Time Needed for Data Collection in Clinical Studies on Fixed Prosthodontics

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Purpose: Realistic appraisals of time and costs are crucial for research grants and financing of clinical studies by sponsors, but little is known about the time actually needed for clinical data collection in dental studies. This survey evaluated the net time of patient contact necessary for collection and documentation of clinical data to establish an empirical base for more efficient study management and budgeting. Materials and Methods: The time needed for the clinical examination of 41 prosthodontic patients in systematic follow-up was recorded. Examination covered dental status, oral hygiene status, and quality assessment of restorations by modified CDA criteria. Completion of the case report forms, data check, and provisions for data retrieval were also included. The recorded times were analyzed to obtain empirical estimates of the time actually needed for specific examination blocks and to detect potential variables of influence. *Results:* Predominant time records were 5 to 10 minutes for dental status (according to status complexity) or hygiene. The time needed for CDA ranking showed a linear correlation to the number of units, approximately 1 minute each. Documentation times were similar to the total contact times of all examination blocks, between 15 and 30 minutes per patient. Conclusion: The overall time for collection and documentation of retrievable data is considerable (about 30 minutes, up to 1 hour). The data provide an empirical base for sound managing and budgeting of follow-up periods in clinical investigations, which is of major importance for the quality of clinical data, and thus for the success and value of clinical investigations. Int J Prosthodont 2004;17:651-656.

Clinical observation and data collection are two basic issues in clinical investigations. Their quality determines the success of any subsequent study procedure. Compared with study preparation, evaluation, or reporting, a clinical examination seems to be no big issue, but serial examinations for data collection on many patients—often over several years in dentistry entail prospective management and constant administration efforts, and they are themselves time consuming. Sound financial planning that adequately anticipates the full-time equivalents is required for a realistic budgeting of staff.

The question considered here is: How long does it take to perform a clinical examination on a patient? Beside this, investigators have to make provisions for completeness, correctness, and retrieval of stored data. The dental literature does not give concrete answers to these issues. Nevertheless, resources and budgeting are important items in the guidelines and regulations concerning the conduction of clinical investigations.¹⁻⁶ Many problems in clinical trials are organizational or administrative in nature, and there is often no adequate data collection philosophy.7(pp 19,46) This results in collecting superfluous data and wasting time and money; patient contact as the way of data collection is a major cost determinant.7(p 119) Therefore, the cost and effort of clinical examinations and data collection should be critically assessed against what is actually necessary to collect to answer the questions underlying a clinical investigation.⁸

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Examination block	Label of time record	Label of calculated examination times	Formula
Dental status	Dental status time (a)	-	-
Oral hygiene status	Hygiene status time (b)	Total status time	a + b
CDA ranking	CDA time (c)	Net contact time	a + b + c
Documentation	Documentation time (d)	Total time	a + b + c + d

Table 1 Composition of the Examinations in Specific Blocks and Related Time Records

CDA = California Dental Association.

The purpose of this survey was to evaluate the net time of patient contact necessary for collection and documentation of clinical data to establish an empirical base for more efficient management and realistic budgeting of clinical investigations. This approach supports the practical hypothesis, common through experience, that more time is necessary than initially believed.

Materials and Methods

The time needed for the extensive clinical examination of 41 patients by one investigator was recorded. All patients were enrolled in systematic long-term observations after prosthodontic treatment; 13 were participants in a randomized clinical trial. The examined restoration types included conventionally cemented crowns and fixed partial dentures (all-ceramic as well as metal-ceramic restorations) and adhesively luted allceramic inlays and veneers. All patients were examined by a standardized protocol covering dental status, oral hygiene status, and clinical assessment of all restorations under specific observation. Besides the description of the dentition, defects, and restorations, the dental status tested tooth vitality (by provoking the tooth's sensibility reaction by application of dry ice) and the endodontic-periodontic integrity of the root apices (by axial tooth percussion testing with the back of the handle of a dental explorer).

The oral hygiene status comprised at least two gingival indices: gingival pocket depth and bleeding on probing at mesio- and distobuccal sites of each tooth using a periodontal explorer (DB 765R 0.2N CPTN, Aesculap). In the 13 patients enrolled in the randomized clinical trial, three oral hygiene indices were recorded: papilla bleeding index (PBI; according to Saxer and Mühlemann⁹; PCP 12 periodontal probe, Hu-Friedy), gingival pocket depth (DB 765R 0.2N CPTN) as outlined above, and approximal plaque index (API; according to Lange¹⁰) after coloring the dental plaque with a two-color disclosing solution (Mira-2-Tone, Hager & Werken).

The clinical assessment of the restorations included a modified ranking according to modified California Dental Association (CDA) criteria,¹¹ detection of adverse events on the restored teeth, and description of the course of the marginal gingiva in relation to the restoration margin if relevant.

Each examination part was performed and timed en bloc by avoiding interruptions as far as possible to exclude recording of time needed for anything other than the examination measures. Interventions, patient information, consulting, as well as social conversation occurred before or after the examination blocks. The measurements of time were performed with an ordinary stopwatch (chronograph type, Jaques Lemans), considering only intervals of 0.5 minute, rounded either down (for times < 15 seconds) or up (\geq 15 seconds).

The examiner started the time record at the beginning of the examination block. He stopped it after having dictated the last finding. All findings were dictated by the examiner to the dental assistant, who recorded them on the case report forms during examination. (The case report forms are available on request from the authors.) The documentation block was performed by the examiner after completion of all examinations. It comprised: (1) completion of the data forms (plausibility, completeness, and correctness of the data); (2) completion of the dental hospital record; and (3) recording of the examination in a basic database for retrieval. Table 1 lists the different time blocks considered.

Time Analysis

The time records were analyzed to reveal their dispersion to obtain an estimate of the mean time required to perform each examination block. These blocks were considered to be the modules relevant for calculation and anticipation of feasible schedules and for realistic budgeting of staff needed for follow-up examinations.

In a second step, the possible systematic effects on the dependent variable—the recorded time—were investigated. Such effects should be filtered from random variation or bias caused by undetectable or unspecific influences such as the daily personal disposition of the examiner and the patient, interruptions during an



Fig 1a Times recorded for dental status examination.

examination block (eg, dental students asking a question), or other events (eg, ringing of the phone). This analysis is concentrated on variables of influence close at hand, as characterized by questions such as:

- What is the influence of the complexity of the dental status? The independent variable complexity was determined by the number of findings that had to be documented for the dental status, eg, defects, restorations, missing/replaced teeth, root fillings: 0 (simple status) = no findings up to 8 in the entire dentition; 1 (average status) = 9 to 16 findings; and 2 (complex status) = more than 16 findings.
- 2. Is there a difference in mean CDA examination times per unit by (1) the mere number of units under observation (learning or fatigue effects); and (2) the cementation mode (ie, conventional cementation or adhesive luting)? For detecting potential learning or fatigue effects, the mean CDA time was calculated by dividing the recorded CDA time by the number of all examined units (ie, the number of abutment teeth being restored) and displayed against the number of units per patient. The influence of the cementation mode was simply evaluated by comparing the mean CDA times per unit by grouping the patients accordingly.
- 3. Is there an influence of the clinical quality of the restorations on the time required for CDA ranking? The independent variable "clinical quality" was indicated by the mean number of deficiencies (CDA ratings other than excellent, A) and adverse events per observed restoration of one examination: the event ratio.

The evaluations were made graphically; only main effects should be considered.



Fig 1b Times recorded for oral hygiene status determination.

Results

In 42 clinical examinations on 41 patients with fixed prosthodontics, the time to record the dental status ranged from 3.5 to 17.0 minutes. Most of the dental status records required a net examination time of about 5 to 10 minutes (Fig 1a). A considerable part of the widespread variation was related to the complexity of the dental situation of the patient. Accordingly, simple situations required approximately 5 minutes on average, whereas complex situations that had to be described by many findings (more than 16) in the dentition entailed about 50% more time for a complete record: approximately 7.5 minutes on average. The patient contact for recording the hygiene status yielded durations of mainly between 5 and 10 minutes (Fig 1b). The overall variation was smaller than that for recording the dental status. With one exception, only examinations including the API, pocket depth measurements, and PBI took more than 8 minutes. A complete recording of dental and hygiene status required a net patient contact (total status time) of 10 to 20 minutes on the whole, with a mean of 14 minutes (Table 2).

The detailed clinical quality assessment of the dental restorations required times (CDA time) from about 1 to 24 minutes, strongly dependent on the number of restorations examined in the patient. The data indicated a mean time need of about 1 minute per restoration (per restored tooth as the actual unit of observation) as a useful approximation. This empirical approximation seemed to be independent of the overall number of units examined in one patient, as an approximated value of 1 minute was almost constant for all numbers of restored teeth under observation: The exact mean values per unit varied in the range of 0.6 to 2.5 minutes, with a median (= mean) of 1.2 minutes (interquartile range 1.0 to 1.3 minutes, standard deviation 0.3). However, no clear tendencies were detectable, as the

Recording	Mean	Standard deviation	Total range
Dental status time	7.0	2.5	3.5-17.0
Hygiene status time	7.0	2.0	4.0-11.0
Total status time	14.0	2.8	10.0-22.0
CDA time	8.8	5.1	1.0-24.0
Net contact time	22.8	6.0	11.0-40.0
Documentation time	25.1	7.5	12.5-38.0
Total time	48.0	9.9	25.5-66.0

 Table 2
 Results of the Time Recording (min)

CDA = California Dental Association.





Fig 2a (*left*) Times calculated for net patient contact recorded during dental status plus hygiene status plus CDA ranking determination (see Table 1).

Fig 2b (below left) Recorded documentation times.

Fig 2c (below) Total times calculated.



confidence intervals of the arithmetic means were at the most overlapping among the number of units per patient. Comparatively, a certain dependence of the mean time per unit on the event ratio could be detected by linear fit, suggesting an increase of about 12 seconds per additional adverse finding per observation unit. The cementation mode seemed to have an influence on the time required for the CDA ranking.

The resulting total net contact times on the patients yielded durations of mainly 15 to 30 minutes (Fig 2a). The times recorded for the documentation procedures of the data could be described as statistically similar to that calculated for collecting the data completely (Table 2 and Figs 2a and 2b). In the case of patients attending their first follow-up visit, the investigator had to search the whole general dental record for data such as insertion dates, possible failures, or adverse events during dental treatment; then label it; and finally enter the data into the basic database. This required 5 to 10 minutes more than the documentation of patients who had already been examined at least once during follow-up.

So far, the majority of the protocoled follow-up visits in the above-mentioned clinical studies required total times of 30 to 60 minutes (Table 2 and Fig 2c) to examine the patient, record and document this data, and provide retrievability of the documentation.

Discussion

This evaluation yielded empirical estimates for net examination times on patients to establish a base for

better cost data, which are needed for more realistic timetables and respective calculations for study personnel conducting follow-ups.^{7(p 47)} Moreover, such schedules might even enhance establishment of a structured and feasible observation strategy.

Considering activities needed to provide general dental care, exchange information, and make social conversation with the patient, it seemed inappropriate to consider single minutes or seconds. Therefore, the data distributions were illustrated as histograms labeled with 5-minute increments. According to that arbitrary categorization, the data indicated that a net time of about 5 minutes of patient contact might be sufficient to record a simple dental status. In comparison, recording a complex situation entailed a duration of about 10 minutes, or one additional 5-minute block. The consideration in blocks of 5 minutes has simultaneously been a cut-off (effect) for those aspects of variation that might be mainly caused by undetectable bias, such as the personal disposition of the investigator and the patient, or time spent for social conversation as a "nuisance" variable. However, the extent and variation of the empirically found examination times, which were often not merely explicable by the dental situation itself, might have considerable impact on the costs to be budgeted for staff. Consequently, enough time should be scheduled for "buffering" serial examinations in clinical investigations.

The time needed for recording hygiene status was obviously less affected by the complexity than was the time needed for recording dental status. To read hygiene indicators is almost the same regardless of a tooth's restoration status. In the case of recording pocket depths and bleeding on probing, 4 to 8 minutes (one or two 5-minute blocks) might be sufficient. If API is included as a third indicator, a net time of at least 10 minutes—two 5-minute blocks—should be foreseen/ scheduled. Pocket depths and bleeding on probing required only one clinical intervention for both records (pocket probing), whereas the full regimen of PBI, pocket depths, and API (in this order) required three interventions, one for each record.

This illustrates the impact of actually needed contact times on the observation strategy. So far, an important question for investigation planning must be: Which indicators are essential for data collection and clinical decision making with respect to the predefined objective?

Follow-up examinations limited to dental and oral hygiene status seemed to be an issue not of 5 to 10 minutes, but rather of 15 to 20 minutes, including the inevitable social aspects that are important for patient motivation and compliance with the aims of a study. Both are crucial for lowering the loss to follow-up over the years.^{7(p 160)}

The calculation of the examination time needed for single restoration assessment must be based on the number of units under observation. The approximation of 1 minute per unit seemed reasonable here. According to the plausible influence of the event ratio, patients who have been restored years ago should be calculated with a time buffer of 1 additional minute per 4 or 5 restored units. For patients with a mid-range number of restorations (2 to 3 units per quadrant; the mean value in this investigation was 8 units in total), 10 minutes might be manageable. No learning or fatigue effects have been detected with increasing numbers of units; nevertheless, such effects might be present, but because of the limited amount of data, the observed time variation could not be reduced to them.

The clinical assessment of conventionally cemented restorations took less time than that of adhesively luted restorations. A possible explanation is that adhesively luted (multifacial) all-ceramic inlays and veneers tend to have complex and extended margin courses that have to be completely inspected for gaps, secondary caries, and marginal discolorations. In comparison, many conventionally cemented crowns and fixed partial dentures have subgingival margins. In those cases, the CDA criterion "marginal discoloration" was assessed as "not viewable" by definition. In the latter cases, the modified CDA ranking could be completed faster, since it was reduced by 25%, one of four criteria. In addition, adhesively luted restorations usually have supragingival margins.

Conclusions

This methodic evaluation surveyed follow-up examinations on the essential kinds of fixed dental restorations. Within its limits, the following conclusions were drawn with respect to study management and budgeting:

- A dental status determination including tooth sensibility and tooth percussion requires about 5 to 10 minutes (for simple vs complex dental situations). The hygiene status records require in general similar or slightly less time.
- For assessing the clinical quality of fixed dental restorations, 1 minute per restored tooth seems to be realistic and sufficient.
- Because of the observed variations that can be neither foreseen nor explained simply by the dental situation, clinical investigators should consider time buffers suitable for the examination schedule.
- Approximately the same time will be required for completion of the documentation as for the complete clinical examination of a patient.

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Literature Abstract

Biomechanical comparison of straight and staggered implant placement configurations

Buccal and lingual offset was proposed to be an effective way to reduce potential risk of overloading posterior partial implant-supported prostheses. This study photoelastically compared the stresses generated by a staggered implant configuration with those generated by implants placed in a straight line. The implants were placed in two life-size photoelastic models of an adult human left mandible. The implants were placed in a straight configuration line in one model and in a buccolingual staggered configuration in the other. For the staggered configuration scheme, the anterior and posterior implants were located 1.5 mm lingually. In the straight-line configuration, the middle implant was located 1.5 mm buccally. Restorations were screwed on the abutments with gold retaining screws. Simulated vertical and lateral functional loads were applied to the prostheses at a fixed location. The stress patterns that developed under subsequent load were attributed to the applied load and were recorded photographically. The result showed that higher stresses were developed around the middle implant in the staggered placement configuration for vertical loading; and the anterior and posterior implants with the straight configuration under lateral loading condition. The staggered placement changed stress distribution, but did not provide overall improved stress conditions. The authors concluded that both the straight and staggered placement configurations, with carefully designed occlusion, could be employed clinically, providing sufficient bone is present.

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