Quality of Life in Multiply Injured Patients

Development of the Trauma Outcome Profile (TOP) as Part of the Modular Polytrauma Outcome (POLO) Chart

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Abstract

Background: Health-related Quality of Life (QoL) has gained increased attention in medicine but a specific QoL instrument for trauma patients does not yet exist. Following the recommendations of a recent international consensus conference, the Polytrauma Outcome (POLO) Chart, a modular (generic plus disease-specific) instrument was developed for systematic outcome assessment of multiply injured patients as part of the German Trauma Registry. The development of the disease-specific module, the Trauma Outcome Profile (TOP), is described.

Methods: Phase I – item collection, including a pilot study; phase II – item reduction; phase III – pre-testing in 70 polytraumatized patients and 70 controls with minor injuries. The instrument covers the four domains of QoL: physical, psychological, social, and functional capacity. Factor analysis and inter-item correlation was used to investigate relationships between items.

Results: The initial phase generated 175 questions. In phase II the number of items was reduced to 64 by statistical analysis and clinical experts. Pre-testing with factor analysis generated a final instrument with eight dimensions: depression, anxiousness, post-traumatic stress disorder, social interactions, daily activities, mental functioning, pain and physical functioning. Two questions on body image and satisfaction were added. The TOP is currently being validated (phase IV).

Conclusions: Together with the Glasgow Outcome Scale (GOS), the EuroQoL, and the SF-36, the TOP module is part of the POLO-Chart. It is the first disease-specific instrument for QoL assessment in patients with multiple injuries. The extended development process has enabled all relevant aspects of a patient's status after trauma to be considered. This instrument will be used by the German Trauma Registry for systematic follow-up investigations. The TOP can also be used as a standardized stand-alone screening measurement in follow-up investigations for individual trauma patients.

Key Words
Quality of Life · Multiple injuries · Outcome measure · German Trauma Registry

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Introduction

Apart from sports and leisure activities, the most frequent causes of severe trauma are occupational and motor accidents involving cars, motorcycles, bicycles and pedestrians. Two-thirds of the victims are male with a peak age between 20 and 45 years. An analysis of 14,110 patients in the German Trauma Registry between 1993 and 2002 revealed that 63% of all trauma

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patients sustained injuries to the extremities, followed by head injuries (61%), injuries of the thorax (48%), and of the abdomen (27%) [1]. Fortunately, due to improvements in emergency and acute care, about 82% of severely injured patients [Injury Severity Score (ISS) ≥ 16] survive today [1]. It is therefore of utmost importance for outcome research to look beyond survival rates and to focus on the quality of survival.

Besides physical and functional consequences [2, 3] patients are faced with significant psychological and social problems. Especially during the first 6 months following an accident, clinically relevant mental disorders can be observed in trauma patients. Predominant symptoms are post-traumatic stress disorder (PTSD) or acute stress disorder (ASD), anxiety and affective disorders [4–12]. Moreover, studies report physical limitations of up to 80% 12 months post-trauma [13]. As a consequence, restrictions in the ability to carry out daily activities, problems in partnership, marriage, or other social relationships occur [14–16].

In 1991 the Meran Consensus Conference on QoL after Surgery recommended that QoL is a multidimensional construct which covers four domains: physical state, psychological wellbeing, social relations, and functional capacity [17]. For trauma patients appropriate generic measures were recommended for use by an international consensus conference on "Quality of Life after Multiple Trauma" in 1999 [18]. The aim of this conference was to develop guidelines for specific QoL assessments after different types of injuries at consecutive time points. Up to date, there was little standardization regarding the measurement of QoL after trauma. In this area, assessment of QoL was usually performed by means of a variety of different, often self-developed and non-validated questionnaires. A comparison of results between studies was therefore not possible [18].

At this conference, invited experts from different disciplines and countries discussed QoL issues in relation to four groups of patients: children with traumatic brain injury, adults with traumatic brain injury, adults with multiple injuries, and adults with spinal cord injuries. The major problems and the affected domains of QoL at different time points in each patient group were identified. Instruments for QoL assessment in these patients were recommended from the available literature.

Specifically recommended for inclusion in all QoL evaluations were: the Glasgow Outcome Scale (GOS) [19] since the assessment of QoL in trauma patients after severe head injury is difficult; a brief index instrument that would provide a one-dimensional estimation of QoL, the EuroQoL [20]; and a generic QoL questionnaire with wide-spread international acceptance, the SF-36. The SF-36 contains 36 items that form eight scales and two summary measures of physical and mental health. Originally developed in United States, the SF-36 has been translated, culturally adapted and validated in many different languages for adults and children [21–27].

There are three main approaches used to assess QoL [28]. First, generic or global measures are used for assessment across a wide range of diseases or different populations. An example is the Medical Outcomes Study 36-Item Short Form (SF-36) questionnaire [29]. Second, disease- or condition-specific measures often include clinical symptoms and signs which are typical for a certain disease. They are applied only to specific subgroups of patients. An example of a disease-specific measure is the Gastrointestinal Quality of Life Index [30]. Third, in the modular approach, QoL is measured by a core set of items (global QoL), supplemented with disease-specific items. An example for a modular assessment is the European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire 30 (QLQ-C30) [31–33]. Unfortunately the modular approach is not yet very common, although it has many positive aspects. First, the core measure permits a comparison of general health in different patient groups as well as a comparison with healthy subjects. In addition, the disease-specific module considers the disease-related problems of the patients. Prior to the work described in this paper a modular approach had not been applied to traumatized patients [17, 34].

The purpose of this paper is to describe the development of a novel disease-specific instrument to assess QoL after multiple injuries, the Trauma Outcome Profile (TOP), and to provide an English version of that instrument. The TOP was designed to be used both, as part of the modular Polytrauma Outcome (POLO) Chart in clinical trials and quality assurance, and as a stand-alone screening instrument for routine use in follow-up investigations of individual trauma patients.

Materials and Methods

Theoretical Background

As a result of two international consensus conferences [17, 34] a modular instrument called the Polytrauma Outcome or POLO Chart has been developed by the Working Group on Polytrauma (AG Polytrauma) of the German Society of Traumatology (DGU) [35]. The POLO chart contains the GOS, the EuroQoL, the SF-36, and the TOP as a disease-specific module (Figure 1), which covers the four domains of QoL: physical state, psychological wellbeing, social relations, and functional capacity [17].

The TOP instrument was developed in four consecutive phases [36]. Phase I: development of an item pool (collection of questions); phase II: reduction of the number of items; phase III: pre-testing by patients, controls, and experts; and phase IV: validation, psychometric testing, and standardization. Phases I to III will be presented here; phase IV has recently been completed and the results will soon be published.

Phase I: Development of an Item Pool

Development of an item pool was based on a systematic review of the to-date literature from medical, rehabilitative, and methodological sector including existing QoL measures and related articles [22, 25, 31–33, 37–39]. For psychological wellbeing, items on depression, anxiousness and PTSD were chosen. The social domain was covered by items related to friends, family, and occupation. Functional items incorporated areas such as ability to perform self-care, to manage usual daily activities, to work, or to participate in recreational activities. The response sets were graded in a four- or five-step format from "true" to "false" on a scale from 0–10 (pain items).

In order to obtain an exhaustive list of relevant items the item pool was presented to a broad group of professionals working in the field of trauma, such as nurses, surgeons, psychologists, methodologists, and postgraduate physicians for review and supplementation. This resulted in the first version of the questionnaire, in which each domain contained 18 questions, plus 17 questions about pain in different body regions. On the last page of the questionnaire, two open questions were added, one about problems relevant to the patient but not adequately covered by the questionnaire, and another about the patient's ranking of the five most important items. In total, the initial item pool of the TOP module contained 175 questions with a closed response format, plus 2 open questions.

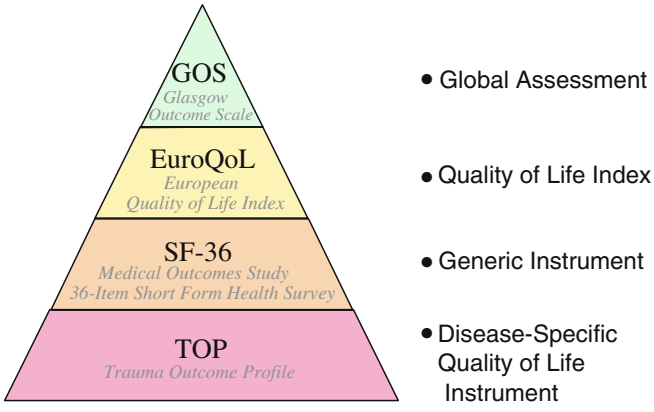

Figure 1. The modular structure of the Polytrauma Outcome (POLO) Chart.

Phase II: Reduction of Items

Between April 1 and May 31, 1998, the first version of the TOP questionnaire was filled out by 28 polytrauma patients treated in the Surgical Department of the University of Cologne between 1995 and 1996. Patients were informed about the aim of the study and were asked to fill out the questionnaire anonymously. Except for some core information on gender, age and year of accident, no personal data were collected. Completed questionnaires were returned by mail in neutral prepaid envelopes.

Based on the results of this pilot testing, items were reduced and modified using statistical analysis and expert opinion. For each item, descriptive statistics were calculated, and for each domain (psychological, social, physical, functional), items were ranked according to these results. The decision to keep or discard an item was based on a consensus decision of the development group (physicians and psychologists) using the following item selection criteria: discriminant validity, clinical relevance, and patients' comments about importance and completeness.

Phase III: Pretest

In this phase the TOP module was pre-tested on trauma patients and control subjects. Prior to pre-testing, response categories for items related to pain and physical impairments were changed to a ten-step numerical rating scale (0–10; NRS) in order to increase their discriminatory ability. The other items used a three- or five-step answer format.

The TOP module and the SF-36 were administered to 70 polytrauma patients from the German Trauma Registry (accident between 1/1996 and 9/1997). Patients were treated in one of the five founding hospitals of the Registry (Celle, Essen, Hannover, Cologne, and Munich). Trauma patients were asked to complete the questionnaires during their 2 years of follow-up examination. Seventy control patients, treated in one of the aforementioned hospitals for isolated fractures or joint injuries were asked to fill out the questionnaires while being treated for the removal of osteosynthesis material or for routine control.

Statistical Analysis

Data was entered into a data base (Epi Info) and statistical analysis was performed with SPSS (SPSS Inc., Chicago IL, vers. 9.0). Besides descriptive analyses, a factor analysis (using the Equamax rotation method)

was conducted to provide information on item grouping (factors) and the contributions of the individual items to each factor. To arrive at interpretable factorial results the orthogonal Equamax rotation method was used, by rotating the factors in a manner in which communality and explained variability remain consistent and only the matrix of the factor loadings change. This method enables an easier interpretability of both the factors and the variables. Using this method every variable yields a high loading on only one factor, which makes it easy to give each factor an interpretation [37].

This information, along with Spearman's inter-item correlation, was used to assist item selection. Differences between the polytrauma and control group were evaluated by the Mann–Whitney U test [37].

Results

Item Pool Generation and Reduction (Phases I and II)

The Item Pool

As a result of the pilot testing, the 175 items of the TOP were divided into three parts: items specifically relevant for trauma patients, general items concerning QoL, and items which were rated as not important by the patients. Most of the patients used the open questions for additional comments. For example, several patients claimed that the sequelae of head injuries were not adequately addressed.

Reduction of Items

• Psycho- social domain: With the aim of developing a practical questionnaire, and because of the interaction of psychological and social aspects, these two domains were combined into one psycho-social domain. For each dimension within this domain (depression, anxiousness, PTSD and social interactions) four items were selected, two items based on their ranking, and two items from the physicians' or the patients' comments. Thus the psycho-social domain finally consisted of 16 items and 4 dimensions.

• Physical domain/pain: Patients did not have problems responding to the items but the detailed questions concerning each single body region proved to be too complex. Therefore the number of items for the physical/pain domain was reduced considerably. The reduced list of 14 body regions is presented in Figure 2. Each region is rated in terms of intensity on a numerical scale from 0 to 10. Additionally, four questions about quality and quantity of pain, coping strategies and medication and their effectiveness were included.

• Functional capacity: In this domain patients' comments were carefully considered in selecting items about the consequences of head injury, which in their opinion were not adequately addressed. Five additional questions reflecting lack of concentration, loss of memory, easy distractibility, changes in personality, and motor difficulties were therefore added. Another five items about physical functioning were selected based on the statistical ranking and the physicians' opinion. Additionally, similar to the pain assessment, the same 14 body regions were selected to describe the degree of limitation of physical functioning in detail (on a ten-step scale). In total, the functional domain contains 14 body regions, 4 items on daily activities and 4 items on mental functioning.

As a result of the open questions within the pilot study, further questions were incorporated as a supplement. These questions were about difficulties with institutions, the need for help, and employment status, retraining, and recent changes in income. Altogether the number of items in the TOP was reduced from 175 to 64.

Pretest with Trauma Patients and Controls (Phase III)

As demonstrated in Table 1, the polytrauma and the control group were comparable according to gender, age, family status, educational level and occupation. The majority of polytrauma patients (80%) had injuries of the lower extremities. Seventy percent of the control group had fractures of the ankle joint. The mean ISS was 17 in the trauma group and 4 in the control group.

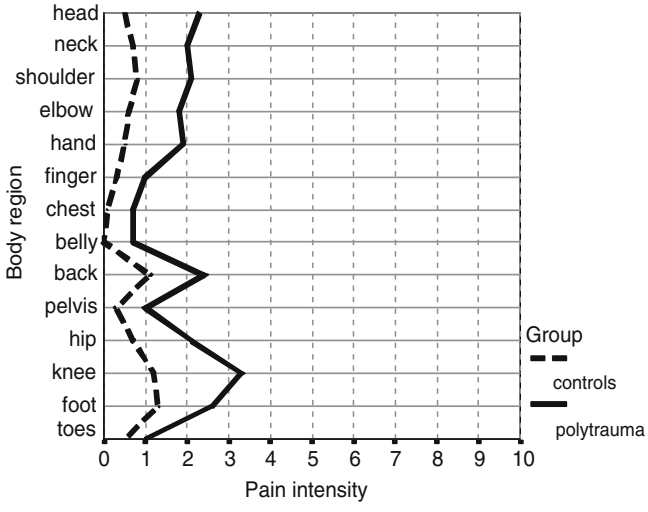

Figure 2. Intensity of pain in 14 different body regions, for polytrauma patients (solid line; n = 70) and controls (dashed line; n = 70. 0 ="no pain", 10 = "unbearable pain").

Table 1. Demographic data for polytrauma patients and controls (phase III).

	Trauma group (n = 70)	Control group (n = 70)
Gender (males; n %)	39 (55.7%)	40 (57.1%)
Age (mean, range)	36.3 (9–69)	37.0 (18–71)
Marital status (n %)		
· Single, without partner	18 (25.7%)	17 (24.3%)
· Single, with long-term partner	17 (24.3%)	18 (25.7%)
· Married	26 (37.1%)	29 (41.4%)
· Separated/divorced	7 (10.0%)	4 (5.7%)
· Widowed	2 (2.9%)	2 (2.9%)
Education (n %)		
· Primary/secondary school	24 (34,3%)	16 (22.9%)
· Secondary modern school	18 (25,7%)	13 (18.6%)
· High school	9 (12,9%)	15 (21.4%)
· University degree	10 (14,3%)	20 (28.6%)
· Still pupil or student	3 (4,3%)	5 (7.1%)
· School not completed	6 (8,6%)	1 (1.4%)
Profession (n %)		
· Executive employee	4 (5,7%)	7 (10.0%)
· White collar worker	17 (24,3%)	24 (40,0%)
· Blue collar worker	18 (25,7%)	11 (15,7%)
· Self-employed	4 (5,7%)	5 (7,1%)
· Others	27 (38,6%)	19 (27,1%)

Descriptive Evaluation of Pain and Physical Functioning

Data provided by the numerical rating scales on pain intensity and physical functioning is presented in Figures 2 and 3. The polytrauma group showed higher mean values for pain (n = 70, Figure 2) and physical functioning (n = 70, Figure 3) in all body regions than in the control group (pain: n = 70; physical functioning: n = 70). Interestingly, pain scores were highest for knee, foot/ankle and back/spine in both groups. With a few exceptions (pain: toes; functioning: chest, belly, toes) the differences between trauma patients and controls were statistically significant ($p < 0.05$; U test). The general pattern of scores relating to the body regions was similar in both dimensions.

Furthermore, history of pain and functional limitations before the trauma had to be recorded, since it may influence perception of pain and functional limitations resulting from the accident. Therefore, a set of items referring to the social status (education, profession, etc.) as well as pain and functional limitations before the accident assembled in a section called "PRE Status". Supplementary open questions about difficulties with authorities, need for help, employment status, etc. were summarized as "POST Status".

Both, PRE and POST Status questions are not part of the QoL assessment, but rather are meant to provide important additional information for interpretation of results.

Factor Analysis

The main principal component analysis for grouping the items revealed six factors (with values ≥ 0,4), which explained 69% of the variance. The first factor included items describing cognitive and emotional limitations such as lack of concentration, irritability, lack of attentiveness, decreased ability to enjoy oneself, discouragement, and increased thoughtfulness. These items were all related to mental and emotional problems in the psycho-social domain and mental functioning.

The second factor incorporated items that were related to physical and functional abilities for activities of daily living. These items included the impact of pain on these activities as well as items from the psychosocial domain (e.g. occupational problems) and body areas (e.g. restricted productivity).

Interestingly, the third factor grouped items typical of PTSD, including anxiety and avoiding the scene of the accident. Under the fourth factor, only items describing the psychological domain were found. These were items related to depression (e.g. loss of meaning of life) and anxiousness (e.g. an increase in thoughts about unimportant things), as well as items about the social situation (e.g. stress in the partnership). In the fifth and sixth factor the items reflected the pain domain. Details of the analysis are given in Pirente et al. [35].

Item Selection

In order to identify items that described similar concepts, an inter-item correlation matrix was calculated. Items with a high correlation ($r > 0.50$) were either combined, or the questions were reworded.

The descriptive analysis (frequency tables and mean values) of all questions revealed a distribution strongly skewed to the right, indicating that the majority of respondents had only minor or no impairment. A ranking was performed according to increasing mean values of the answers.

In order to identify those items which best differentiate between trauma patients and controls, answers for both groups were compared statistically. Most items of the psychosocial domain, for example, showed highly significant differences ($p \leq 0.01$, U test), and there was no item with $p > 0.10$.

In order to develop a practical instrument, the number of items per dimension was restricted to four. The selection of the first two items was determined by their

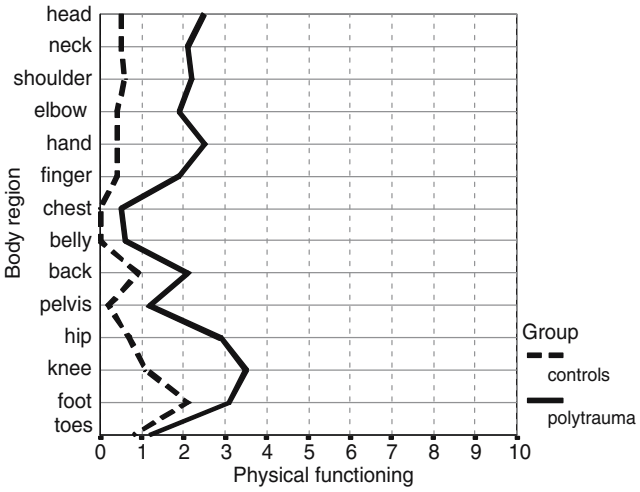

Figure 3. Physical functioning in 14 different body regions for polytrauma patients (n = 70) and controls (dashed line; n = 7). 0 = "full function", 10 = "no function".

rank order and the fact that they loaded on the same factor. If there were several appropriate items, selection was made on the basis of group comparisons, and whether the question could have a direct therapeutic or supportive consequence. To elaborate discriminative ability of the questionnaire, a sharper wording was chosen of a few items in the final questionnaire. Moreover, all items were standardized to the extent that all answer options are rated on a five-point Likert scale.

The instrument was easily understandable, considered acceptable with respect to face validity by an expert team of members of the AG Polytrauma (trauma surgeons from different hospitals). Based on suggestions from that group and on trauma patients' comments, two additional items about body image and general contentment were added as well as supplementary questions about the degree of suffering to the ratings of pain and physical functioning. The final version of the questionnaire is given in the Appendix.

Validation and Translation (Phase IV)

In the mean time the validation process of the TOP has been finished. One hundred seventy-two trauma patients and 166 controls were included. No item was added or discarded as a result of this process; only two dimensions have been renamed. Figure 4 contains the final structure; and the final wording is presented in the Appendix. The results of the validation process as well as a user manual for the instrument are currently under preparation.

The instrument has been translated from the German original version into UK English by professional translators. The translation process consisted of two independent forward translations and two back translations. In all cases where differences to the original version were observed, reconciliations between the developer and native speakers took place. Furthermore, a linguistic validation on five patients was performed. The process was additionally supervised by accompanying proof reading and developer reviews.

Discussion

Since QoL has become increasingly accepted as an important outcome in medicine and specifically in trauma, an increasing number of studies assessing this endpoint has been published [3, 13, 17, 26, 34, 40–42]. However, little standardization has been applied to the measurement of QoL in this area. Comparisons across different trauma populations are therefore difficult.

In 1999, a consensus conference on QoL after multiple trauma suggested, that QoL of polytraumatized patients should be assessed using a modular approach [34]. In line with these recommendations, and supported by a grant of the DFG (Deutsche Forschungsgemeinschaft), the AG Polytrauma of the German Society of Traumatology (DGU) developed a trauma-specific module, the TOP.

As recommended in the Meran Consensus Conference on Quality of Life 1991 [17], the TOP covers four domains, the physical, psychological, social and functional domain, that make up QoL. Factor analysis as well as theoretical and practical considerations extracted eight dimensions comprising 54 items plus 2 additional single questions. The structure of the TOP is shown in Figure 4. It is supplemented by a PRE Status and a POST Status which cover important aspects for interpretation of results.

The TOP is meant to be used both, as an individual measure in routine clinical practice as a screening instrument, and for research purposes as part of a modular QoL instrument, the POLO chart.

TOP as a Screening Instrument

By covering the relevant domains of QoL the TOP enables a physician to identify efficiently the patient's problems and to estimate their subjective importance. Areas of low QoL could then be evaluated more deeply, or the patient could be referred to other professionals qualified to help with that specific problem. For example, if the assessment shows that the patient has financial problems following trauma, the patient can be referred to social workers, whilst psychological referral can be initiated if the results indicate that he/she might have developed a PTSD. Trauma-specific questions like "Some things I see or hear put me back to the situation

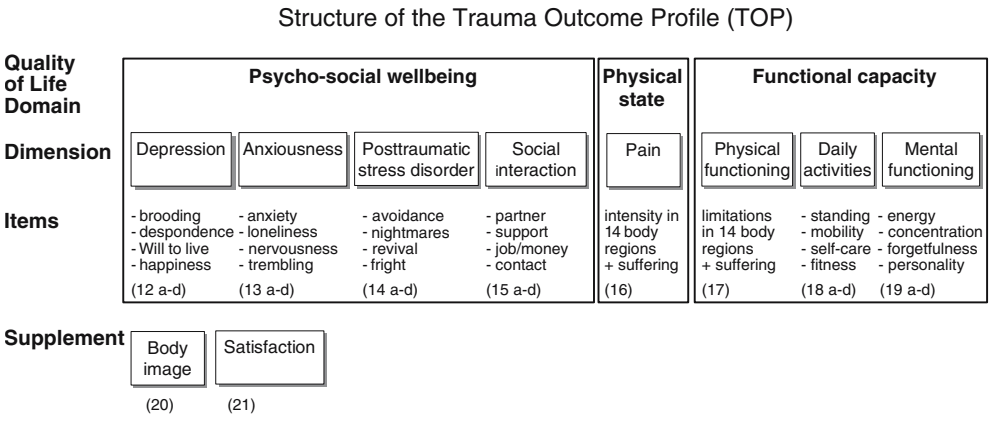

Figure 4. Domains, dimensions and items of the Trauma Outcome Profile (TOP). The numbers below each box refer to the respective question in the TOP; see **Appendix** (see pp 54–62)

of the accident", which cannot be found in any other QoL questionnaire, are of great diagnostic value. However, the TOP is neither developed for psychological diagnostic purposes nor should it be applied as a substitute for specific instruments, like the Impact of Event Scale for PTSD diagnostic. Furthermore, the use of the TOP is not intended to replace the communication between physician and patient but rather to give helpful guidance. Certain subjective limitations may only be identified by the TOP which otherwise would have been overseen.

For a comfortable application and a simple interpretation of the results, a software presenting the results as a graphical profile immediately after assessment is currently being developed. As such, the TOP would overcome one of the major shortages of QoL assessments. Up to now QoL assessment was done nearly exclusively for research purposes and had hardly any consequences for the individual patient in daily surgical routine. By means of an efficient instrument and simple graphic presentation of results, efficient interventions could be initiated rapidly. Moreover, the approach is not time consuming, since it takes only 7–10 min to fill out the TOP questionnaire which could be done whilst waiting for the doctor in the outpatient setting.

Scientific Use of TOP

For scientific purposes the TOP is used as a part of the modular POLO chart. It provides a systematic and objective tool for outcome assessment after trauma and allows repeated assessment over time. Together with generic measures of QoL, it enables comparisons among trauma patients as well as between trauma patients and other disease groups. Used in conjunction with the SF-36, the EuroQoL, and the GOS, the POLO chart is the first condition-specific health-related QoL questionnaire for severely injured patients. In clinical investigations it can be used to evaluate the effectiveness of clinical interventions (surgery, medication, physical and psychological therapy, rehabilitation) by determining the patients' QoL at predefined time points.

Future detailed analyses will show to what extent the specific TOP module is able to identify problems that are not covered by generic instruments.

Comparison to SF-36

A generic instrument like the SF-36 does not include health concepts such as cognitive functioning, family functioning, communication health distress and symptoms or problems that target a specific disease group.

The mental health domain of the SF-36 for instances, consists only of items referring to depressive symptoms. Although, this is an important outcome after trauma, it does not suffice the needs of an outcome measure for trauma patients. Studies report prevalence rates of PTSD between 18–68% [2, 7–9, 42], and 8–42% of patients show signs of anxiety [10–11, 15, 43–45]. Therefore, these dimensions had to be included into a disease-specific trauma outcome measure. Similarly, questions in the social domain of the SF-36 are very brief and neither cover the necessary aspects of perceiving social support nor the occupational and financial consequences, crucial for trauma patients [15, 46–47]. Moreover, the SF-36 does not cover concepts related to cognitive functioning, as concentration and forgetfulness, which represent a major impairment in a patient's life [48].

The most relevant specific symptom after multiple trauma is pain. Gehling et al. [49] found that 61% of operated patients suffer from pain 7–9 months after the accident. Twenty-five percent of patients report pain to be their biggest problem [50, 51]. Studies have further shown that outcomes of QoL, including physical functioning and pain, depend to a great extent on the region of injury. Injuries to extremities account for the majority of injuries (56–93%), followed by brain (35–97%) and thorax injuries [52]. Patients with head

and/or extremity injuries suffer a long time from major functional impairments. Especially patients with injuries of lower extremities suffer up to 80% from such impairments [53]. Therefore an exhaustive and distinguished list of body regions regarding the degree of pain and the degree of functional impairment was considered most essential.

As suggested by others, the SF-36 is best used as a generic core instrument which needs supplementation of a more precise measure to detect changes over time in a specific group [54]. The SF-36 shows substantial floor and ceiling effects especially for the two role scales. In addition, the bodily pain and social functioning scales show notable ceiling effects [55–58]. For the role functioning scale floor effects were greater for populations with multiple medical conditions and for those disabled due to physical and mental problems [55]. Kopjar [56] found that 40% of patients with activity restrictions had ceiling scores according to role limitations. Consequently, floor and ceiling effects are also expected to appear in multiply injured patients, which diminishes the ability of this measure to detect changes over time in that group of patients. A disease-specific instrument, constructed to satisfy the needs and issues of traumatized patients covering relevant domains in great detail, is expected to be more able to discriminate among trauma patients.

The TOP was also designed for a stand-alone application as a screening instrument in routine follow-up of individual trauma patients. Moreover, the questions of the TOP always focus on changes due to the traumatic event. The so-called PRE Status evaluates pain and functional limitations before the accident, in order to be able to identify the effect of trauma more clearly.

Limitations

Although subjective decisions within such a complex development process cannot be completely denied, we believe that the methodological knowledge available in the team can compensate this shortage [28, 30]. Decision to include or discard an item was based on strict statistical criteria as well as on professional decisions based on the experience of practicing trauma surgeons.

It could further be criticized that the instrument was developed and pre-tested on a small sample of patients with mainly extremity fractures. Although extremity injuries represent the majority of injuries with an incidence of up to 90% [52], the instrument has to be validated on a larger and more representative sample to account for the heterogeneity of injuries. Another point to be addressed in further research is the time point between assessment and trauma. In our pretest, the time point of assessment for trauma patients was 2 years post-trauma and only few months for the control group. In the validation study, however, this has been controlled for.

Further research addressing the validity and reliability of the measure over time, its responsiveness to change and sensitivity to various health problems is required. Furthermore, interesting results could be expected if QoL is linked with type and severity of trauma, or with aspects of therapeutic interventions, like length of stay on ICU. The basis for this kind of research has now been established: a translation of the instrument into several languages is actually ongoing and a user manual is available from the authors. The English version of the TOP presented in the Appendix has been derived from the German original, using established techniques of forward and back translations and pilot testing in patients. Moreover, the TOP is going to be used for QoL assessment in an international multi-centre study on trauma patients.

The lack of availability of an appropriate instrument can no longer be an excuse for not considering the patients' QoL in future investigations.

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Appendix

Polytrauma Outcome Chart (POLO Chart)

This sheet is to be completed by the doctor with the patient – Module PRE Status

Name / Initials: _____ **Sex:** Female ❑ 1
Male ❑ 2

Age at accident: _____ **Date of accident:** _____
Trial number: _____ **Today's date:** _____

This module should only be completed once, at the patient's first Follow-up appointment, to determine the patient's personal situation **before the accident**. The aim is to obtain a better assessment of the patient's situation after the accident in comparison with their initial situation.

Marital status at time of the accident:
❑ 1 Single
❑ 2 Living with partner
❑ 3 Married
❑ 4 Separated
❑ 5 Divorced
❑ 6 Widowed

Education at time of the accident: Did your education continue after age 16?
❑ 1 Yes
❑ 2 No
❑ 3 Unknown

Do you have a University degree or equivalent professional qualification?
❑ 1 Yes
❑ 2 No
❑ 3 Unknown

Occupation at time of the accident:
❑ 1 Employed
❑ 2 Self-employed
❑ 3 Retired
❑ 4 Housework
❑ 5 Student
❑ 6 Seeking work
❑ 7 Unable to work
❑ 8 Other, please specify: _____

Polytrauma Outcome Chart (POLO Chart)

This sheet is to be completed by the doctor with the patient – Module PRE Status

Pain before the accident

For each of the following areas of the body, please indicate (by circling a number) the degree of pain that you experienced where 0 = no pain and 10 = unbearable pain, before the accident:

	0 = no pain										10 = unbearable pain
Head	0	1	2	3	4	5	6	7	8	9	10
Neck	0	1	2	3	4	5	6	7	8	9	10
Shoulder / Upper Arm	0	1	2	3	4	5	6	7	8	9	10
Elbow / Lower Arm	0	1	2	3	4	5	6	7	8	9	10
Wrist / Hand	0	1	2	3	4	5	6	7	8	9	10
Fingers	0	1	2	3	4	5	6	7	8	9	10
Chest	0	1	2	3	4	5	6	7	8	9	10
Stomach	0	1	2	3	4	5	6	7	8	9	10
Back / Spine	0	1	2	3	4	5	6	7	8	9	10
Pelvis	0	1	2	3	4	5	6	7	8	9	10
Hips / Thigh	0	1	2	3	4	5	6	7	8	9	10
Knee / Lower Leg	0	1	2	3	4	5	6	7	8	9	10
Ankle / Foot	0	1	2	3	4	5	6	7	8	9	10
Toes	0	1	2	3	4	5	6	7	8	9	10

If you marked at least one of the body areas above with 1 or more:

Overall, how badly did you suffer from the pain mentioned above?

- ❑ 0 Not at all
- ❑ 1 A little
- ❑ 2 Quite a lot
- ❑ 3 A considerable amount
- ❑ 4 Extremely

Polytrauma Outcome Chart (POLO Chart)

This sheet is to be completed by the doctor with the patient – Module PRE Status

Physical functioning before the accident

For each of the following areas of the body, please indicate (by circling a number) the degree of restriction on your physical functioning where 0 = full functioning and 10 = no functioning, before the accident:

	0 = full functioning										10 = no functioning
Head	0	1	2	3	4	5	6	7	8	9	10
Neck	0	1	2	3	4	5	6	7	8	9	10
Shoulder / Upper Arm	0	1	2	3	4	5	6	7	8	9	10
Elbow / Lower Arm	0	1	2	3	4	5	6	7	8	9	10
Wrist / Hand	0	1	2	3	4	5	6	7	8	9	10
Fingers	0	1	2	3	4	5	6	7	8	9	10
Chest	0	1	2	3	4	5	6	7	8	9	10
Stomach	0	1	2	3	4	5	6	7	8	9	10
Back / Spine	0	1	2	3	4	5	6	7	8	9	10
Pelvis	0	1	2	3	4	5	6	7	8	9	10
Hips / Thigh	0	1	2	3	4	5	6	7	8	9	10
Knee / Lower Leg	0	1	2	3	4	5	6	7	8	9	10
Ankle / Foot	0	1	2	3	4	5	6	7	8	9	10
Toes	0	1	2	3	4	5	6	7	8	9	10

If you marked at least one of the body areas above with 1 or more:

Overall, how badly did you suffer from the degree of restriction on your physical functioning mentioned above?

- ❑ 0 Not at all
- ❑ 1 A little
- ❑ 2 Quite a lot
- ❑ 3 A considerable amount
- ❑ 4 Extremely

Polytrauma Outcome Chart (POLO Chart)

This sheet is to be completed by the patient – Module Top

MODULE TOP (Trauma Outcome Profile)

We would like to use the following statements to assess the effects of your accident on how you are today. Please consider **only the last 4 weeks** when giving your answers.	Applies to me	Applies broadly to me	Applies partly to me	Barely applies to me	Does not apply to me
12a I have sometimes tended to brood too much	1	2	3	4	5
12b I have sometimes felt despondent (discouraged) about the future	1	2	3	4	5
12 c I have sometimes thought seriously about whether I want to live any longer	1	2	3	4	5
12d Sometimes nothing has made me happy	1	2	3	4	5
13a I have sometimes suffered from anxiety and/or panic attacks	1	2	3	4	5
13b I have sometimes been afraid of being on my own	1	2	3	4	5
13c I have noticed that I have become more nervous and irritable	1	2	3	4	5
13d I have sometimes suffered from palpitations and/or sweating and/or trembling	1	2	3	4	5

DO YOU REMEMBER THE ACCIDENT?	❑ 1 yes ❑ 0 no

We would like to use the following statements to assess the effects of your accident on how you are today. Please consider **only the last 4 weeks** when giving your answers.	Applies to me	Applies broadly to me	Applies partly to me	Barely applies to me	Does not apply to me
14a I have tried not to think about the accident	1	2	3	4	5
14b I have suffered from nightmares and restlessness at night	1	2	3	4	5
14c Some things that I have seen or heard have taken me back to the accident and frightened me	1	2	3	4	5
14d I have become more easily startled	1	2	3	4	5
15a As a result of the accident, my relationship with my girlfriend/boyfriend/partner /spouse has suffered	1	2	3	4	5
15b I have no longer felt as well supported by those around me (relatives / friends)	1	2	3	4	5
15c I have had financial problems or problems with my job	1	2	3	4	5
15d Contact with those around me (relatives / friends) has worsened	1	2	3	4	5

Polytrauma Outcome Chart (POLO Chart)

This sheet is to be completed by the patient – Module Top

Pain after the accident

16. For each of the following areas of the body, please indicate (by circling a number) the degree of pain that you have experienced where 0 = no pain and 10 = unbearable pain, especially over the last four weeks:

	0 = no pain										0 = unbearable pain
Head	0	1	2	3	4	5	6	7	8	9	10
Neck	0	1	2	3	4	5	6	7	8	9	10
Shoulder / Upper Arm	0	1	2	3	4	5	6	7	8	9	10
Elbow / Lower Arm	0	1	2	3	4	5	6	7	8	9	10
Wrist / Hand	0	1	2	3	4	5	6	7	8	9	10
Fingers	0	1	2	3	4	5	6	7	8	9	10
Chest	0	1	2	3	4	5	6	7	8	9	10
Stomach	0	1	2	3	4	5	6	7	8	9	10
Back / Spine	0	1	2	3	4	5	6	7	8	9	10
Pelvis	0	1	2	3	4	5	6	7	8	9	10
Hips / Thigh	0	1	2	3	4	5	6	7	8	9	10
Knee / Lower Leg	0	1	2	3	4	5	6	7	8	9	10
Ankle / Foot	0	1	2	3	4	5	6	7	8	9	10
Toes	0	1	2	3	4	5	6	7	8	9	10

If you marked at least one of the body areas above with 1 or more:

Overall, how badly did you suffer from the pain mentioned above?

- ❑ 0 Not at all
- ❑ 1 A little
- ❑ 2 Quite a lot
- ❑ 3 A considerable amount
- ❑ 4 Extremely

Polytrauma Outcome Chart (POLO Chart)

This sheet is to be completed by the patient – Module Top

Physical functioning after the accident

17. For each of the following areas of the body, please indicate (by circling a number) the degree of restriction on your physical functioning after the accident where 0 = full functioning and 10 = no functioning, especially over the last four weeks:

	0 = full functioning										10 = no functioning
Head	0	1	2	3	4	5	6	7	8	9	10
Neck	0	1	2	3	4	5	6	7	8	9	10
Shoulder / Upper Arm	0	1	2	3	4	5	6	7	8	9	10
Elbow / Lower Arm	0	1	2	3	4	5	6	7	8	9	10
Wrist / Hand	0	1	2	3	4	5	6	7	8	9	10
Fingers	0	1	2	3	4	5	6	7	8	9	10
Chest	0	1	2	3	4	5	6	7	8	9	10
Stomach	0	1	2	3	4	5	6	7	8	9	10
Back / Spine	0	1	2	3	4	5	6	7	8	9	10
Pelvis	0	1	2	3	4	5	6	7	8	9	10
Hips / Thigh	0	1	2	3	4	5	6	7	8	9	10
Knee / Lower Leg	0	1	2	3	4	5	6	7	8	9	10
Ankle / Foot	0	1	2	3	4	5	6	7	8	9	10
Toes	0	1	2	3	4	5	6	7	8	9	10

If you marked at least one of the body areas above with 1 or more:

Overall, how badly did you suffer from the degree of restriction to your physical functioning mentioned above?

- ❑ 0 Not at all
- ❑ 1 A little
- ❑ 2 Quite a lot
- ❑ 3 A considerable amount
- ❑ 4 Extremely

Polytrauma Outcome Chart (POLO Chart)

This sheet is to be completed by the patient – Module Top

The next statements look at if and how much your physical function is restricted due to the accident. Please consider the last 4 weeks when giving your answers:	Applies to me	Applies broadly to me	Applies partly to me	Barely applies to me	Does not apply to me
18a I have been able to do things whilst standing at home / at my job	1	2	3	4	5
18b I have had to use mobility aids (e.g. crutches, wheelchair etc.)	1	2	3	4	5
18c I have been able to look after myself	1	2	3	4	5
18d I have felt physically fit	1	2	3	4	5
19a I have felt that I have got tired more quickly (when reading / writing / watching television / talking etc.)	1	2	3	4	5
19b I have felt that I have not been able to concentrate for as long as I used to	1	2	3	4	5
19c I have become more forgetful	1	2	3	4	5
19d I have felt that my nature / personality has changed	1	2	3	4	5

	Applies to me	Applies broadly to me	Applies partly to me	Barely applies to me	Does not apply to me
20 The visible consequences of the accident (e.g. scars) have upset me	1	2	3	4	5

	Applies to me	Applies broadly to me	Applies partly to me	Barely applies to me	Does not apply to me
21 Taking all things into consideration, I am satisfied with my current situation	1	2	3	4	5

Polytrauma Outcome Chart (POLO Chart)

This sheet is to be completed by the patient – POST Status

Name / Initials: _____ **Sex:** Female ❑ 1
Male ❑ 2

Age at accident: _____ **Date of accident:** _____
Today's date: _____

Finally, we would like you to answer a few more questions about your current personal situation.

Marital status:
❑ 1 Single
❑ 2 Cohabiting
❑ 3 Married
❑ 4 Separated
❑ 5 Divorced
❑ 6 Widowed

Education:

Did your education continue after age 16?
❑ 1 Yes
❑ 2 No
❑ 3 Unknown

Do you have a University degree or equivalent professional qualification?
❑ 1 Yes
❑ 2 No
❑ 3 Unknown

Occupation:
❑ 1 Employed
❑ 2 Self-employed
❑ 3 Retired
❑ 4 Housework
❑ 5 Student
❑ 6 Seeking work
❑ 7 Unable to work
❑ 8 Other, please specify:_____
❑ 9 Retired, due to age
❑ 10 Retired, due to accident

Polytrauma Outcome Chart (POLO Chart)

This sheet is to be completed by the patient – POST Status

a) Has there been an event after your accident which has been a burden to you and that has or had nothing to do with the accident?

- ❑ 0 No
- ❑ 1 If yes, what?

b) Have you become unemployed as a result of your accident?

- ❑ 0 No
- ❑ 1 Yes
- ❑ 9 Don't know/Not applicable

c) Have you had to retire as a result of your accident?

- ❑ 0 No
- ❑ 1 Yes
- ❑ 9 Don't know/Not applicable

d) Have you had to change your job as a result of your accident?

- ❑ 0 No
- ❑ 1 Yes
- ❑ 9 Don't know/Not applicable

e) Have you suffered financial problems as a result of your accident?

- ❑ 0 No
- ❑ 1 Yes
- ❑ 9 Don't know/Not applicable

f) Have you had problems with public authorities when dealing with something related to your accident?

- ❑ 0 No
- ❑ 1 If yes, what?

g) Would you like more help to resolve the problems caused by your accident?

- ❑ 0 No
- ❑ 1 If yes, what?
- ❑ 9 Don't know/Not applicable

We would like to thank you for your patience and time!