

Pseudo-capsule “coffin” effect: How to prevent penile retraction after implant of three-piece inflatable prosthesis

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MATERIALS AND METHODS

The series includes a group of 46 patient (average age 65.6 s.d. 9.6) studied retrospectively and operated between 1998 and 2012 and implanted with three-piece inflatable penile prosthesis® (*American Medical Systems, Minnetonka, MN, USA*) for severe impotence (AMS 700 CX® or LGX® hereafter respectively named CX and LGX). We divided the population in two groups: the first group, called No Early Activation (hereafter named NEA, N = 27 mean age 62.46 ± 12.04 s.d.) comprises patients who did the first prosthetic activation four weeks after surgery (as indicated in literature and by construction company) (12). The second group is composed of those patients who have activated the prosthesis for the first time immediately after surgery. This group is formed of 19 patients, and it has been called Device Early Activation (hereafter named DEA). The average age was 68.85 ± 7.26. In this group the prosthesis was left inflated about 80% of his volume and deflated the first time after two/three weeks when the patient was able to use (inflate and deflate) the device. In this time we prompted to maintain the penis in full erection at night for almost three/four further weeks.

Penile length was measured with the inflated prosthesis from the pubic bone to the urethral meatus along the dorsum of the shaft by exerting maximum pressure on pubic bone to reduce the fat layer. The circumference was measured in the middle third of the penis. Erectile and flaccid state measures were expressed in centime-

ters. Measurements were made using a meter tailor. Standard error was about 0,5 cm.

In the NEA group we have available measures of the penis only after implantation.

All 19 patients of the DEA group, operated between June 2010 and March 2012, were subjected to measurement of penile length and girth (circumference) before surgery, and then after at least one month (between 1 and 6 months). Preoperative measurements in length and girth of the erection induced by farmaco-prosthesis (ICI) are available in 12 of the 19 patients, as well as the measures of the flaccid penis. In 14 patients the stretched penile length measurements are available.

With reference to the type of prosthesis used, in the NEA group in 22 cases AMS CX prosthesis were used and AMS LGX in 5. In the early activation group (DEA) 15 patients were implanted with a LGX prosthesis and 4 with CX.

The sample is characterized by a predominant diagnosis of entry of vascular disease (N = 22, including 15 patients NEA group, 7 patients group DEA) and pelvic surgery (N = 14, including 4 patients of the NEA, 10 patients DEA group). In the NEA group 4 patients have a diagnosis of induratio penis plastica and 3 other patients diagnosed with a neurological disorder. In a small number of cases, the cause is due to diabetes (1 patient group DEA), fibrosis (1 patient group NEA) and idiopathic (1 patient group DEA) (see Table 1).

Table 1.
Main diagnosis of the total sample.

Main diagnosis	N. Subject			% Subject		
	NEA	DEA	Tot.	NEA	DEA	Tot.
VASCULAR DISEASE (veno-occlusive dysfunction or arterial hypoperfusion)	15	7	22	55.5	36.7	47.7
PELVIC SURGERY (radical prostatectomy, rectal surgery, cystectomy)	4	10	14	14.8	52.6	30.4
IPP (Induratio Penis Plastica)	4	0	4	14.8	0	8.69
NEUROLOGICAL DISEASE	3	0	3	11.1	0	6.52
FIBROSIS	1	0	1	3.70	0	2.17
DIABETES	0	1	1	0	5.26	2.17
DE IDIOPATHIC	0	1	1	0	5.26	2.17
Total	27	19	46	99.9	99.82	99.82

The total sample has a mean follow-up of time equal to 28.7 months after surgery, s.d. 21.9). The group DEA reported a mean follow-up equal to 6.31 months (s.d. 2.6), the NEA group has a longer follow-up because the retrospectively of the study and mean follow-up was 52.1 months (s.d. 41.3 and a range between 11 to 132 months).

All statistical analysis of the penile measures in the tables were made using the program Spss (ver. 17.0; SPSS Inc., Chicago, IL, USA) by using the Student t test (both for independent samples for paired groups) and with $p \leq 0.05$ considered statistically significant.

Surgical technique: in all cases the prosthesis was implanted with single peno-scrotal incision and the reservoir was placed in the Retzius space passing through inguinal canal.

RESULTS

The Tables 2 and 3 show the differences in means values between the different groups and different prosthesis within the same group and the statistical values of means difference in length and girth in flaccid and erect penis in the groups DEA and NEA in post operative data, described below.

The average post implant dorsal length of the erect penis was found in the group NEA (27 patients, CX + LGX) equal to $11.70 \text{ cm} \pm 1.4 \text{ s.d.}$ (range 9-15 cm), in the group DEA (19 patients, CX + LGX) equal to $14.98 \pm 1.7 \text{ s.d.}$ (range 12-19 cm) (Tables 2) with a difference corresponding to 3.28 cm more for the group with early activation (DEA). The analysis with T-test for independent samples shows a significant difference in average penis length between the two groups ($p < 0.05$), $[t(44) = -6.883; p = 0.000]$ (Table 3a).

Considering the DEA group implanted penis, the average dorsal length of the erect penis was $15.35 \text{ cm} \pm 1.0 \text{ s.d.}$ (range 12-19 cm) in patients with implanted prosthesis LGX and $13.80 \text{ cm} \pm 1.5 \text{ s.d.}$ (range 12-16 cm) in patients with implanted prosthesis CX (Table 2), with a mean difference equal to 1.55 cm in favor of the LGX. The analysis with Student t-test for independent samples does not find statistical significance of difference between the CX and LGX prosthesis (both with earlier activation) ($p > 0.05$), $[t(17) = -1.60, p = 0.126]$ (Table 3b).

The samples independent student t-test finds a difference of average statistically significant between the NEA group and the DEA group for the type prosthesis LGX ($p < 0.05$), $[t(18) = 0.196; p = 0.000]$. In fact the dorsal length of the erect penis is 3.45 cm longer in the LGX

Table 2.

Means values between the different groups and different prosthesis within the same group in length (L) and Circumference (C) in post operative data.

	L Erection	L Flaccid	C Erection	C Flaccid	N. Cases
NEA Group					
CX Av. and s.d.	11.66 ± 1.6	10.21 ± 1.7	11.39 ± 0.9	10.45 ± 0.8	22
LGX Av. and s.d.	11.90 ± 0.7	9.90 ± 0.7	11.90 ± 1.5	10.50 ± 1.3	5
CX + LGX Av. and s.d.	11.70 ± 1.4	10.15 ± 1.5	11.48 ± 1.0	10.46 ± 0.9	27
DEA Group					
CX Av. and s.d.	13.80 ± 1.5	13.20 ± 1.5	12.00 ± 0.7	10.10 ± 0.9	4
LGX Av. and s.d.	15.35 ± 1.0	13.70 ± 2.0	12.43 ± 0.8	11.00 ± 1.4	15
CX + LGX Av. and s.d.	14.98 ± 1.7	13.33 ± 1.8	12.26 ± 0.8	10.56 ± 1.4	19

Table 3.

Mean Difference and statistical value between dorsal length and girth in erect penis in the groups DEA and NEA.

	Group	Average Erect Length Values (cm)	Average difference increase in dorsal erect length between mean values in different group (cm)	p.	T-test
- a	DEA and NEA*	(14.98 and 11.70)	3.28	p. 0.000	(t)**
- b	LGX and CX DEA	(15.35 and 13.80)	1.55	p. 0.126	(t)**
- c	LGX DEA and LGX NEA	(15.35 and 11.90)	3.45	p. 0.000	(t)**
- d	CX DEA and CX NEA	(13.80 and 11.66)	2.14	p. 0.025	(t)**
- e	LGX and CX NEA	(11.90 and 11.66)	0.24	p. 0.755	(t)**
	Group	Average Flaccid Length (cm)	Average difference increase in flaccid length (cm)	p.	T-test
- f	DEA and NEA*	(13.20 and 10.21)	2.99	p. 0.000	(t)**
	Group	Average erect girth value (cm)	Average difference increase in girth (cm)	p.	T-test
- a1	DEA and NEA*	(12.26 and 11.48)	0.78	p. 0.011	(t)**

* CX and LGX whole group (DEA/NEA); **(t)= t test for independent samples

DEA group versus LGX NEA group (Table 3c). We found the same result for the prosthesis CX: the average length of the difference between the NEA group and the DEA group is statistically significant ($p < 0.05$), [t(24) = 0.681, $p = 0.025$]: 2.14 cm longer than NEA group (Table 3d). Therefore in both cases the group DEA finds major length on average.

In the NEA group we have found lengths almost similar between CX and LGX prosthesis: the average dorsal length measured in patients with implanted prosthetic LGX (5 patients) was of 11.90 cm \pm 0.7 s.d. and 11.66 cm \pm 1.6 s.d. in patients with implanted prosthesis CX (22 patients) and therefore the samples independent student t-test not finds a difference of average statistically significant ($p > 0.05$), [t(25) = -0.315; $p = 0.755$] (Table 3e).

Group DEA during the postoperative period shows bigger length flaccid measures compared whit NEA group ($p > 0.05$) [t(44) = -6,239, $p = 0.000$] (Table 3f).

The mean circumference of the penis in erection postoperative amounted to 11.48 cm \pm 1.0 s.d. in the NEA group and amounted to 12.26 cm \pm 0.8 s.d. in the DEA group (Table 2). This finding is significant and shows that DEA group has a penis girth of 1cm bigger ($p < 0.05$), samples independent student t-test [t(44) = -2.65; $p = 0.011$] (Table 3a1).

PRE-OPERATIVE DATA OF DEA GROUP: COMPARISON PREOPERATIVE AND POSTOPERATIVE MEASURES IN THE DEA GROUP

The tables 4 show the means values and the statistical values of means difference in length and flaccid penis in the groups DEA in pre e post operative data , described below. The average erect length in the DEA group between the preoperative period (both stretched and ICI) and the postoperative period with type test t-test for paired samples is statistically significant with erect ICI value ($p < 0.05$) [t(11) = -3.018, $p = 0.012$], instead it is not statistically significant with erect stretched value ($p > 0.05$) [t(13) = -1.698, $p = 0.113$]. Therefore we get an erection induced by ICI that has a minor length than the length measured with the prosthesis activated. We did not find statistical significative differences between preoperative stretching penis length and postoperative length in erection.

The DEA group shows postoperative flaccid length 2 cm longer than the preoperative measures (13.33 \pm 1.8 vs. 11.34 \pm 2). The statistical analysis with t-test paired samples demonstrates this by finding statistical significance between these values ($p > 0.05$) [t(12) = 6.040, $p = 0.000$] (Table 4).

RESULTS ON THE PENIS ELASTICITY: COMPARISON WITH ERECT AND FLACCID MEASURES IN THE NEA AND DEA GROUP BETWEEN PRE AND POST OPERATIVE DATA

We named Delta (hereafter Δ) the difference between erect and flaccid dorsal penile length,

and ($\Delta 1$) the difference between erect and flaccid penis circumference, measured in cm.

Delta expresses the degree of elongation/expansion of the penis going from flaccid to erect state, then elasticity of the tissues which constitute the penis. [Delta = erect dorsal length - flaccid dorsal length; Delta1 = circumference erect - circumference flaccid].

Delta and Delta 1, which express the penis elasticity, vary significantly between the pre and post-operative.

Δ (Length variation)

The DEA group shows a Delta dorsal length pre-operative variation of 2.61 and 3.23 respectively whether the length is referred to the penis measured in ICI (intra cavernous injection) or in stretching (see Table 5).

The average difference in length between penile postoperative state erect and flaccid (Δ) of the group NEA is 1.55 cm ; therefore very near to same value delta postoperative group DEA (1.65 cm).

These delta values are not statistically significant with the samples independent student t-test ($p > 0.05$) [t(44) = -0,408, $p = 0.686$] but indicate a very low grade of elasticity of the implanted penis when compared with the same results in normal non implanted penis in which Δ is 2.61 in ICI e 3.23 in stretching: about 1.5 cm longer than postoperative .

As shows in table 5 the preoperative measure in stretching penis was equal to 14.57 \pm 1.50, the average length of pre-operative in ICI was 13.95 cm \pm 1.58. The post operative average length with prosthesis activated was 14.98 cm \pm 1.7. Thus the difference between the average length in stretching and ICI is of 0.62 cm in favor of the stretching length.

Table 4.
Means values and the statistical values of means difference in length and flaccid penis in the groups DEA.

Group DEA	Preoperative	Postoperative	p. T-test (Pired simple test)
Erect length	13.95 \pm 1.5 (ICI)	15.57 \pm 1.5 (STR)	14.98 \pm 1.8
	14.98 \pm 1.8	$p = 0.012$	$p = 0.113$
Flaccid length	11.34 \pm 1.9	13.33 \pm 2.1	$p = 0.000$

Table 5.
Penile elasticity (Δ and $\Delta 1$).

Group	Length preoperative (available with fic in 12 patients, with str. in 14 patients)		Girth preoperative
	Δ		$\Delta 1$
	ICI	STR	
DEA (lgx and cx)	2.61	3.23	2.75
Group	Length postoperative		Girth postoperative
	Δ		$\Delta 1$
NEA (lgx and cx)	1.55		1.02
DEA (lgx and cx)	1.65		1.69

Δ1 (Girth/circumference variation)

Results about the difference in circumference variation of NEA group shows a value equal to 1.02: 0.67 cm lower than the group DEA (1.69 cm) (Table 5).

The difference in circumference in postoperative group of DEA ($\Delta 1$) is lower than the same condition in the preoperative Delta 1 (1.69 versus of 2.75 cm) see Table 5.

The average erect circumference (DEA group) between the preoperative and postoperative period with type test t-test for paired samples are not statistically significant ($p > 0.05$) [$t(9) = 1,369$, $p = 0.204$].

DISCUSSION

Wang *et al.* in 2009 (20) compared erect penile length after inflatable penile three-piece prosthesis (IPP) implantation with erection induced by intracavernosal injection (ICI) before surgery on eleven patients (measuring the dorsal length of the penis from the pubic bone to the top of glans).

At 6 weeks after surgery, all patients were instructed to inflate and deflate the IPP. The erect penile length induced by ICI at the time of penile color duplex Doppler studies in this cohort was $13.2 \text{ cm} \pm 0.4 \text{ s.d.}$ After IPP implantation, the mean erectile length was only $12.4 \text{ cm} \pm 0.3 \text{ s.d.}$ at the sixth week, $12.5 \text{ cm} \pm 0.3 \text{ s.d.}$ at the sixth month and $12.5 \text{ cm} \pm 0.4 \text{ s.d.}$ at the 1-year follow-up, respectively. There were $0.83 \text{ cm} \pm 0.25 \text{ d.s.}$, $0.75 \text{ cm} \pm 0.20 \text{ d.s.}$ and $0.74 \text{ cm} \pm 0.15 \text{ d.s.}$ decreases of erect penile length at the sixth week, sixth month and 1-year measurements after IPP implantation when compared with that induced by ICI ($P < 0.05$). The measurements of penile length at 6 weeks, 6 months and 1 year were not statistically different ($P > 0.05$). This work is the only study that objectively found a significant decrease in erect penile length after prosthesis implant but they do not explain this finding and do not indicate any method to prevent the retraction of the penis after implant. Furthermore the length measured in ICI erect penis are probably lower than those of a natural erection being that they are patients with severe DE and it is also difficult for them to get a 100% with ICI. In other words, lost of length is not taken under consideration. From our experience, DEA patients in fact got an ICI erection of lower dimensions than with use of activated prosthesis.

On the contrary these data are very similar to our results in NEA group (erect dorsal length $11,70 \pm 1.4 \text{ cm}$).

All this demonstrates that the "coffin effect" of pseudo-capsule is a determinative factor of the effective erected penis length. The confirmation comes from the fact that there are no significative differences between the penis length in stretching and the penis length with activated prosthesis (Table 4).

Moreover we found very different results in DEA group where the size of the implanted penis is significantly increased in both types of prosthesis (Cx and Lgx). After the implant in the early activation group the result is a longer erect penis, but also a longer flaccid penis. We believe to have sufficiently demonstrated that the implantation of three-component unless be accompanied by early activation leads to a loss in dorsal penile length

and girth is not negligible: average length dorsal $11.70 \text{ cm} \pm 1.4 \text{ cm}$ and average girth $11.48 \text{ cm} \pm 1.0$ in NEA group. But we demonstrate that early activation of the prosthesis can improve the surgical result in terms of dorsal erect penis. See Table 4.

We believe that the early activation of the prosthesis makes possible to model the pseudo-capsule surrounding the cylinders, in the immediate postoperative period in a state of semi-erection instead of flaccidity, with the result of preventing the coarctation of the penis and reducing the "coffin effect" due to the connective tissue. In order to reduce the "coffin effect" and stop the size loss, it is not necessary, as other authors (6, 8) said, to use preoperative measures like penile expanders, but the early activation is enough.

DELTA and DELTA 1 (penile elasticity)

Our results show that penile prosthesis provides penis flaccid state measures greater than the pre-operative condition. We see a difference in the delta value between preoperative e postoperative period. In the postoperative period both DEA group (with $\Delta = 1.65 \text{ cm}$) to NEA group (with $\Delta = 1.55 \text{ cm}$) have a delta length minor about 1 cm than preoperative ($\Delta = 2.61 \text{ cm}$) (Table 5).

This means that the effect coffin determined by the pseudo capsule after implantation results in less elasticity of the penis that occurs in the largest in the state of flaccidity but stretches less when going from flaccid to erection. Similar considerations can be made for the circumference (girth) where there is a loss of almost 1 cm in the $\Delta 1$ value after the implant device even with early activation in comparison with the preoperative measures (2.75 vs. 1.69).

As well the variation of the circumference of the penis without a prosthesis ($\Delta 1$) is 2.75 versus 1.02 in the NEA group and 1.69 in the DEA group. This findings confirms that in addition to the loss of one cm of circumference there is also a lower elasticity of the implant linked to the coffin effect ($\Delta 1$ differences in the different groups). In essence, the implanted penis is a penis bigger respect the preoperative state of flaccidity but tends to be less elastic albeit retaining substantially the size only in the DEA group in comparison to preoperative size.

So, while in NEA group we get length values in a flaccid state definitely lower than DEA but more similar to the preoperative ones, in erection the values of this group are definitely lower than the DEA group (significant) and the preoperative DEA group. This might mean that the pseudo-capsule, once formed on the activated prosthesis (DEA group) is bigger and so it allows bigger penis dimensions than with activated prosthesis even in a flaccid state and also bigger than the preoperative. In other words, once the pseudo-capsule is formed, it determines the penis dimensions also in a flaccid state other than in erection, no matter what the dimension of the prosthesis which is only free to move inside the pseudo-capsule like a sliding door. Our study demonstrates as the activation of the prosthesis immediately after surgery, contrary to what is indicated by the literature and by the manufacturer company, both at the moment the only practical able to limit the inevitable creation of pseudo capsule and able to respond terms solving the dissatisfaction of

patients and therefore the problem of penile size after implantation of a penile prosthesis debated for some time. Wilson *et al.* (21) in 2006 showed that the prosthesis if it is kept active for a sufficiently long period (about 3 hours per day) can function as the pseudo-capsule expander already formed. We believe it is better to inflate even before (immediately after surgery) so as to prevent the formation of the pseudo-capsule on the deflated prosthesis. It is true that the prosthesis can function as an expander, but it is better to use it from the beginning to prevent the "coffin effect".

The pseudo-capsule surrounding the reservoir in our experience seems to be less important. In fact we only have two cases of self-inflation in the DEA group which didn't require any treatment.

Shaeer 2010 (7), claims that the loss in size after prosthetic implant can be connected to the intervention but does not show this and does not suggest any techniques to prevent this negative result. Our study demonstrate the existence of a real reduction of the penis after prosthetic implant due to pseudocapsule and also shows that the "coffin effect" can be modulated.

Deveci (5) claims that the implanted penile prosthesis does not have a negative impact on penile length when compared to the pre implant stretching penile length: "Despite an absence of measurable penile length changes, the majority of men (71%) complained of subjective length loss. The reason for this is not well defined but may be related to a comparison with their penile length before the onset of ED". We disagree about his statement "Treatment satisfaction scores do not depend on subjective penile length loss". In his study over 70% of the patients complain about the reduced penis size. We think that this cannot be neglected and it could be explained considering that the stretching penis is about 1/1.5 cm shorter than the natural erect penis. Their conclusions are based on the confrontation with penis in stretching which is shorter than a penis in physiological erection. Moreover, obtained penis measures are not available.

In this respect, the reliability of the measures stretching Wessells *et al.* (22) prospectively measured flaccid an penile length was 12.4 cm, and average length with pharmacological erection (ICI) was 12.9 cm. Stretched penile length correlated closely with erect penile length. In this study it was 5 mm shorter in stretched penis.

In the NEA group the average erect length (11.70 cm) is almost 1 cm shorter than the average length in stretching in normal Italian males studied by Ponchietti (23) (12.5 cm) and not 0.5 cm less than normal erect state. This might mean that the average value of erect penis of the NEA group is about 1.3 cm shorter than the erect penis length of normal Italian males without prosthesis (12,5 + 0,5 =13 cm).

We have obtained opposite results (14.57 in Stretching and 13.95 in ICI) probably in relation to the severity of ED in our series.

The ICI in this condition do not provide a full erection and this justifies this difference. In DEA group the average length is very similar to stretched preoperative value. Our data show how the group DEA penis length in stretching preoperative is almost exactly the same after implantation of a penile prosthesis (14.57 cm \pm 1.5 vs 14.98 cm \pm 1.7 no statistically significative).

LGX

Our data as shown in table 2 are that the prosthesis LGX for their constructive characteristics would seem to ensure a gain in terms of size in the erect penis only if the implant is associated with earlier activation. In fact the average penis length between LGX and CX in the NEA group are similar: 11.90 versus 11.66 (Table 3) and there is difference of average statistically significant between the NEA group and the DEA group for the type prosthesis LGX: the dorsal length is 3,37 cm longer in the LGX DEA group versus LGX NEA group.

When it comes to the penis girth it increases in the DEA group of 0,53 cm (Table 2).

Otherwise we found as the reduction in length of the penis in patients implanted seems real: 11.70 cm in the NEA group. Especially, the LGX implanted if it is not activated earlier does not provide any advantage over the CX. The Early Activation appears to provide an effective increase in size when compared to preoperative erection: 2.61 cm with ICI.

Levine LA and Rybak, 2010 (8) observe that there is no recognized reliable technique to gain length once the device is placed. On the contrary, our study demonstrates that after the surgery it is possible to maintain the preoperative dimensions.

SUPPLEMENTARY REFERENCES

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