Phallosan Study

Statistical Report

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Introduction

Phallosan is an orthopaedic stretch belt for penis enlargement which was launched on the market in 1999. Between July 2005 and January 2005 a study of the effectiveness of Phallosan was carried out under the patronage of Professor Dr. Sohn, Chief Physician at the Urological Clinic at the Markus Hospital in Frankfurt am Main. The data was collected by the clinic's Senior Consultant, Dr. Hanikel.

The results of 24 patients from the study were used for evaluation purposes. Two patients were classified as dropouts, but these had no post-baseline measurements and have been excluded from the analyses. They were only included in the analysis of satisfaction levels in the form of a worst-case analysis and classed as dissatisfied. A further 5 patients were marked 'to follow' in the study data and have been excluded (for the time being) from the analysis.

The main purpose of this statistical report is to determine whether a (statistically) significant change in penis girth and length can be identified after using Phallosan for six months. For this purpose, univariate characteristics were calculated for these parameters and t-tests conducted of the significance of the enlargement. An allowance was made for the fact that due to repeated application of the test it was a multiple test problem.

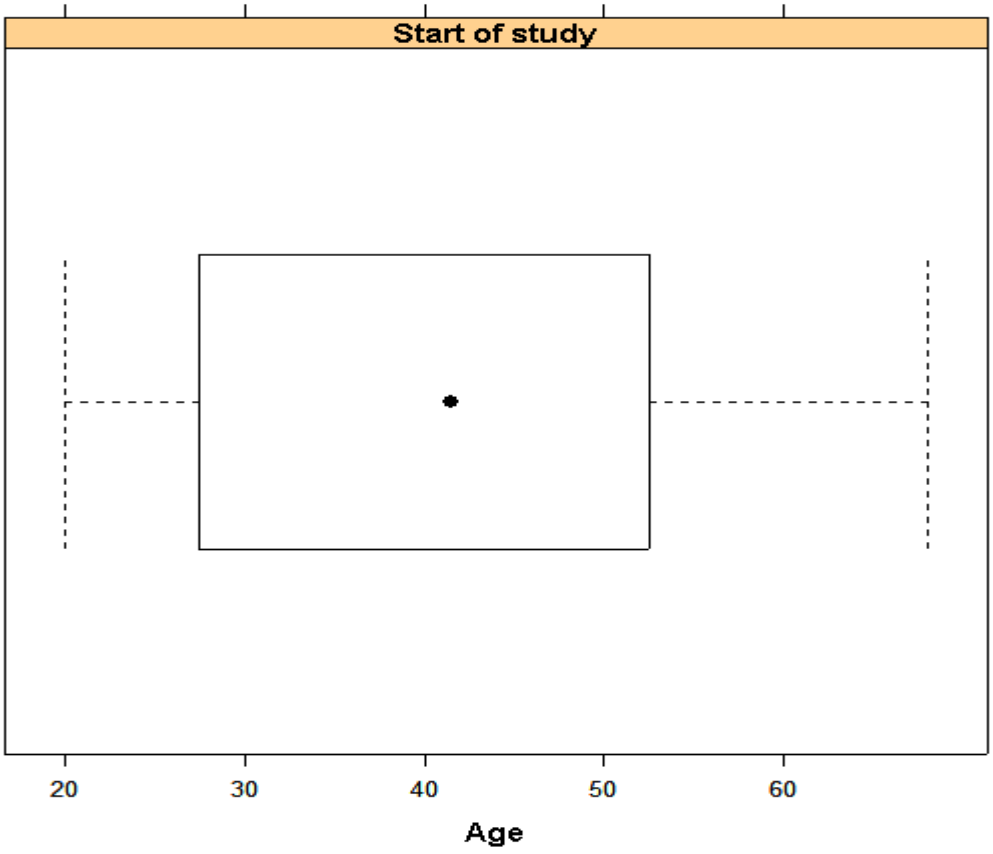
Age of patients

The following table shows univariate characteristics of age distribution of the patients.

Minimum	.25-quantile	Median	Mean	.75-quantile	Maximum	Variance	Standard variation
20.0	27.5	41.5	41.4	52.5	68.0	197.9	14.1

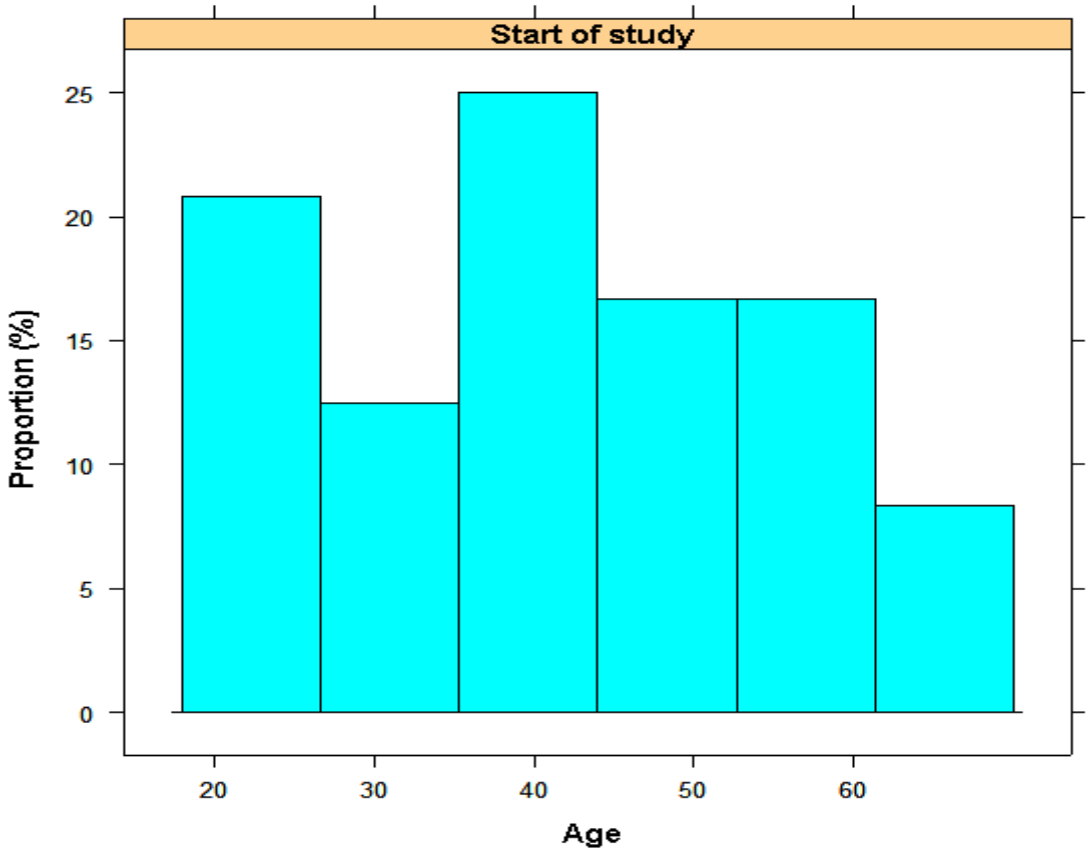
The youngest patient was 20 years old, the oldest 68 years old. The mean and median values of 41.4 and 41.5 closely approximated each other. The following boxplot and histogram show a graphical representation of the distribution.

Figure 1: Boxplot of age[1]



[1] Boxplot of age

Figure 2: Histogram of age[2]



[2] Histogram of age

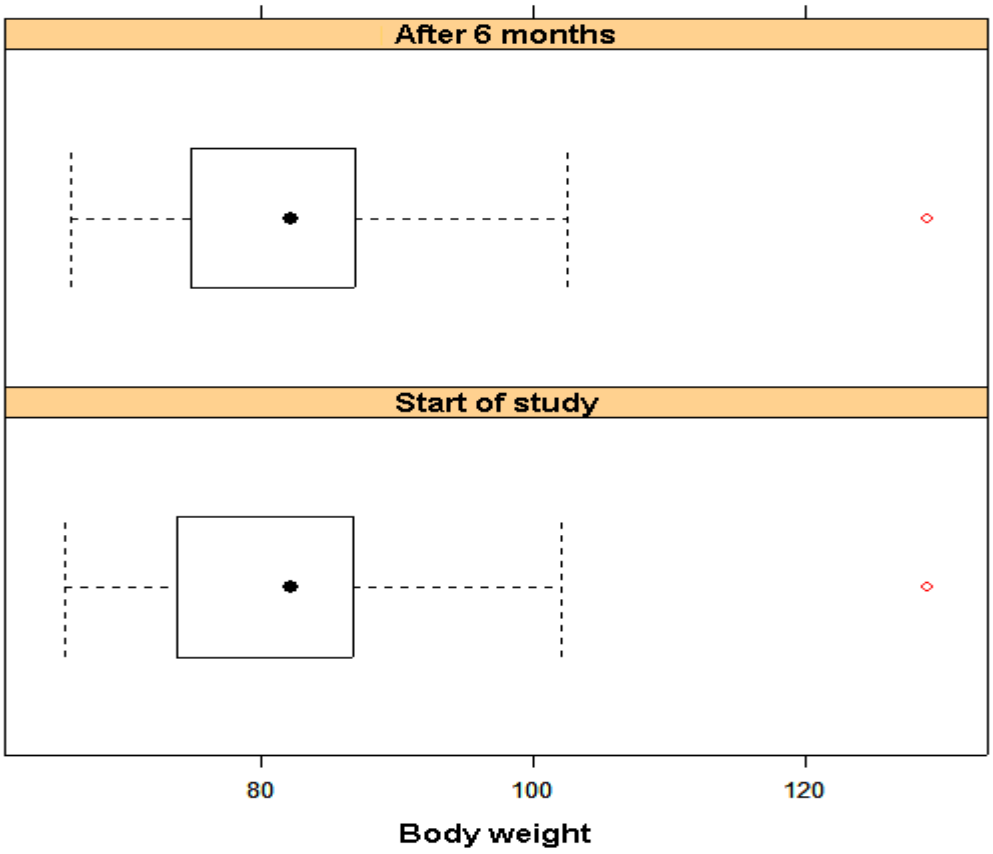
Body weight

The variable body weight was measured at both the start and end of the study.
The following table summarizes the results at the start of study.

	Minimum	.25 quantile	Median	Mean	.75 quantile	Maximum	Variance	Standard variation
Start of study	65.5	73.7	82.2	82.9	86.7	129.0	178.1	13.3
After 6 months	66.0	74.8	82.2	83.6	86.9	129.9	172.8	13.1

Only slight changes in these variables appeared in the course of the study.
The minimum body weight at the start of the study was 65.5 kg, the maximum 129.0 kg. Here again, the mean and median values of 82.9 and 82.2 closely approximated each other. This remained the case at the end of the study, when the mean value was 83.6 kg and median 82.2 kg.
Two patients weighed more than 100 kg. At 129.0 kg Patient No. 17 was significantly heavier than all other patients. This is also clearly recognizable in the following boxplot, in which this patient is classified as a runaway.

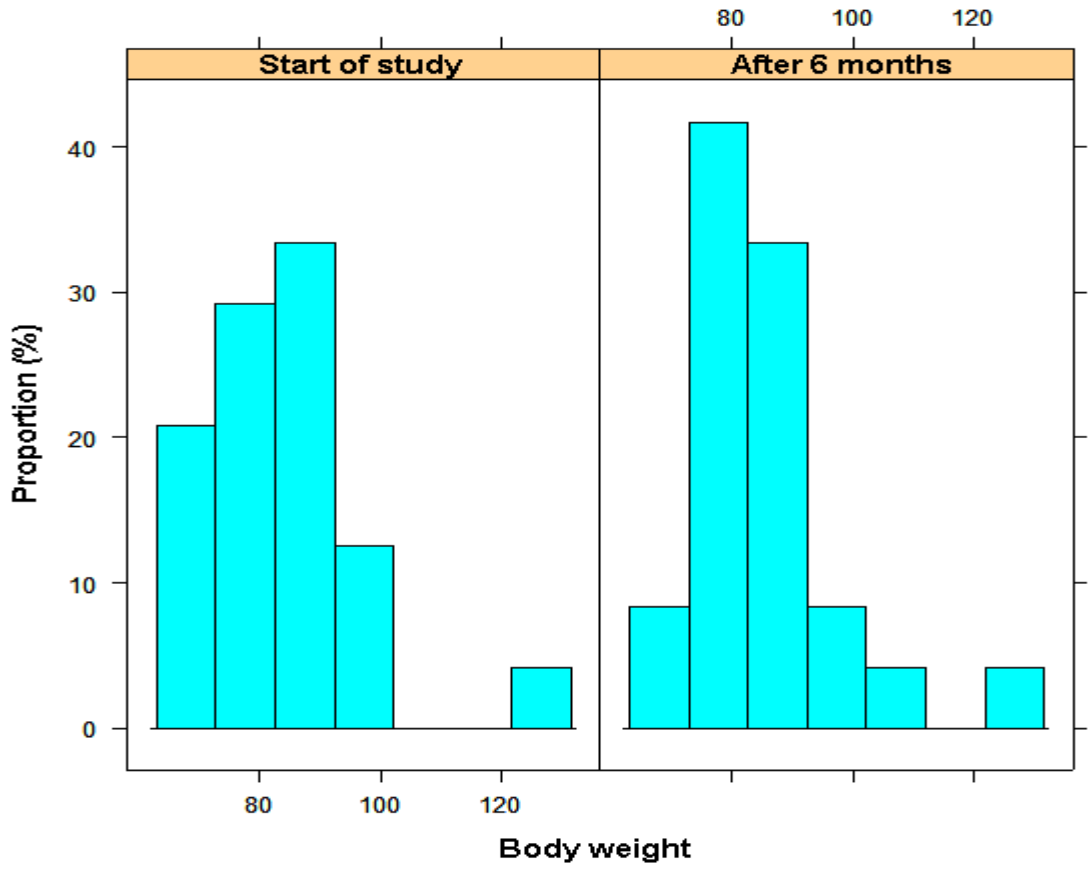
Figure 3: Boxplot of body weight[3]



The histogram also clearly shows Patient No. 17 as a runaway.

[3] Boxplot of body weight

Figure 4: Histogram of body weight[4]



[4] Histogram of body weight

Penis girth

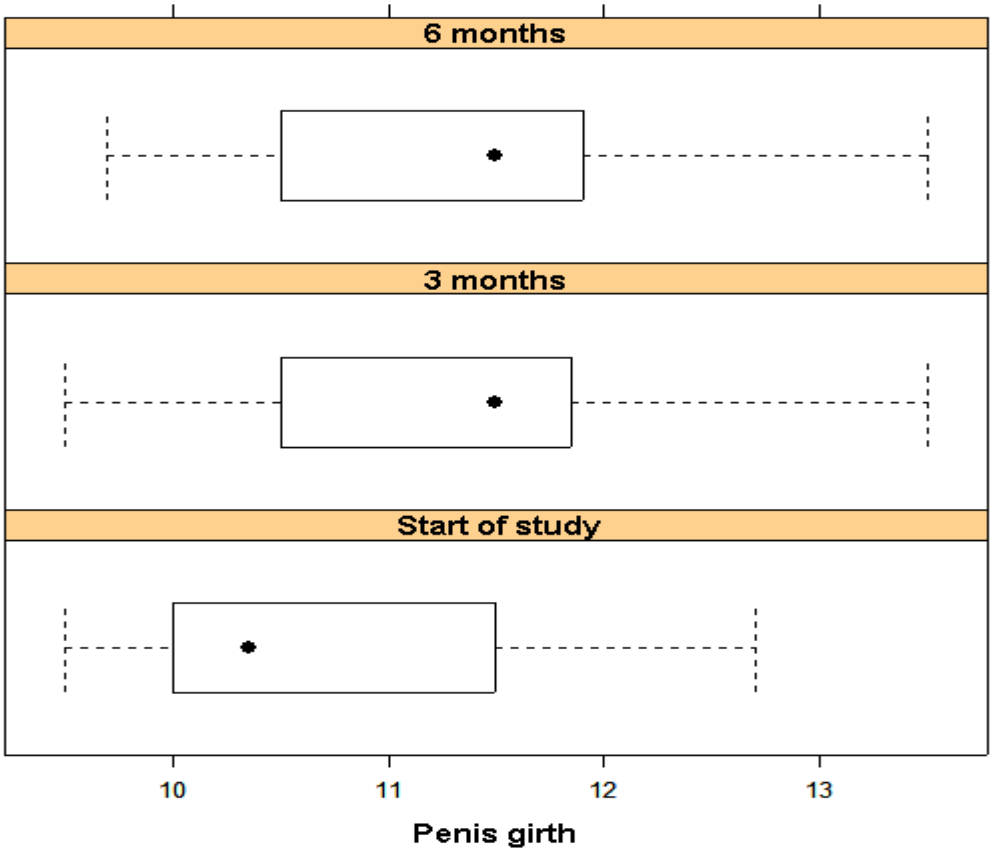
Penis girth was measured three times: at the start of the study, then 3 months and 6 months into the study. The following table shows the univariate characteristics.

	Minimum	.25 quantile	Median	Mean	.75 quantile	Maximum	Variance	Standard variation
Start of study	9.50	10.00	10.40	10.60	11.50	12.70	0.94	0.97
After 3 months	9.50	10.50	11.50	11.30	11.85	13.50	1.14	1.07
After 6 months	9.70	10.50	11.50	11.40	11.90	13.50	1.14	1.07

The minimum penis girth at the start of study was 9.50 cm, the maximum 12.70 cm. The mean was 10.60 cm with a standard variation of slightly less than 1 cm.
After 3 months the minimum size remained at 9.50 cm, but an increase was determined in both the mean at 11.30 cm and the maximum at 13.50 cm.
After 6 months the minimum size at 9.70 cm had somewhat increased compared to previous measurements. The mean was 11.40 cm and the maximum 13.50 cm.

The following figure shows the boxplots in the course of time for penis girth.

Figure 5: Penis girth in the course of time[5]

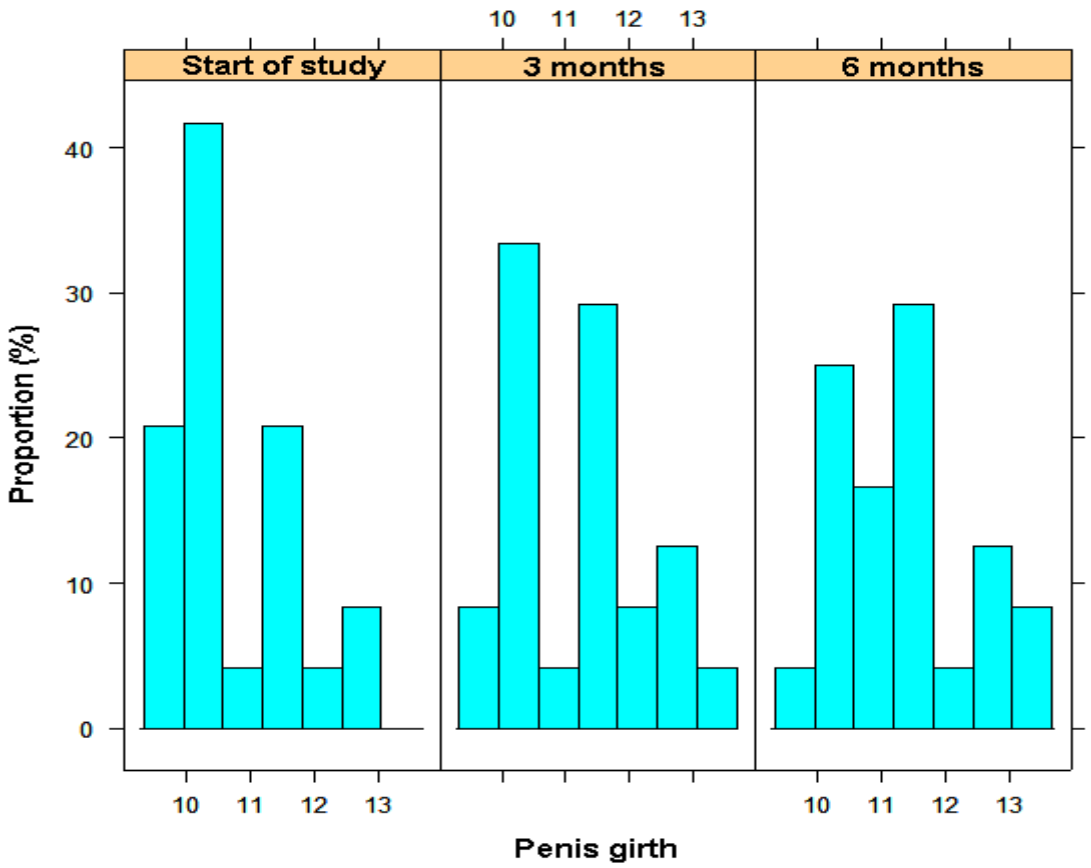


[5] Penis girth in the course of time

As can be seen from the table, the distributions after 3 months and after 6 months are very similar.

The following figure shows the histogram of penis girth at the various points in time.

Figure 6: Histogram of penis girth[6]



The following table shows the change in penis girth after 3 and 6 months.

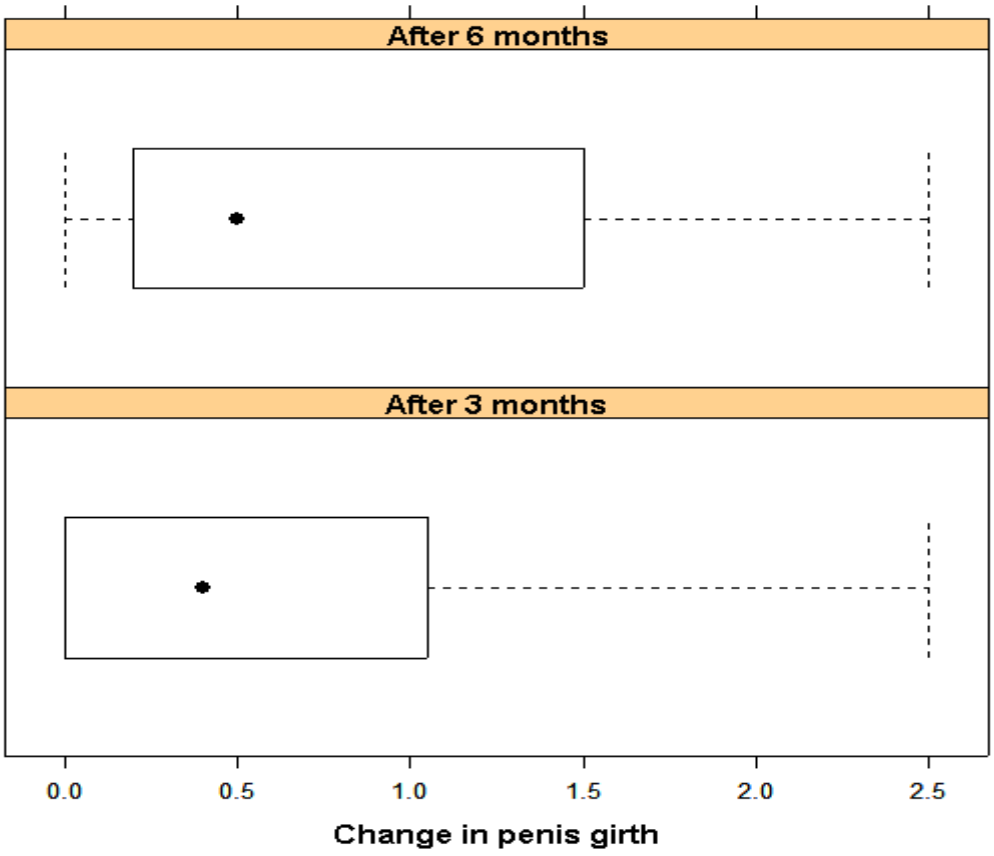
	Minimum	.25 quantile	Median	Mean	.75 quantile	Maximum	Variance	Standard variation
After 3 months	0.00	0.00	0.40	0.64	1.05	2.50	0.56	0.75
After 6 months	0.00	0.20	0.50	0.80	1.50	2.50	0.54	0.73

On average, penis girth increased by 0.64 cm after 3 months and by 0.80 cm after 6 months. The minimum and maximum increases in both cases were 0.00 and 2.50 cm respectively.

The following boxplot shows the changes in penis girth.

[6] Histogram of penis girth

Figure 7: Boxplot of change in penis girth[7]

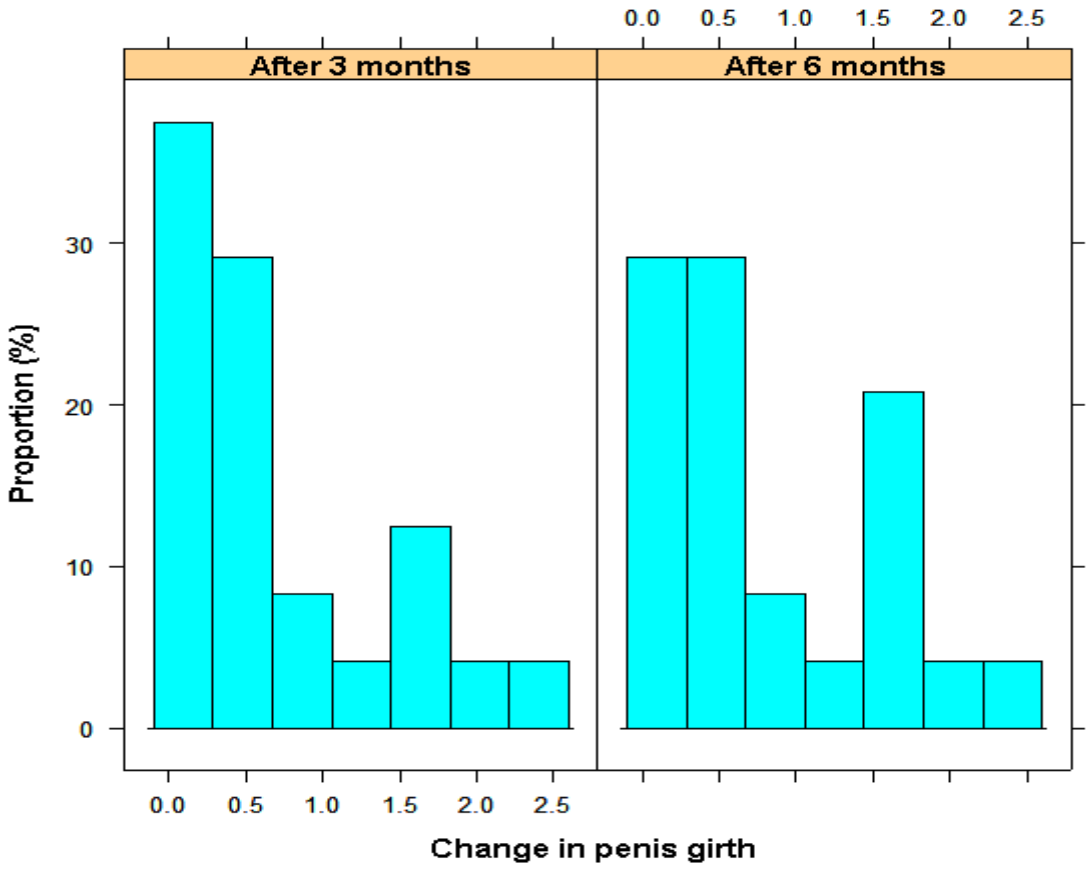


The graph clearly shows the change in the two quartiles, whilst maximum and minimum have remained unchanged.

The last graph is the histogram.

[7] Boxplot of change in penis girth

Figure 8: Histogram of change in penis girth[8]



[8] Histogram of change in penis girth

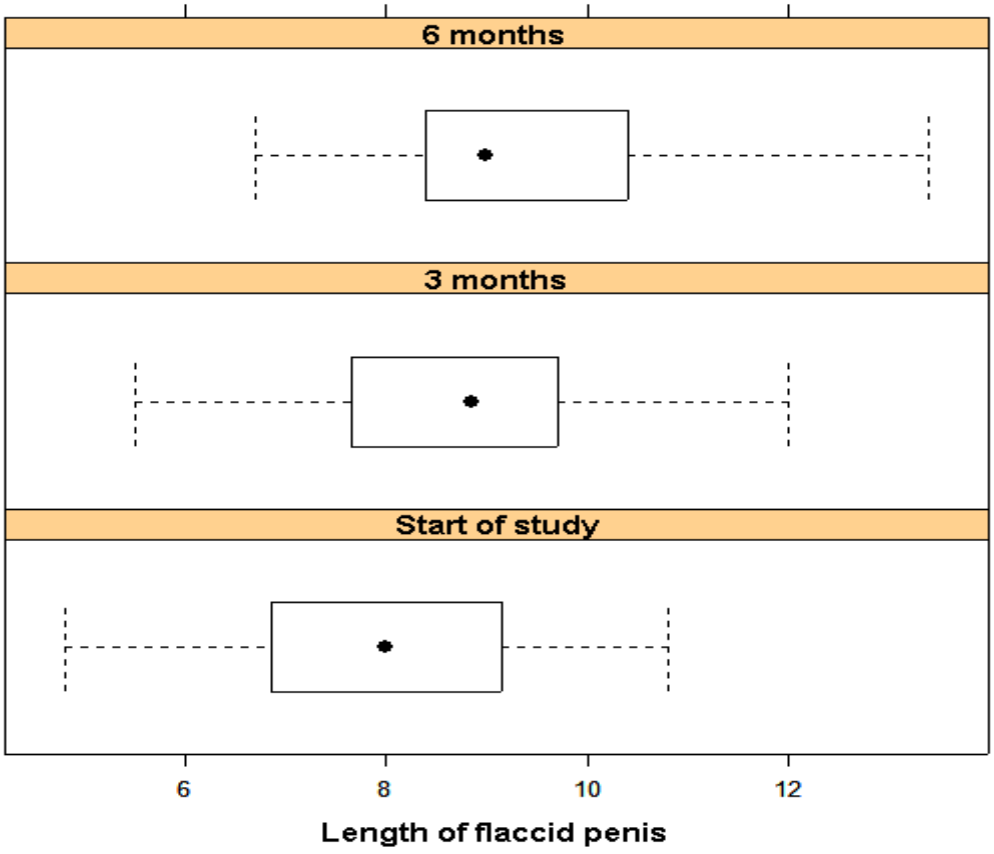
Length of flaccid penis

In this section we examined the length of the flaccid penis. The following table shows the univariate figures at all three examination points.

	Minimum	.25 quantile	Median	Mean	.75 quantile	Maximum	Variance	Standard variation
Start of study	4.80	6.85	8.00	7.90	9.15	10.80	2.61	1.62
After 3 months	5.50	7.65	8.85	8.74	9.70	12.00	2.55	1.60
After 6 months	6.70	8.40	9.00	9.38	10.40	13.40	2.53	1.59

At the outset of the study the mean was 7.90 cm, the minimum 4.80 cm and the maximum 10.80 cm. The mean increased to over 8.74 cm after 3 months and 9.38 cm after 6 months. During this time the standard variation remained virtually constant.

Figure 9: Boxplot of flaccid penis length[9]

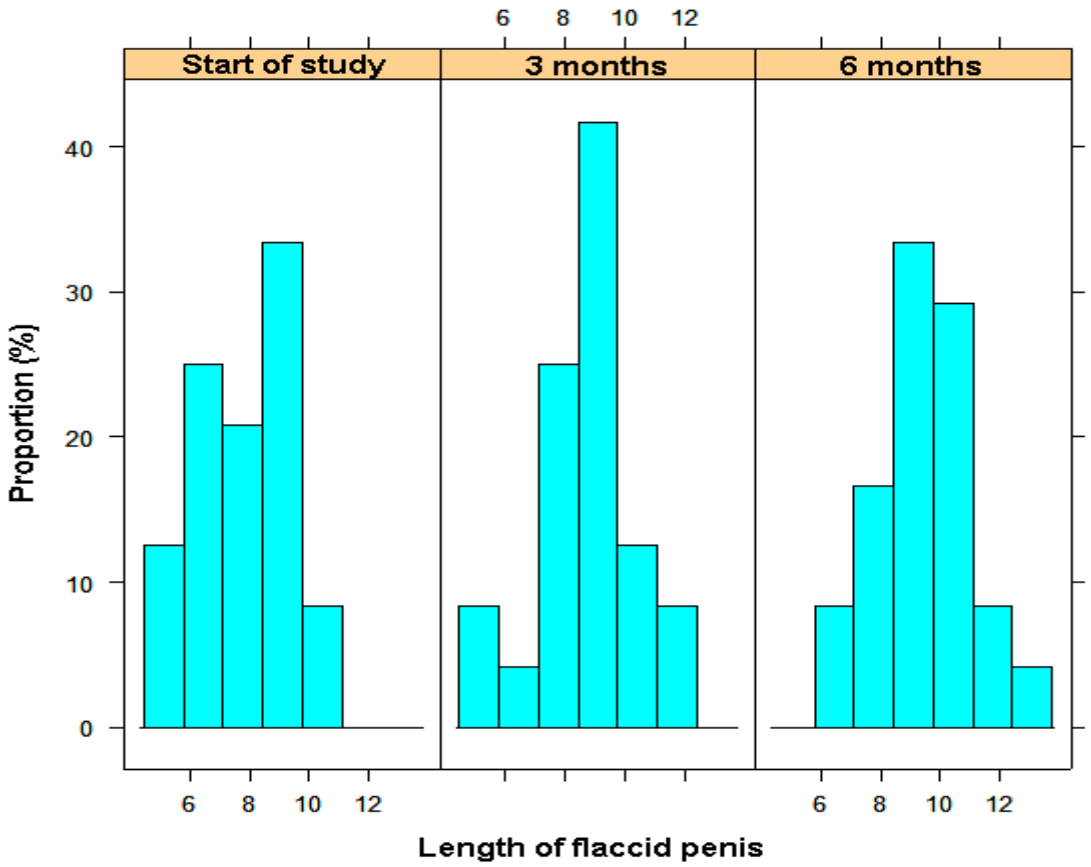


The change in penis length is clearly visible in the boxplot.

Figure 10: Histogram of flaccid penis length[10]

[9] Boxplot of flaccid penis length

Figure 10: Histogram of flaccid penis length[10]



As can be seen in the representation of penis length in the course of time, the penis increased in length over the given period. The following table summarizes the changes at the two points in time.

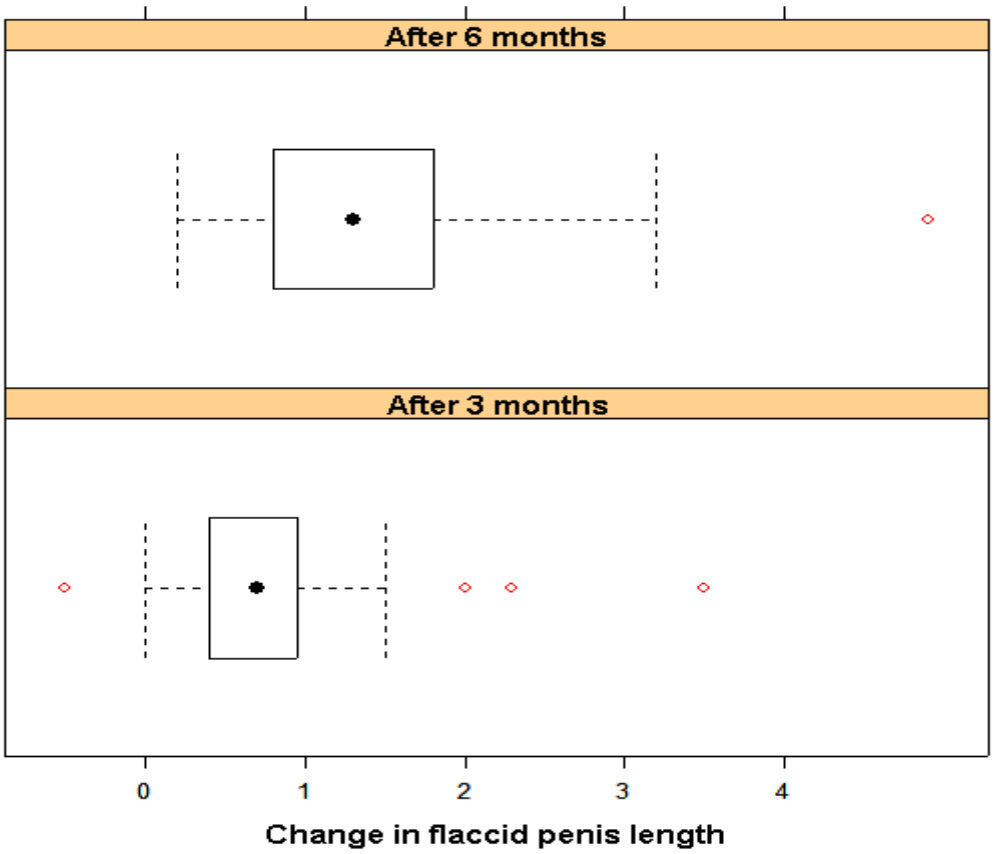
	Minimum	.25 quantile	Median	Mean	.75 quantile	Maximum	Variance	Standard variation
After 3 months	0.00	0.40	0.70	0.83	0.95	3.50	0.70	0.84
After 6 months	0.20	0.85	1.30	1.47	1.80	4.90	1.04	1.02

The mean change after 3 months was 0.83 cm, the maximum was 3.50 cm. After 6 months the mean increased to 1.47 cm and the maximum to 4.90 cm. In both cases the maximum was attributable to Patient No. 26.

The following figure shows the boxplot of change.

[10] Histogram of flaccid penis length

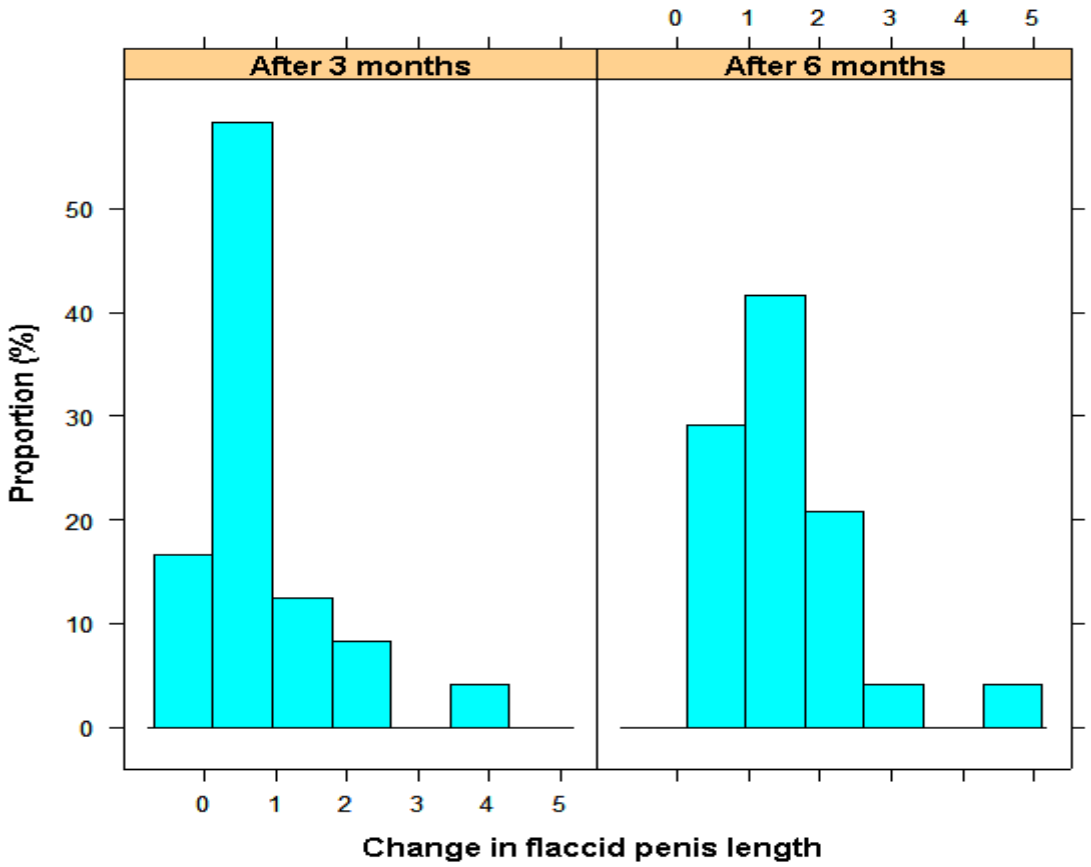
Figure 11: Boxplot of change in flaccid penis length[11]



The increase in length is clearly visible in the boxplots. It is also evident that further lengthening took place after the first 3 months. Due to limited scattering of data in the change after 3 months, four patients were classified as runaways. After 6 months this applied only to the patient with the greatest increase in size.

[11] Boxplot of change in flaccid penis length

Figure 12: Histogram of change of flaccid penis length[12]



[12] Histogram of change of flaccid penis length

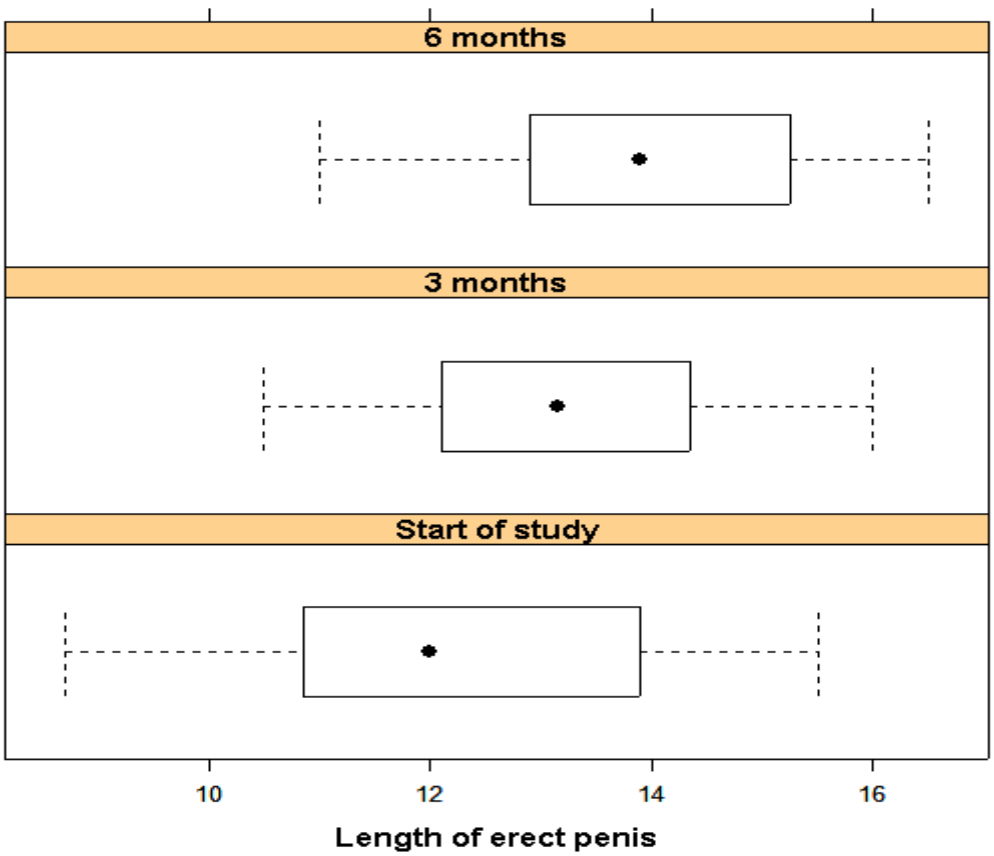
Length of the erect penis

We now turn to the length of the penis when erect. The following table shows the univariate statistics at all three times of measurement.

	Minimum	.25 quantile	Median	Mean	.75 quantile	Maximum	Variance	Standard variation
Start of study	8.70	10.85	12.00	12.30	13.90	15.50	3.11	1.76
After 3 months	10.50	12.10	13.20	13.40	14.35	16.00	2.58	1.61
After 6 months	11.00	12.90	13.90	14.10	15.25	16.50	2.44	1.56

The mean changed in the course of time from 12.30 cm to 13.40 cm and 14.10 cm. There was only a relatively slight change in the maximum (from 15.50 cm at the start of the study to 16.50 cm after 6 months). In contrast, there was a significant change in the minimum value from 8.70 cm to 11.00 cm. This is also shown in the limited variance of data.

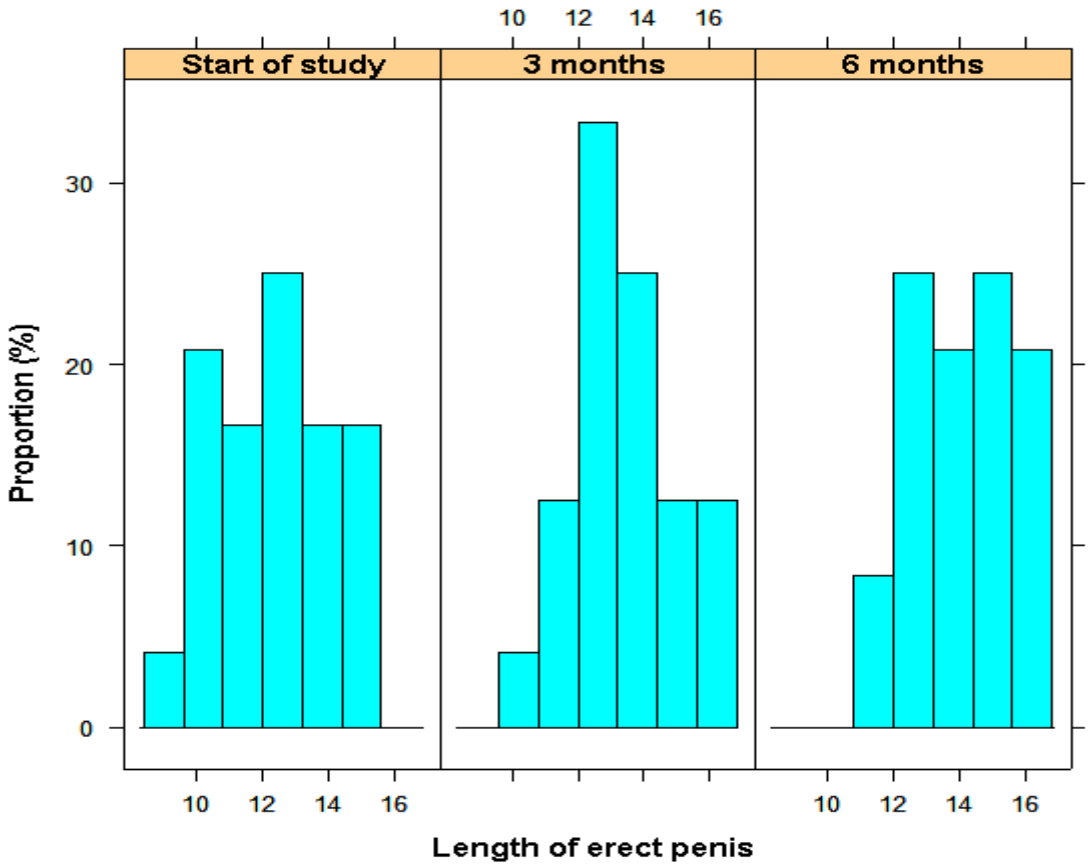
Figure 13: Boxplot of penis length when erect [13]



The boxplot clearly shows the change in penis length over the course of time.

[13] Boxplot of penis length when erect

Figure 14: Histogram of penis length when erect[14]



As can be seen in the representation of penis length in the course of time, the penis increased in length over the given period. The following table summarizes the changes at the two points in time.

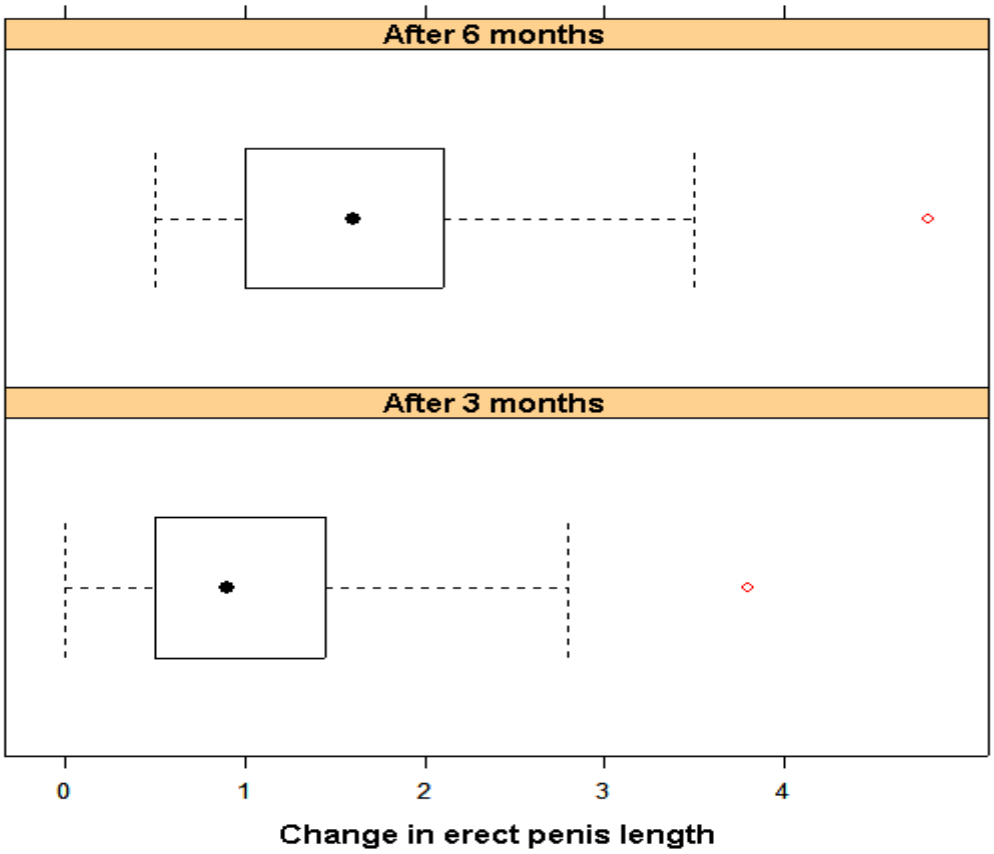
	Minimum	.25 quantile	Median	Mean	.75 quantile	Maximum	Variance	Standard variation
After 3 months	0.00	0.50	0.90	1.05	1.45	3.80	0.81	0.90
After 6 months	0.50	1.00	1.60	1.78	2.10	4.80	1.08	1.04

The mean change after 3 months was 1.05 cm, the maximum 3.80 cm. After 6 months the mean increased to 1.78 cm, the maximum to 4.80 cm. In both cases the maximum was attributable to Patient No. 3.

The following figure shows the boxplot of change.

[14] Histogram of penis length when erect

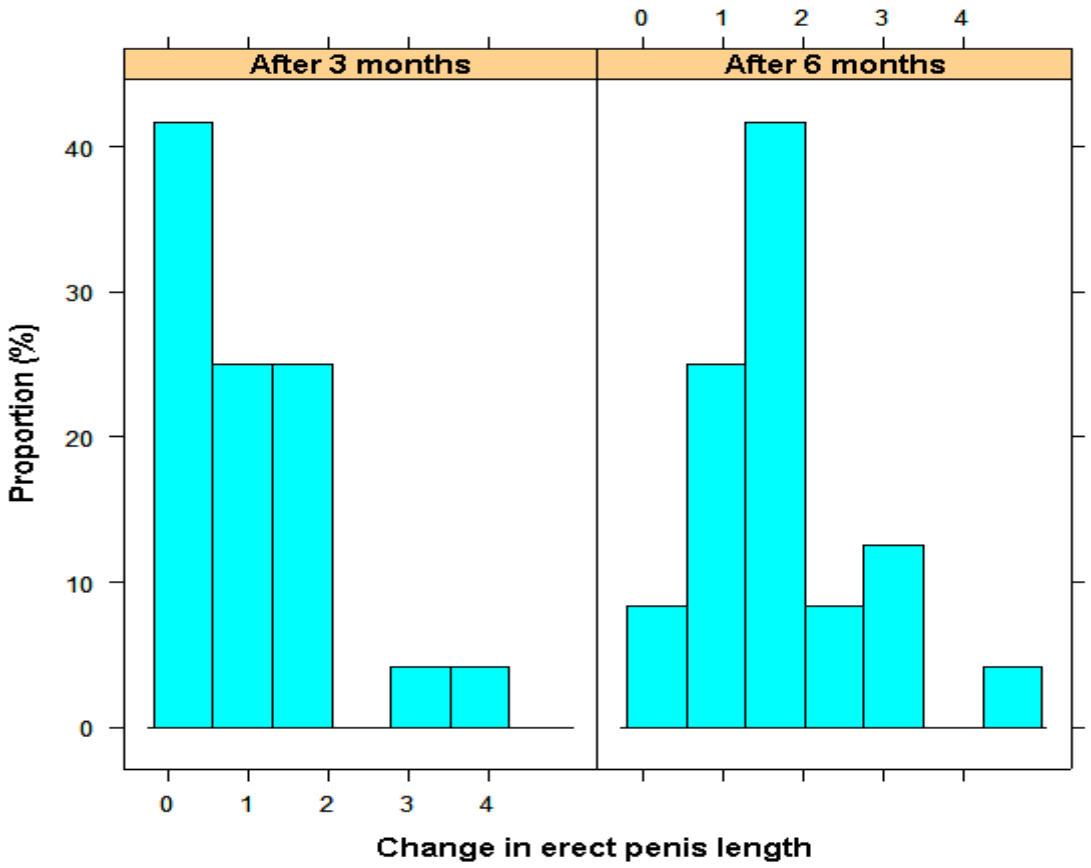
Figure 15: Boxplot of change in erect penis length [15]



The increase in length can be clearly seen in the boxplots. It is also evident that further lengthening takes place after the first 3 months.

[15] Boxplot of change in erect penis length

Figure 16: Histogram of change in erect penis length [16]



[16] Histogram of change in erect penis length

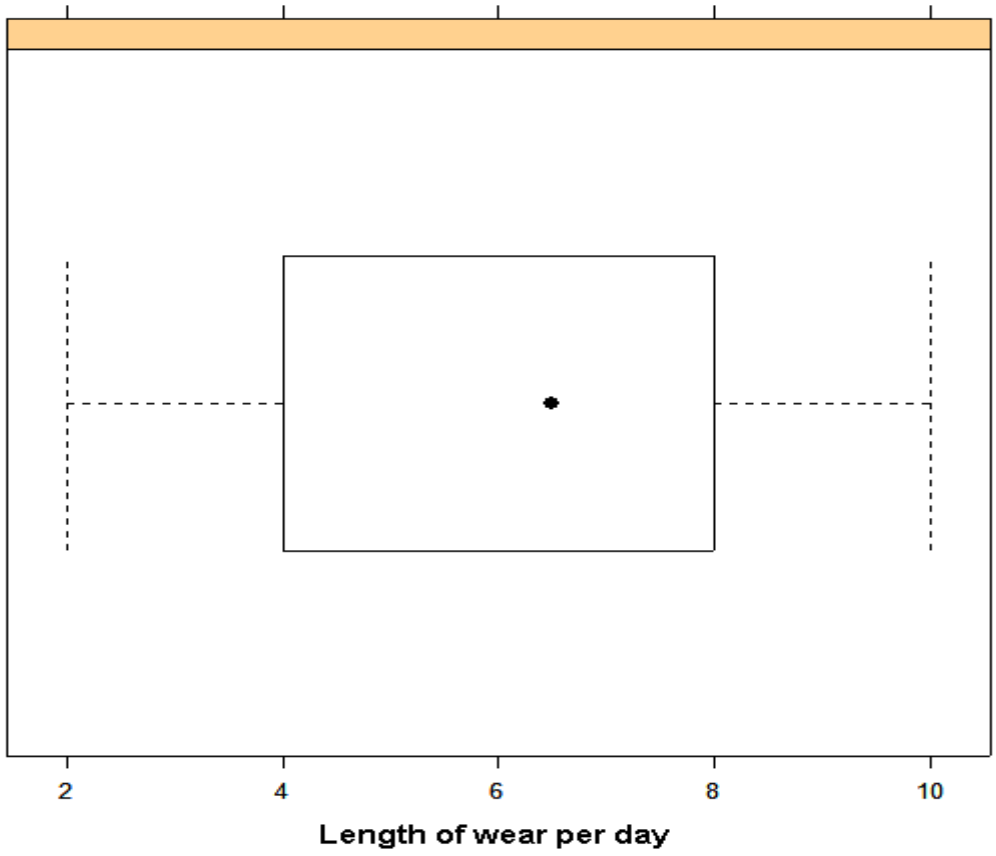
Length of wear

The following table shows univariate characteristics of length of wear per day.

Minimum	.25 quantile	Median	Mean	.75 quantile	Maximum	Variance	Standard variation
2.00	4.00	6.50	6.23	8.00	10.00	5.35	2.31

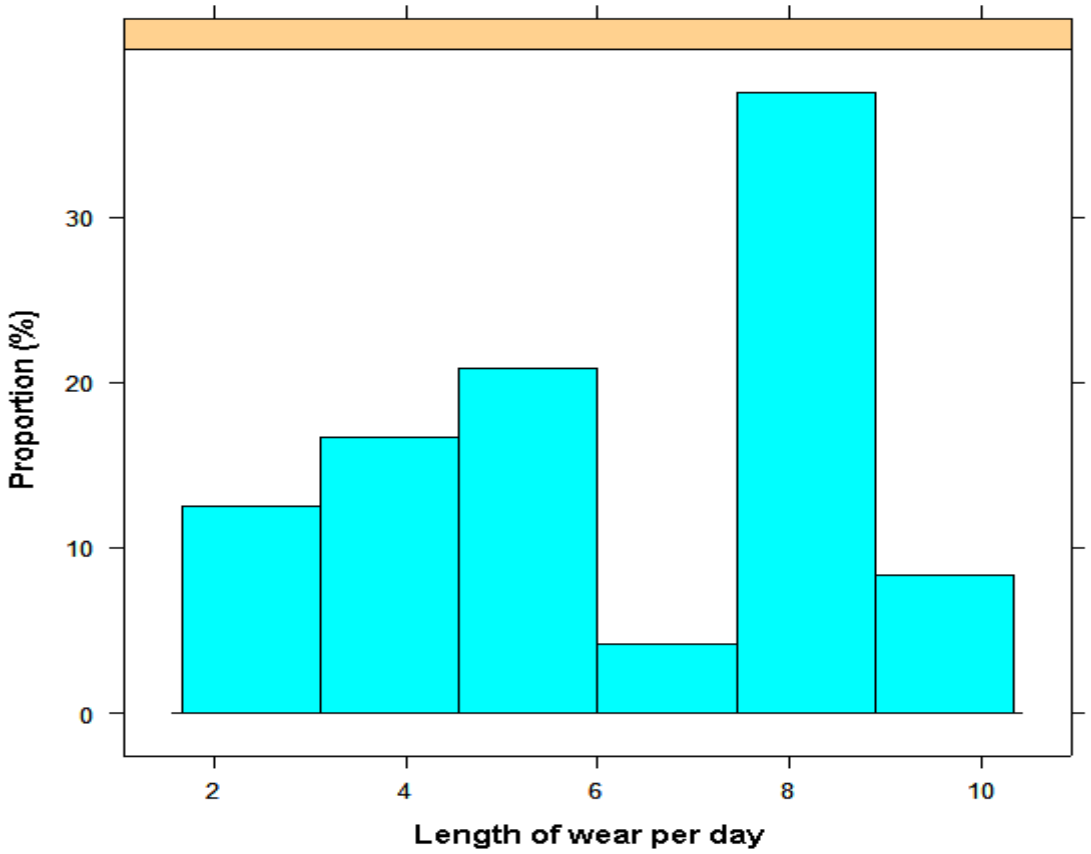
On average, Phallosan was worn for more than 6 hours. The maximum was 10.00 hours, the minimum 2.00 hours.
The following boxplot and histogram contain a graphic representation of distribution.

Figure 17: Boxplot of length of wear[17]



[17] Boxplot of length of wear

Figure 18: Histogram of length of wear [18]



Penis deviation

A value of 60° was determined in one patient at the start of the study. After using Phallosan for six months this declined to 40°. No other patient showed any deviation.

[18] Histogram of length of wear

Erection behaviour

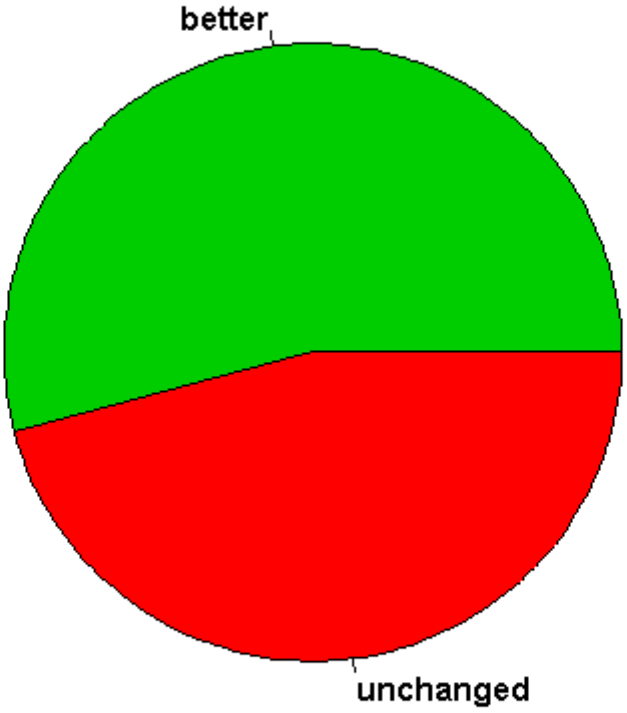
When asked about erection behaviour after using Phallosan for six months, the patients responded with ‘unchanged’ or ‘better’. The frequencies are summarized in the following table.

	Unchanged	**Better**
Frequency	11	13
Percentage	45.8	54.2

Over half of the patients stated that their erections were better after 6 months that at the outset of the study.

The following pie chart contains a graphic representation of these results.

Figure 19: Pie chart of erection behaviour [19]



[19] Pie chart of erection behaviour

Duration of erection

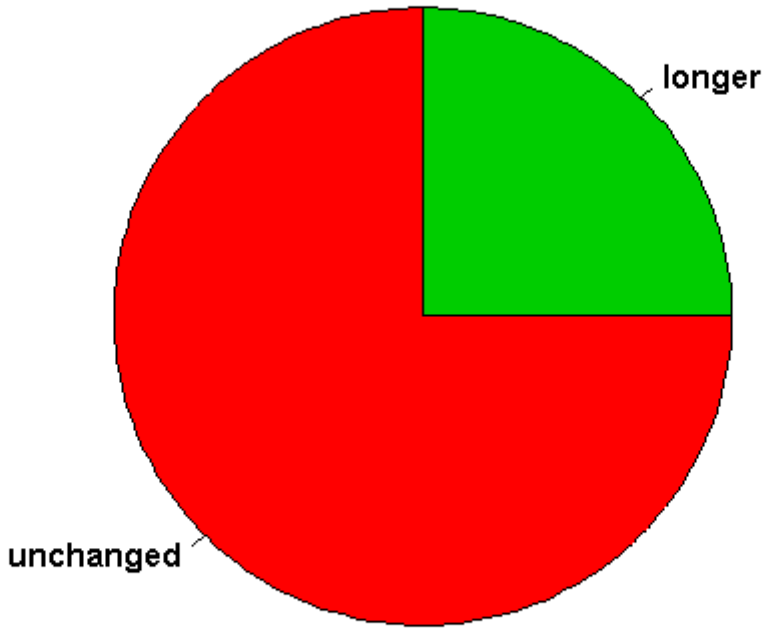
When asked about the duration of their erection, the patients the responded with ‘unchanged’ or ‘longer’. The frequencies are summarized in the following table.

	Unchanged	Longer
Frequency	18	6
Percentage	75.0	25.0

One in four patients claimed to have a longer erection.

The following pie chart contains a graphic representation of these results.

Figure 20: Pie chart of duration of erection [20]



[20] Pie chart of duration of erection

Erection hardness

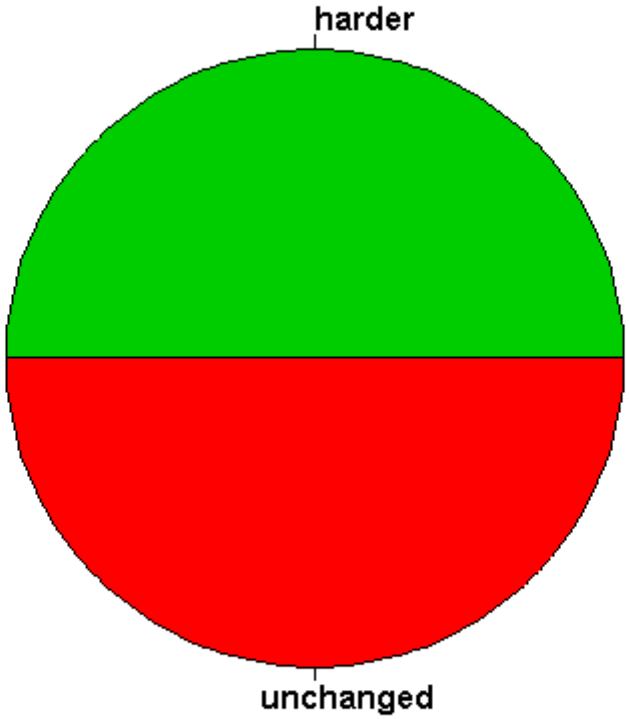
When asked about erection hardness, the patients the responded with ‘unchanged’ or ‘harder’. The frequencies are summarized in the following table.

	Unchanged	Harder
Frequency	12	12
Percentage	50.0	50.0

Half of the patients claimed that their erection was harder than at the start of the study.

The following pie chart contains a graphic representation of these results.

Figure 21: Pie chart of erection hardness [21]



[21] Pie chart of erection hardness

Ejaculation

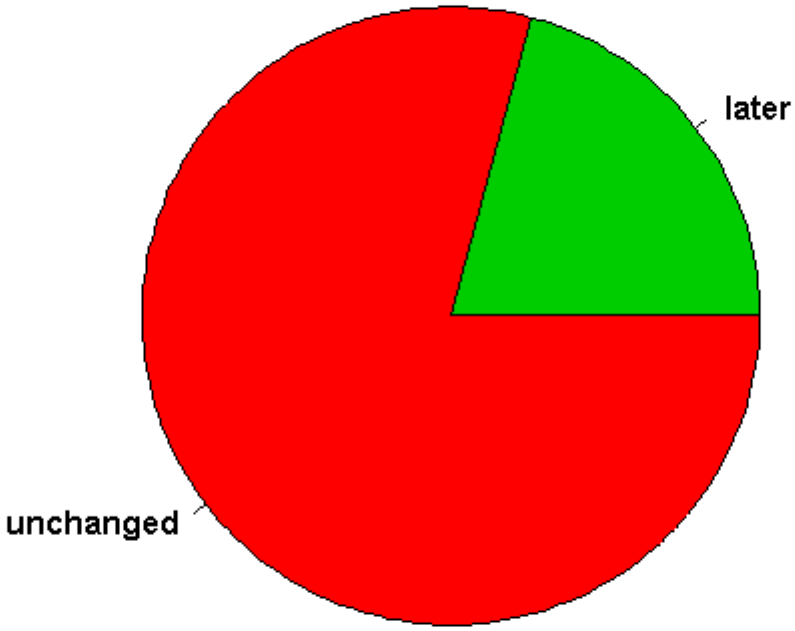
When asked about ejaculation, the patients the responded with ‘unchanged’ or ‘later’. The frequencies are summarized in the following table.

	Unchanged	**Later**
Frequency	19	5
Percentage	79.2	20.8

Approximately one in five patients claimed a longer period until ejaculation.

The following pie chart contains a graphic representation of these results.

Figure 22: Pie chart of ejaculation [22]



[22] Pie chart of ejaculation

Sensitivity

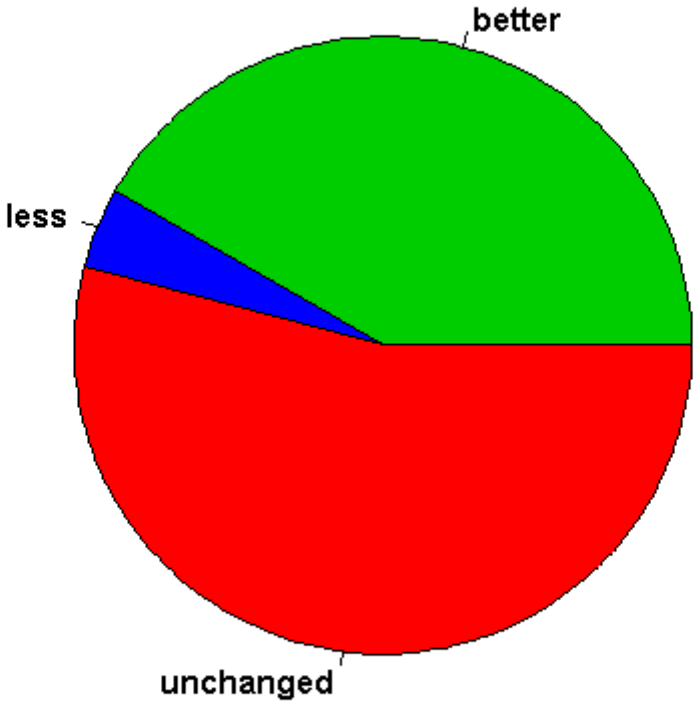
When asked about sensitivity, the patients the responded with ‘less’, ‘unchanged’ or ‘better’. The frequencies are summarized in the following table.

	Less	**Unchanged**	**Better**
Frequency	1	13	10
Percentage	4.2	54.2	41.7

In one case sensitivity was stated as ‘less’. Over 40% of the patients claimed improved sensitivity.

The following pie chart contains a graphic representation of these results.

Figure 23: Pie chart of sensitivity [23]



[23] Pie chart of sensitivity
Due to rounding differences the total is higher than 100%

Libido

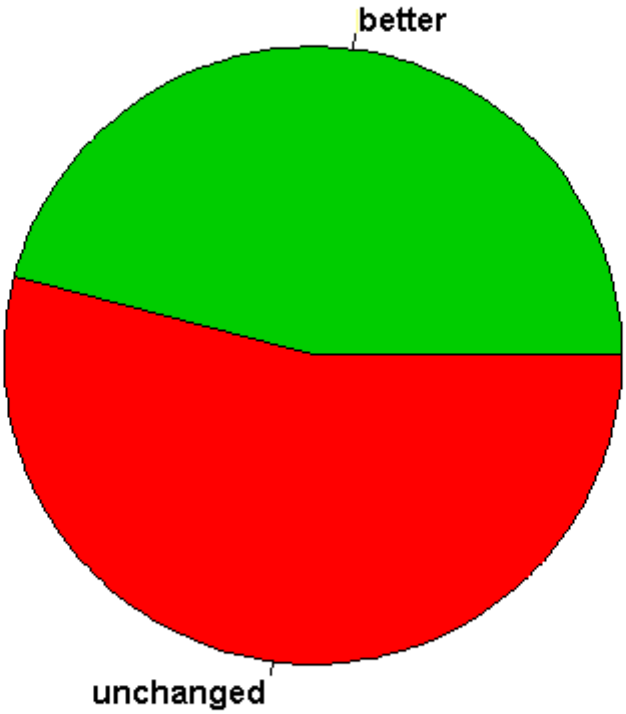
When asked about libido, the patients the responded with ‘unchanged’ or ‘better’. The frequencies are summarized in the following table.

	Unchanged	**Better**
Frequency	13	11
Percentage	54.2	45.8

Almost half of the patients claimed improved libido.

The following pie chart contains a graphic representation of these results.

Figure 24: Pie chart of libido [24]



[24] Pie chart of libido

Satisfaction

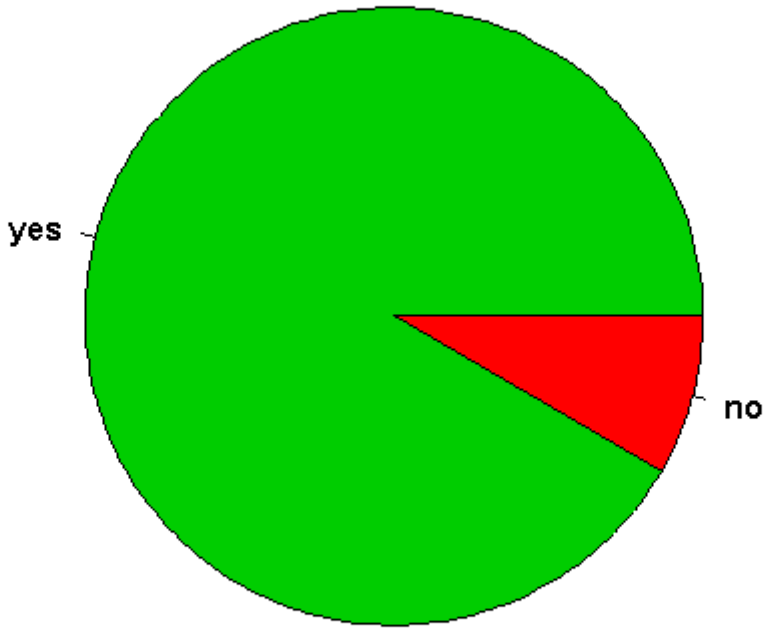
At the end of the study the patients were asked about their level of satisfaction with Phallosan. The frequencies are summarized in the following table. Only patients who completed the study were included.

	No	**Yes**
Frequency	2	22
Percentage	8.3	91.7

Over 90% of patients were satisfied with Phallosan after using it for six months.

The following pie chart contains a graphic representation of these results.

Figure 25: Pie chart of satisfaction level [25]



[25] Pie chart of satisfaction level

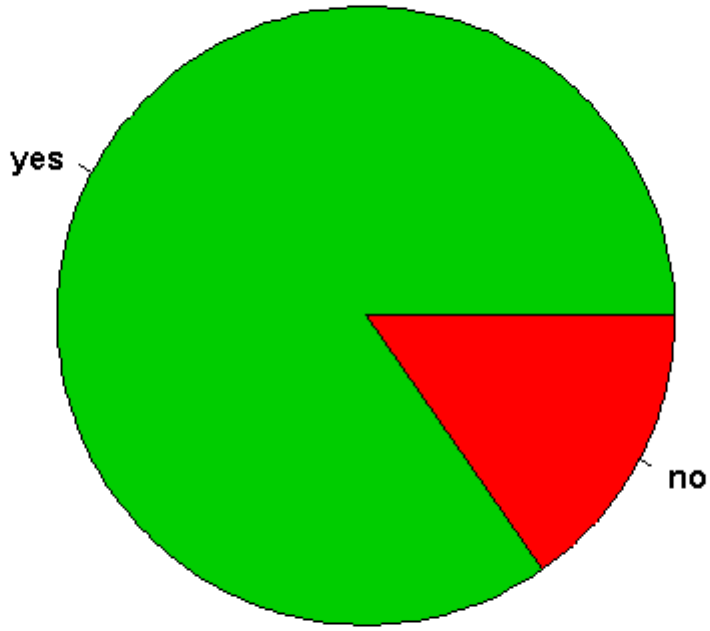
Assuming the dropouts were also ‘dissatisfied’ with Phallosan, the following table results.

	No	**Yes**
Frequency	4	22
Percentage	15.4	84.6

According to this, almost 85% of the patients were satisfied with Phallosan after using it for six months.

The following pie chart contains a graphic representation of these results.

Figure 26: Pie chart of satisfaction level of dropouts [26]



[26] Pie chart of satisfaction level of dropouts

Cross-classification of erection behaviour and duration of erection

	Duration of erection	
Erection behaviour	**Longer**	**Unchanged**
Better	5	8
	20.8%	33.3%
Unchnaged	1	10
	4.2%	41.7%

The largest patient group (41,7%) rated both erection behaviour and duration of erection as unchanged.

Cross-classification of erection behaviour and ejaculation

[27]	Ejaculation	
Erection behaviour	**Later**	**Unchanged**
Better	5	8
	20.8%	33.3%
Unchanged	0	11
	0.0%	45.8%

The largest patient group (45,8%) rated both erection behaviour and ejaculation as unchanged.

Cross-classification of erection behaviour and ejaculation

	Ejaculation	
Erection behaviour	**Later**	**Unchanged**
Better	2	4
	8.3%	16.7%
Unchanged	3	15
	12.5%	62.5%

Most of the patients (62,5%) rated both erection behaviour and ejaculation as unchanged.

[27] Due to rounding differences the total is not 100%

Cross-classification of sensitivity and libido

[28]	Libido	
Sensitivity	**Better**	**Unchanged**
Better	8	2
	33.3%	8.3%
Unchanged	2	11
	8.3%	45.8%
Less	1	0
	4.2%	0.0%

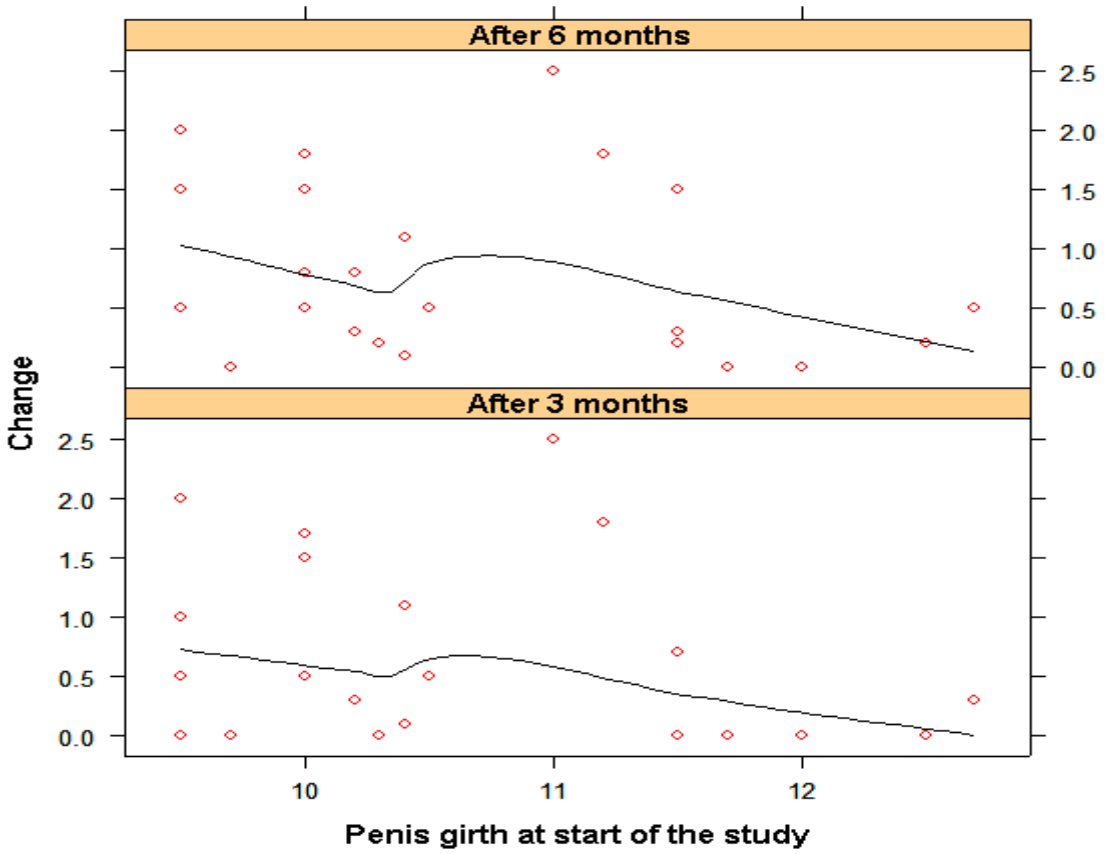
The largest patient group (45.8%) rated both sensitivity and libido as unchanged.

[28] Due to rounding differences the total is not 100%

Investigation of the correlation between penis girth at start of the study and subsequent change

The following figure shows a scatter plot of penis girth at start of the study and the change after 3 or 6 months. A smoothed curve is shown for comparison.

Figure 27: Scatter plot of penis girth [29]



The diagram does not contradict the assumption of linear correlation. A simple linear regression has therefore been fitted.
The estimated values can be taken from the following table:

	Parameter	Estimated value	Estimation error	p-value	R^2
After 3 months	Absolute member	2.664	1.698	0.13	0.0613
	Increase	-0.191	0.159	0.24	
After 6 months	Absolute member	2.711	1.667	0.12	0.0570
	Increase	-0.180	0.156	0.26	

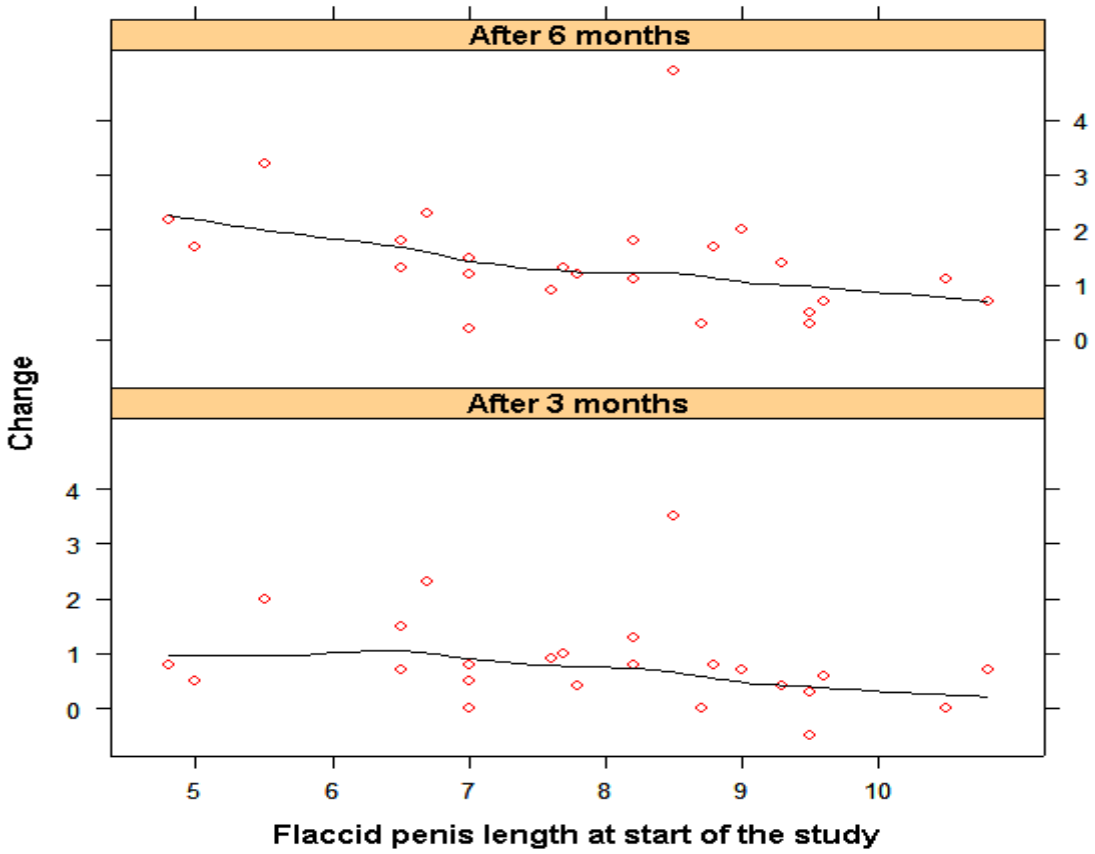
In both cases adjustment to the data is not optimal, as the points deviate strongly from the assumed straight line. The correlation between the starting value and change is not significant at either point in time.

[29] Scatter plot of penis girth

Investigation of the correlation between flaccid penis length at the start of the study and subsequent change

The following figure shows a scatter plot of the length of the flaccid penis at the start of the study compared to change after 3 or 6 months. Here again, a smoothed curve is shown for comparison.

Figure 28: Scatter plot of penis length when flaccid [30]



The diagram does not contradict the assumption of linear correlation. A simple linear regression has therefore been fitted.
The estimated values can be taken from the following table:

	Parameter	Estimated value	Estimation error	p-value	R^2
After 3 months	Absolute member	1.995	0.855	0.029	0.0822
	Increase	-0.147	0.106	0.180	
After 6 months	Absolute member	3.161	1.019	0.005	0.1150
	Increase	-0.214	0.126	0.105	

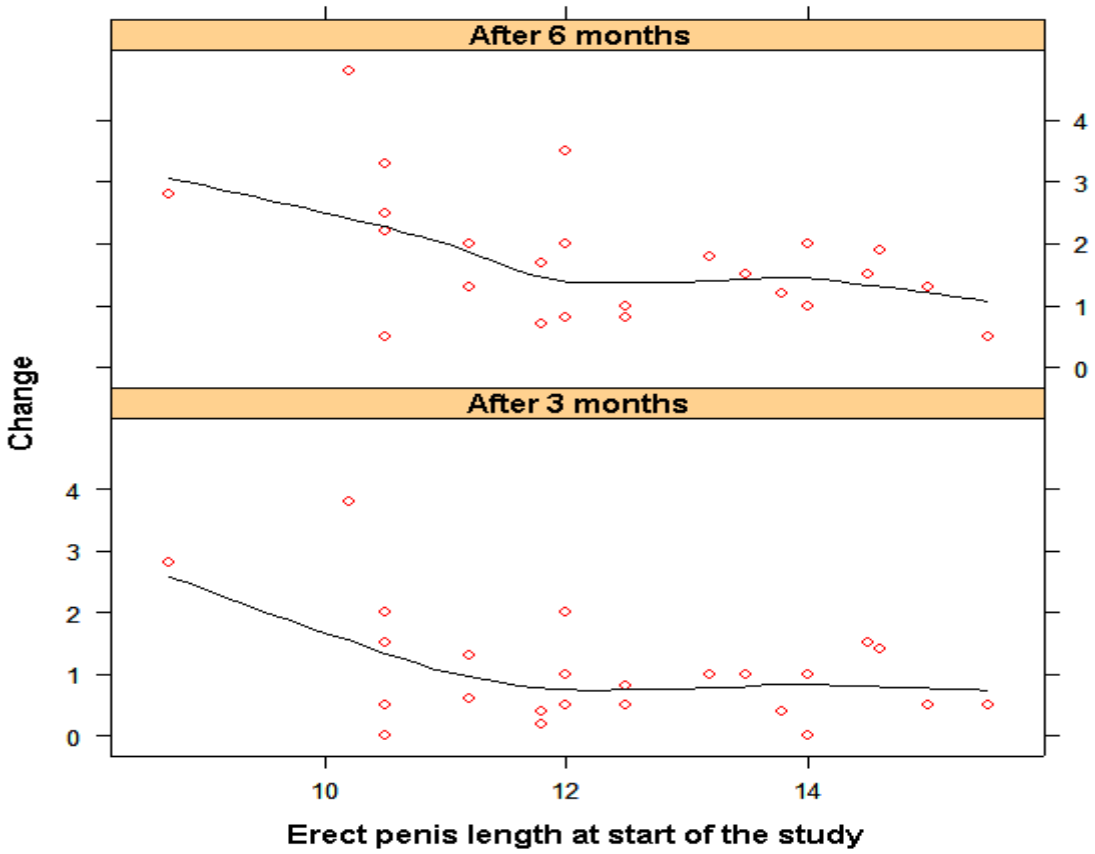
In both cases adjustment to the data is not optimal, as the points deviate strongly from the assumed straight line. The correlation between the starting value and change is not significant at either point in time.

[30] Scatter plot of penis length when flaccid

Investigation of the correlation between erect penis length at the start of the study and subsequent change

The following figure shows a scatter plot of the erect penis length at the start of the study compared to change after 3 or 6 months. Here again, a smoothed curve is shown for comparison.

Figure 29: Scatter plot of penis length when erect [31]



The diagram does not contradict the assumption of linear correlation. A simple linear regression has therefore been fitted.
The estimated values can be taken from the following table:

	Parameter	Estimated value	Estimation error	p-value	R^2
After 3 months	Absolute member	3.707	1.227	0.0063	0.179
	Increase	-0.2155	0.099	0.0396	
After 6 months	Absolute member	5.248	1.374	0.00094	0.228
	Increase	-0.282	0.110	0.01815	

In both cases adjustment to the data is not optimal, as the points deviate strongly from the assumed straight line. The correlation between the starting value and change is not significant to 5% at either point in time.

[31] Scatter plot of penis length when erect

Inference statistics

In this section, t-tests were used to investigate the significance of change in the three measured penis sizes. The so-called OLS method was used for the purpose. In the course of the investigation, however, it became clear that the Bonferroni method would be completely adequate. For this purpose the (multiple) significance level was evenly divided among all tests. In our case, three t-tests were conducted. The (multiple) significance level was set at 5%. Each individual test is thus conducted at the level of 1.67%.

Primary hypothesis

The primary hypothesis determines whether there is a significant change in three penis measurements after using Phallosan for six months. The following table shows the t-statistic values and the respective p-values.

	t-statistik	p-value
Penis girth	5.33	< 0.001
Penis length when flaccid	7.07	< 0.001
Penis length when erect	8.37	< 0.001

All tests are significant to the level of 1.67%. All sizes thus show a significant change after six months of use.

Secondary hypothesis

The secondary hypothesis whether there is already a significant change in three penis measurements after using Phallosan for three months. The following table shows the t-statistic values and the respective p-values.

	t-statistik	p-value
Penis girth	4.18	< 0.001
Penis length when flaccid	4.87	< 0.001
Penis length when erect	5.72	< 0.001

All tests are significant to the level of 1.67%. All sizes thus show a significant change after three months of use.

List of figures