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NOCTURNAL PENILE TUMESCENCE AND RIGIDITY IN MEN WITHOUT COMPLAINTS OF ERECTILE DYSFUNCTION USING A NEW QUANTITATIVE ANALYSIS SOFTWARE

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ABSTRACT

Nocturnal penile tumescence and rigidity data were collected during 3 successive nights of home monitoring from 44 men screened for normal sexual functioning. The subjects were well distributed during the interval with an age of 31 to 81 years. Penile brachial indexes, biothesiometry measures and testosterone levels were evaluated. Two new time-intensity measures of tumescence (tumescence activity units) and rigidity (rigidity activity units) were used to summarize erectile activity. A high correlation ($r > 0.84$, $p < 0.001$) was found between these summary parameters. It was observed that at least 2 nights of monitoring were required to characterize a subject adequately because some men had single nights with no measurable erectile activity. There were low correlations among penile brachial index, biothesiometry and testosterone outcomes, and nocturnal penile tumescence and rigidity measurements. There was a decrease in measurements of tip rigidity with increasing subject age ($r = -0.238$, $p < 0.05$) and an increase in tip rigidity associated with penile girth during erectile events ($r = 0.505$, $p < 0.001$). Cumulative distributions of rigidity and tumescence activity units were developed to permit a simple, direct comparison of other nocturnal penile tumescence and rigidity findings to results in the study population.

KEY WORDS: penile erection, impotence, software

The role of nocturnal penile tumescence monitoring in helping to distinguish psychogenic from organic impotence has been the subject of research for several decades.[1, 2] Although useful, tumescence monitoring alone without information on penile rigidity imposed limitations on the diagnostic inferences that could be drawn concerning the adequacy of erectile function.[3–9] The recognition of the need to consider penile tumescence and rigidity led to the development of sensing and recording techniques that allowed for the simultaneous monitoring of both of these dynamic characteristics of erections.

The use of nocturnal penile tumescence and rigidity monitoring added another dimension to the evaluation of erectile dysfunction.[10–12] Functional impotence with normal nocturnal tumescence could then be explained when nocturnal rigidity information was incorporated in the diagnosis. Furthermore, it became possible to document more subtle cases, such as patients in whom there was a dissociation of penile base and tip rigidity during nocturnal monitoring.[10, 12] When a quantification of the level of rigidity was added to information about the interval during which nocturnal erections occurred, erectile events could then be described and categorized.

To estimate the use of nocturnal penile tumescence and rigidity testing, the results should first be evaluated in terms of the ability to distinguish men with and without erectile dysfunction. Among men with dysfunction, it should further provide useful information to identify those with organic precursors from those with psychogenic disorders. Since the etiologies of dysfunction are often complex, and impotent men frequently exhibit combinations of organic and psychogenic causes, the contribution of nocturnal penile tumescence and rigidity testing to unraveling the issues in dysfunction is yet to be fully understood. Our study had 2 primary objectives: 1) to develop additional normative nocturnal penile tumescence and rigidity data on men without complaints of erectile dysfunction and 2) to determine the level of variability in results that could be expected in this population. Related to these objectives was evaluating the impact of aging on nocturnal penile tumescence and rigidity results.

MATERIALS AND METHODS

Subjects. Volunteers 31 to 81 years old were recruited for participation in the study (table 1). The study was approved by our Institutional Review Board and all subjects signed an informed consent form before enrollment. Subjects were recruited from men reporting to the medical center for medical conditions unrelated to sexual function or from men responding to an advertisement. Participants were selected from men who were in good general health, had no history of erectile dysfunction and, by self-reporting, were sexually active during the last year (that is successful sexual intercourse at least once a month). Medical histories of the 44 men who participated in the study included coronary artery disease in 3, hypertension in 11, chronic obstructive pulmonary disease in 1, transient ischemic attack in 1, renal failure with successful renal transplantation in 1, abdominal aneurysm repair in 1 and prostatectomy in 2.

Histories. Medical and sexual histories were obtained from all volunteers before enrollment. General vascular and neurological health, urological function, and use of medications alcohol and tobacco were all examined.

Home monitoring. Nocturnal penile tumescence and rigidity were evaluated with a commercially available home monitor. The RigiScan* monitor has been used in several previous studies of erectile function and has been described previously.[10–14] After a demonstration of the device in the office, the study subjects were instructed to take the un

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* Dacomed Corp., Minneapolis, Minnesota.

TABLE 1. *Patient histories (mean ± standard deviation)*

	Decade of Pt. Age (yrs.)				
	31–40	41–50	51–60	61–70	71–
No. subjects	5	11	9	8	9
Av. age in interval	35.8 ± 3.8	44.5 ± 3.0	56.9 ± 2.9	65.6 ± 2.8	75.4 ± 4.0
Frequency of intercourse/mo.	5.4 ± 2.4	10.1 ± 7.4	8.2 ± 8.9	5.1 ± 4.9	2.9 ± 1.5
Intercourse success rate (%)	100.0 ± 0.0	99.9 ± 0.3	88.8 ± 18.1	97.0 ± 6.7	93.4 ± 8.5
Frequency of intercourse at peak/mo.	14.0 ± 9.0	12.7 ± 9.5	14.0 ± 13.7	16.1 ± 17.6	5.0 ± 2.6
Intercourse success rate at peak (%)	100.0 ± 0.0	99.9 ± 0.3	88.8 ± 18.1	97.0 ± 6.7	95.0 ± 7.1

home and use it on 3 successive nights to monitor penile activity. They were instructed to take no sedatives or sleeping pills, not to drink beverages containing alcohol or caffeine, and to refrain from sexual activity until the completion of data gathering.

After home monitoring, data stored in the RigiScan device were transferred to disk, printed in graphic form and analyzed with a new version of RigiScan Summary Analysis software provided by the manufacturer. The software is used to scan the graphic data, and convert and display rigidity and tumescence information in numeric form to provide a quantitative analysis of the data. The software recognizes erectile activity as an event if there has been a 20% increase in base loop circumference persisting for at least 3 minutes. Short duration erectile events (that is less than 3 minutes) would be displayed on the graphic printout but would not be counted by the software. The software used in this study (Version 3.00) identifies erectile events in a somewhat different manner than the previously released versions and contains additional statistical features not previously available. Summary statistics provided by the software include number of detected events, event durations (cumulative time that tumescence was greater than 20% of baseline tumescence), average tumescence and rigidity readings during events, and integrated time-intensity area measures of tumescence (tumescence activity units) and rigidity (rigidity activity units).

Laboratory tests. Blood samples were drawn from subjects for total testosterone levels. Doppler ultrasound readings were obtained from brachial, right and left penile arteries to calculate penile brachial indexes. Biothesiometry measurements were made on the right and left index fingers, right and left penile mid shaft areas, and glans penis.

Statistical methods. Standard statistical techniques were used to summarize and analyze study results. When descriptive statistics are used, such as sample means, the associated population standard deviations are also given. Tests of differences between sample means were done using Student's t tests or by performing a 1-way analysis of variance (fixed effects). Components of variance in RigiScan readings were estimated using random effects analysis of variance. Correlations between study measures were estimated by calculating Pearson product-moment correlation coefficients.[15]

RESULTS

The subject population of 44 men ranged from 31 to 81 years old and were well distributed over the intervening 5 decades (table 1). All subjects had self-reported normal sexual functioning and presented with no history of erectile dysfunction. The reported current frequency of intercourse in the group ranged from 1 to 30 occurrences per month. The highest reported frequency occurred in the 41 to 50-year age group and steadily decreased with subject age. Subjects had a reported successful intercourse rate of at least 88% across all decades. There was no discernible trend in average testosterone levels or Doppler penile brachial indexes in the 5 groups. Biothesiometry values tended to increase with subject age.

Nocturnal penile tumescence and rigidity monitoring was done on 3 successive nights. Of the subjects 28 had analyzable data for the 3 nights, 13 had data for 2 nights and 3 had only 1 night of usable data, for a total of 113 nights or sessions of data. Missing nights (total of 19) resulted from a combination of various technical problems. Collected tumescence and rigidity data from the penile base and tip were processed by the associated RigiScan microcomputer software to obtain graphical representations and statistical summaries.

To facilitate interpretation of the time-rigidity data a new summary parameter, rigidity activity unit, was developed, which represents the product of the minutes spent at a given rigidity level times the rigidity value expressed in decimal form (from 0.00 to 1.00). This product is calculated on a point by point basis during an event (RigiScan rigidity sampling interval is 30 seconds) and summed across the entire event. It is evaluated separately for the penile base and tip, and is equivalent to a standardized measurement of the area bounded by the time-rigidity tracings.

A similar parameter, tumescence activity unit, was also developed for summarizing penile base and tip tumescence results during erectile events. In this case, the durations of an erectile event were multiplied by the percentage increase of the associated event tumescence, expressed in decimal form, over the estimated baseline tumescence level. The resulting tumescence activity units can be interpreted as area measurements of the region bounded by the time-tumescence tracing and the estimated baseline.

Using the summary measures of tumescence and rigidity activity units for the penile base and tip, differences in subject responses between nights of nocturnal penile tumescence and rigidity monitoring were examined for subjects who had 3 complete nights of data. There was a high degree of uniformity of results between nights in mean tumescence and rigidity activity units, and in their variability as measured by the associated standard deviations. With the exception of slightly elevated results for the penile base value on night 1, there were no significant differences between nights on any of the calculated measures (analysis of variance, $p > 0.15$). There was no evidence of any decreased erectile activity, or "first night" effects, on the first session of monitoring. This information indicated that the results of nocturnal penile tumescence and rigidity monitoring can be pooled across nights of observation. The average time spent at different rigidity levels during erectile events was tabulated during the processing of the nocturnal penile tumescence and rigidity data.

The average duration of sleep (table 2) was approximately 7 hours in subjects younger than 71 years, with those older having somewhat longer average sleep periods (analysis of variance, $p = 0.28$, not significant). The number of events per night ranged from 0 to 11. Some subjects had single night data that showed little or no erectile activity. There were 3 to 7 events in 77% of the subject nights monitored. For subjects 31 to 70 years old the average number of events was 3.8 to 5.5 erectile episodes per night (analysis of variance, $p < 0.05$). Patients in the 71 year and older group had significantly more average events per night but the total duration of the associated event times (81.9 minutes) was the lowest of the 5 groups, indicating shorter average event times. Total aver-

TABLE 2. *Comparison of sleep duration, number of erectile events and event duration (mean ± standard deviation)*

	Decade of Pt. Age (yrs.)				
	31–40	41–50	51–60	61–70	71+
No. nights	12	31	25	26	19
Sleep duration (mins.)	428.5 ± 91.4	411.8 ± 54.4	410.8 ± 67.1	426.9 ± 79.6	451.6 ± 57.5
No. erectile events*	5.6 ± 2.2	4.7 ± 1.5	3.7 ± 1.8	4.6 ± 1.9	5.3 ± 3.0
Total event duration (mins.)†	140.1 ± 57.2	132.0 ± 55.6	88.4 ± 47.2	93.6 ± 39.1	81.9 ± 46.9
Event duration/sleep time (%)	32.8 ± 11.6	32.5 ± 14.4	21.0 ± 10.8	21.9 ± 8.7	18.3 ± 11.0

* Analysis of variance test of difference between decades, $p < 0.05$.
† Analysis of variance, $p < 0.001$.

age event duration was significantly greater in the subjects 31 to 50 years old than those in the latter decades (analysis of variance, $p < 0.001$).

For tip rigidity, 63% of the variance associated with individual night rigidity activity units was due to inter-subject differences (37% due to intra-subject measurement). For base rigidity (rigidity activity units) almost identical results were obtained.

Since some of the subjects (15) had prior existing medical conditions (for example, coronary artery disease and hypertension) that might be related to erectile function, a comparison was made of the tumescence and rigidity activity units between those with and without identified conditions. There was no significant difference in tumescence and rigidity activity units between these 2 groups (t test for mean difference, all $p > 0.05$).

The correlation between tumescence and rigidity activity units for the penile base and tip provides an indication of the reproducibility of these parameters as measures of erectile function, and the consistency of the relationship between tumescence and rigidity in this subject population. The relationship between tip tumescence (tumescence activity units) and rigidity (rigidity activity units) shows a high degree of correlation between the 2 parameters. The linear correlation coefficient between the tip tumescence and rigidity activity units ($r = 0.872$) was highly statistically significant ($p < 0.001$). Similar findings were obtained for the relationship between base tumescence and rigidity activity units ($r = 0.879$), base and tip tumescence activity units ($r = 0.837$), and base and tip rigidity activity units ($r = 0.943$), all of which were significant ($p < 0.001$).

Although there is a general downward trend of tip rigidity (rigidity activity units) associated with increasing subject age, there is considerable variability in subject responses. The correlation of tip rigidity activity units to subject age ($r = -0.238$) was significantly different from zero ($p < 0.05$) but its small value is indicative of a weak relationship between subject age and rigidity. Similar trends were also found in the other parameters (tip tumescence activity units and base tumescence and rigidity activity units), which al showed general decreases with subject age but had low cal culated correlations.

A more significant effect was found in the relationshi between the penile size during an erection and the resultan rigidity (fig. 1). The larger the girth of the penis during th event, the larger the associated rigidity finding. The associ ation between the tip rigidity activity units and the tip cir cumference during events had a correlation of $r = 0.50$ ($p < 0.001$) and similar findings were also found for the penil base.

Frequently, evaluations of nocturnal penile tumescenc and rigidity findings have used ad hoc criteria for norma erectile activity.[10, 12, 14] These informal standards sugges that there should be 4 to 6 events during a night of monitor ing, with each event lasting at least 10 minutes and havin an associated rigidity level of 60 to 70% or more. Cumulativ distributions of the frequency of total event times per nigh when rigidity values were greater than 60% are given i figure 2 for the penile base and tip. A subject with 4 to events, each of which lasted 10 minutes at 60% or more o the penile tip, would yield an event time of 40 to 60 minutes which would be between approximately the 40th and 70t percentiles of the study results on the graph. In other words approximately 40% of subject nights would have shorter t tal event times (due to a combination of fewer events, shorte event durations or lower rigidity).

A summary of the tumescence (tumescence activity unit and rigidity (rigidity activity units) findings for the subje population can be found in figure 3. The cumulative distr bution of tumescence and rigidity activity units for the peni base and tip is presented, enabling one to estimate the va ious percentiles associated with any given set of nocturn penile tumescence and rigidity findings. Since the tume cence and rigidity activity units have the same basic unit measure (a unitless fraction multiplied by time in minutes they can be displayed on the same scale. A consistent rel

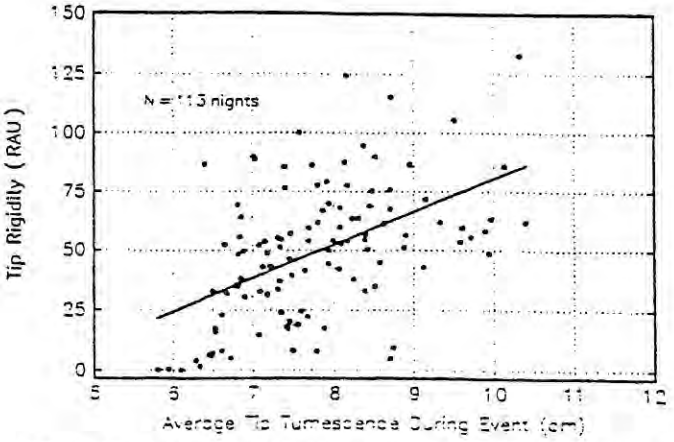

FIG. 1. Tip rigidity in rigidity activity units (*RAU*) versus average event tumescence.

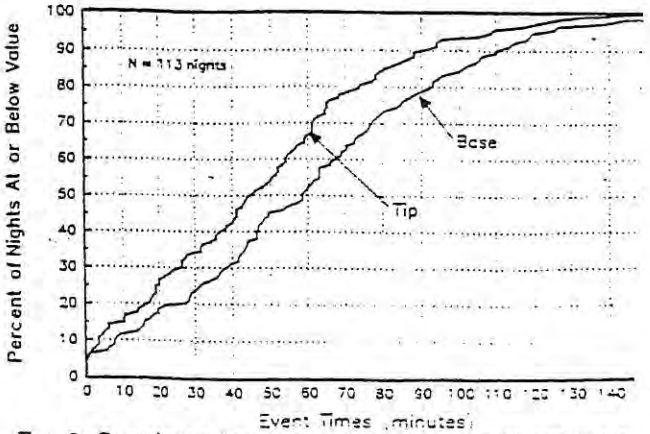

FIG. 2. Cumulative distribution of event times with penile rigi values of more than 60%.

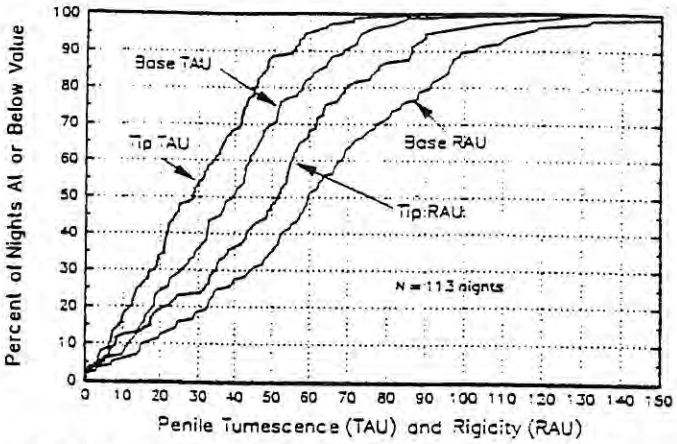

FIG. 3. Cumulative distribution of penile tumescence activity units (*TAU*) and rigidity activity units (*RAU*).

tionship is maintained among the 4 measurements. Base rigidity values as measured by rigidity activity units are consistently higher than associated tip rigidity activity units, and base tumescence activity units are larger than those of the tip. It can be seen, for example, that a subject with a tip rigidity activity unit of 10 is below the 10th percentile of the population results, and 1 with a rigidity activity unit of 90 is at the 95th percentile. For this study population, the tip rigidity activity units can be taken to be approximate estimates of the associated percentile ranking.

The correlations between RigiScan measures (tumescence and rigidity activity units) and laboratory measures were evaluated. In this study population no significant correlations were found between RigiScan measurements and laboratory determinations, nor were there measurable correlations between the laboratory values themselves (all $p > 0.05$).

DISCUSSION

There was a high degree of uniformity in the nocturnal penile tumescence and rigidity results observed in the study population. The consistency of the RigiScan measurements of tumescence and rigidity is a necessary attribute of nocturnal penile tumescence and rigidity monitoring if it is to be used to distinguish normal men from those with erectile dysfunction. Findings from this group of self-selected men, without complaints of sexual dysfunction, represent a larger sample of normative data across a wider age range than has previously been reported.[10, 12–14]

The use of time-intensity area measures of tumescence (tumescence activity units) and rigidity (rigidity activity units) was an effective method of summarizing dynamic nocturnal penile tumescence and rigidity readings into simple, meaningful parameters. This procedure has the effect of emphasizing or weighting periods with high rigidity and damping intervals with low rigidity. The calculation is consistent with the traditional practice of assigning importance to elevated rigidity in interpreting the quality of the erection for performing intercourse. It has the advantage of summarizing for a night the multi-episode, dynamic response (that is factors of frequency, duration and intensity) into a single, summary value. Correlations performed on study subjects indicated that no increase in useful information or discrimination power was obtained by limiting consideration to only rigidity levels of greater than 40%. With these parameters there were general trends of decreased tumescence and rigidity levels with increasing subject age but subject-to-subject differences were large enough to prevent the use of subject age as a significant predictor of erectile function in this population. There were no significant differences in results among the 3 nights of monitoring, indicating that no "first night" effect was present.

Our findings of a significant relationship between subject age and nocturnal erections, as measured by the RigiScan, are consistent with other studies done in normal men. Karacan[16] and Reynolds[17] et al, Schiavi,[18] and Ware and Hirshkowitz[19] examined nocturnal penile tumescence measurements using all night polysomnography in men without sexual dysfunction, and found weak to moderate inverse relationships between subject age and number of erectile episodes, total tumescence time and tumescence time as a proportion of sleep time. Differences by subject age were generally strongest in the older age groups. We found that the number of erectile episodes increased with subject age, whereas the aforementioned studies noted decreased episodes in the older groups. This discrepancy is probably due to the fact that others used a 5-minute minimum criterion for defining an episode, whereas we used a 3-minute cutoff. Since older men have more fragmented sleep, the RigiScan is likely to detect more episodes of brief erections. Reynolds et al found no relationship between subject age and rigidity as measured by buckling pressure and visual estimation.[17] We found a weak, although significant, correlation between tip rigidity as measured by rigidity activity units and subject age.

A perhaps unexpected finding was that the circumference of the tumescent penis was significantly correlated with the rigidity recorded, implying that a penis of greater circumference manifests greater rigidity. This finding may be due to several factors, including physical characteristics of the erect penis and features characteristic of the RigiScan method of determining rigidity.

Although the RigiScan results were consistent, there was considerable variability in individual responses during the 3 nights of monitoring. Previous findings have shown that 15 to 20% of the patients with no identifiable evidence of organic impotence have abnormal nocturnal penile tumescence results.[6] Others have documented the effects of sleep disturbance factors on nocturnal penile tumescence findings.[20, 21] Six of our 44 men had little or no tip rigidity detected on at least 1 of the 3 nights, which demonstrates that 2 or 3 nights are needed to characterize a subject adequately. Evidence of significant erectile activity during a single night, as measured by tumescence and rigidity activity units, may conversely be sufficient to demonstrate the potential for normal functioning.

The most useful results from this study population, for researchers or clinicians who interpret nocturnal penile tumescence and rigidity testing, may be the statistical distributions of tumescence and rigidity activity units, which summarize erectile activity. The tumescence and rigidity activity unit estimates permit a simple characterization of a set of monitoring data. The distributions (fig. 3) can be compared to nocturnal penile tumescence and rigidity results from individuals or groups of patients, for whom the question may be "How normal are these findings?". If results from an individual are available, one can use the distribution in figure 3 to estimate the percentile ranking that 1 night of data would have, compared to this group. If results are available for a group of patients the nocturnal penile tumescence and rigidity data could be similarly summarized as a cumulative frequency display, and statistically tested for equality with the present set of curves.

It is likely that 3 nights of nocturnal penile tumescence and rigidity data for an individual undergoing monitoring would lead to 3 different percentile values, if compared to the curve in figure 3. Therefore, the most helpful strategy in evaluating the nocturnal penile tumescence and rigidity of an impotent man may be to determine the percentile rank of the tip rigidity activity units for the night with the highest RigiScan measurements. For example, an individual may have low

RigiScan measurements for 2 nights but show tip rigidity activity units that fall at the 50th percentile, which would indicate the potential for normal erectile function.

Recently, Sohn et al introduced the "best erection" concept to establish a simple and examiner independent grading system for the entire RigiScan monitoring period.[22] This method addresses the issue of nocturnal erectile capacity for full erection, which may prove to aid in the diagnostic assessment of impotence with further study. On the other hand, our approach offers a more detailed evaluation of 1 or more whole night erectile activity. This format then allows one to compare cumulative data of 1 individual to a range of normative experience (fig. 1) rather than to a set of criteria. By establishing a simple, reliable technique of assessing RigiScan results this test could become a more useful tool in the comprehensive evaluation of individual erectile function. In addition, it may provide a stronger model to use when comparing other clinical investigations of erectile function, such as dynamic pharmaco-cavernosometry and penile duplex sonography.

Our study provides some normative results of nocturnal penile tumescence and rigidity testing in a population who had no objective evidence or subjective complaints of erectile dysfunction. The use of the cumulative distributions of tumescence and rigidity activity units derived in our study provides a convenient way to compare rapidly the percentile ranking of other nocturnal penile tumescence and rigidity readings against this population. Future studies should examine these newly developed measurements of nocturnal penile tumescence and rigidity in a population of men with complaints of erectile dysfunction.

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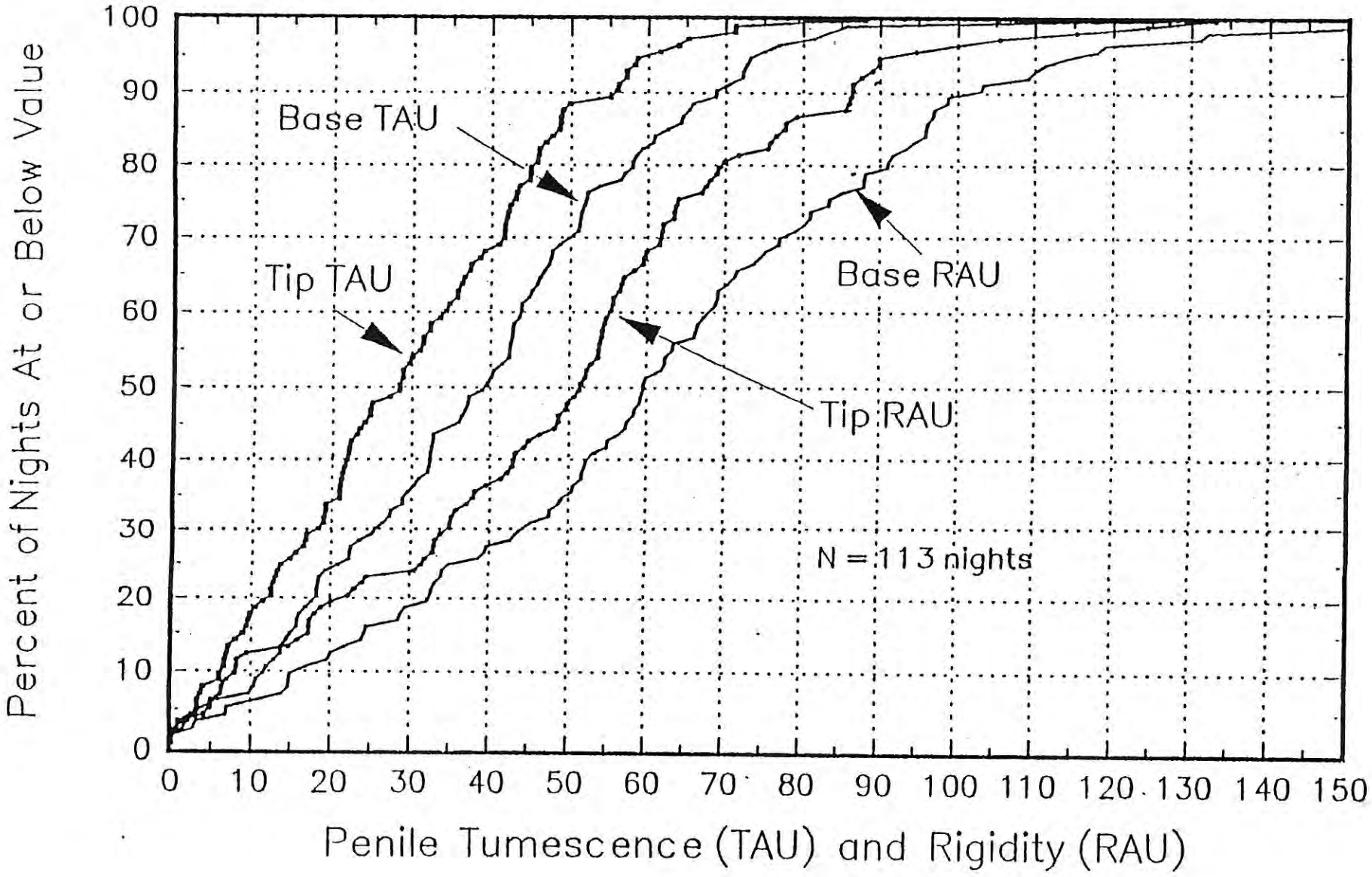
Percent of Nights At or Below Value
100
90
80
70
60
50
40
30
20
10
0
Base TAU
Tip TAU
Base RAU
Tip RAU
N = 113 nights
0 10 20 30 40 50 60 70 80 90 100 110 120 130 140 150
Penile Tumescence (TAU) and Rigidity (RAU)