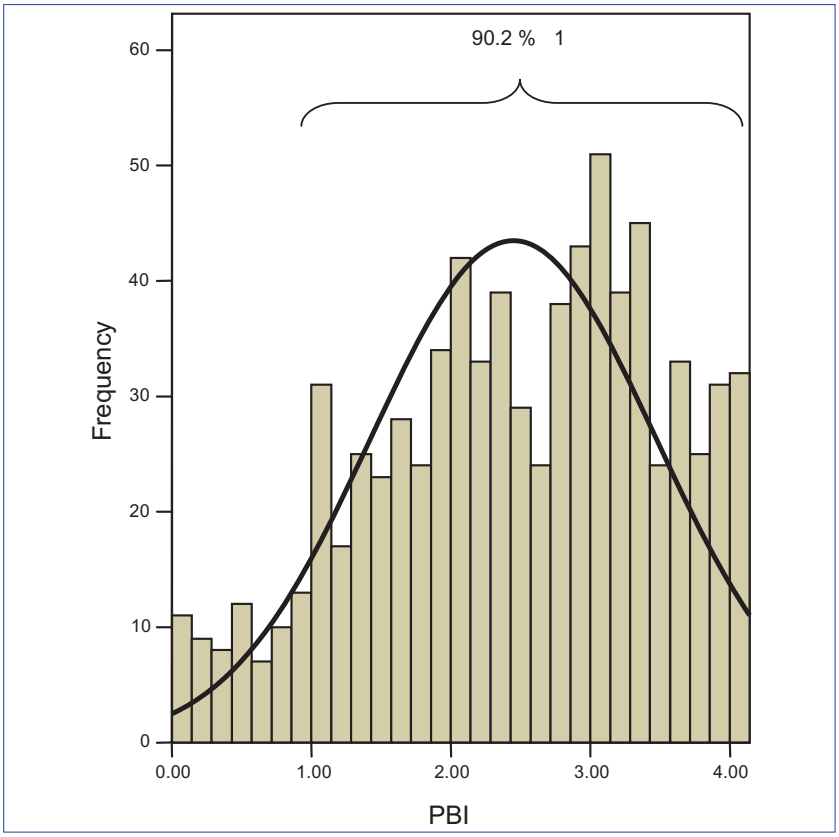


Figure 4: Frequency distribution of Patient Benefit Index (PBI) after 4–6 weeks acne therapy. Mean = 2.45; Std.Dev. = 1.02; n = 780.

patients with mild to moderate acne, the utility of the PBI was shown on over 900 patients as well as substantially a high degree of benefit of therapy with a combination product containing benzoyl peroxide and clindamycin. The reduction in case numbers in the course of the study in comparison to the time point of inclusion is not unusual in an observational study. It might lead to a clinically relevant selection effect but does not affect the validation test.

In conclusion, the PBI is a benefit instrument with which the patient benefit of acne therapy can simply and reliably be assessed. While it can be an advantage for a differential benefit evaluation and for health services planning to depict a broad spectrum of benefit relevant to the patient – as the PNQ and PBQ do, outcome research requires a bundled benefit parameter, which summarizes patient benefit in a single value, if possible. Being an index, this is possible with the PBI. The distribution of characteristic values of the PBI of different samples can also directly be compared and be used in outcome analyses. The combined use of several outcomes

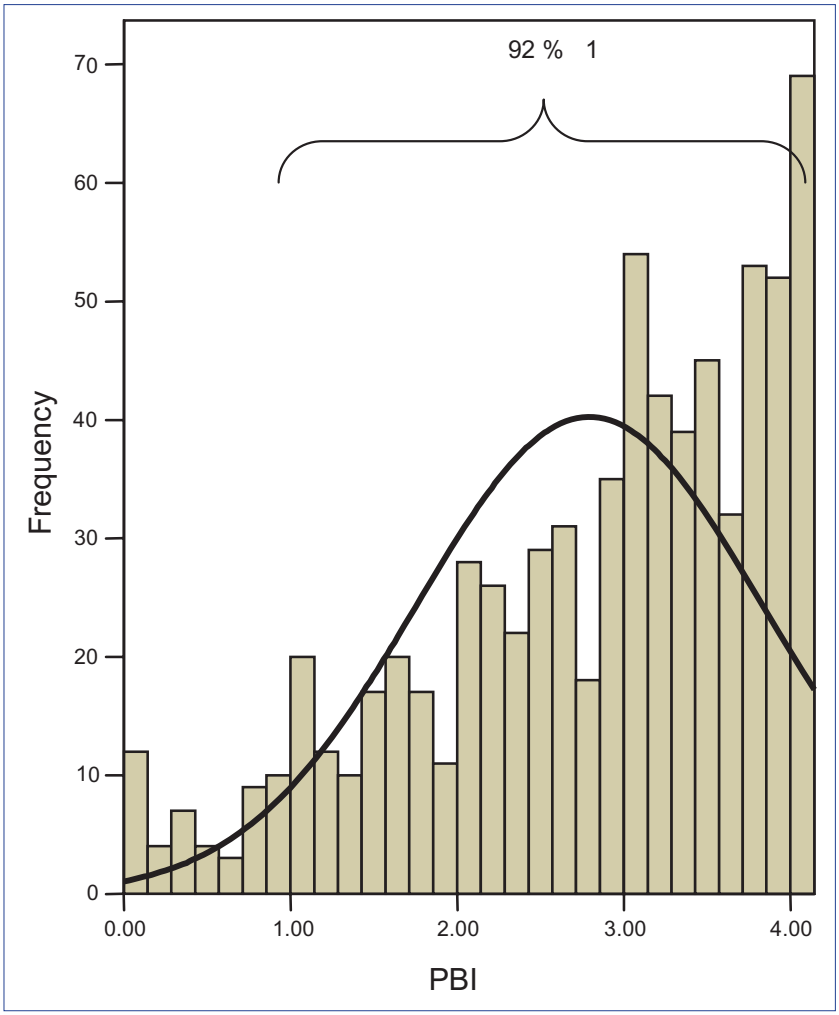


Figure 5: Frequency distribution of Patient Benefit Index (PBI) after 10–12 weeks acne therapy. Mean = 2.79; Std.Dev. = 1.04; n = 731.

Table 3: Construct validity of the PBI: Correlation with other outcome parameters at time point V2 and V3.

Correlation of the PBI with …	r =	p	n =
Further recommendation at V2	0.532	0.01	776
Global patient assessment at V2	0.541	0.01	774
Global physician assessment at V2	0.386	0.01	771
Global physician assessment at V3	0.457	0.01	725
Physical well-being at V3	0.538	0.01	728
Mental well-being at V3	0.632	0.01	724
Productivity in profession and daily life at V3	0.457	0.01	708
Social contacts at V3	0.547	0.01	726
Recreational activities at V3	0.525	0.01	719
LQ in general at V3	0.627	0.01	725

r: Pearson correlation coefficient; p: Significance (2-sided each); n: Sample size: V2: Visit 2 after 4–6 weeks; V3: Visit 3 after 10–12 weeks.

methods with a) clinical score, b) quality of life questionnaire and c) patient-defined benefit evaluation (PBI) would be advisable. <<<

Conflict of interest
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