ORIGINAL RESEARCH

EVALUATION OF THE ADHESIVE PROSTHESIS "SILIMA DIRECT" BY MASTECTOMYZED PATIENTS IN FRANCE

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ABSTRACT

Objective: Breast cancer is the most prevalent malignant disease in women. The loss of a breast is a highly traumatizing event for the woman; thus, surgical or non-surgical methods of reconstruction can improve quality of life. In the present study, we aimed to assess patient satisfaction with two different models of adhesive external breast prosthesis and to compare them with the previously worn models.

Materials and Methods: A questionnaire was mailed to 240 women using one of the two prosthesis models. 154 questionnaires were returned, 41 of which were not eligible for evaluation. Most items were rated on a verbal scale (VRS).

Results: After a prosthesis-free period of about 4.5 years, the women wore both models of the "Silima direct" for almost 2 years. The assessment of both models was mainly positive. The average VRS scores were just above 2 out of 5 points, which corresponds to a "good" rating. The lighter model scored better results. Of the patients, 73.6% were overall at least "satisfied" with the lighter model as compared to 58.3% with the model of normal weight. In comparison with the Amoena adhesive epithesis and other prosthesis models worn previously, the "Silima direct" and particularly the light model was perceived to be better in almost all criteria.

Conclusion: External adhesive breast prostheses are a valuable method of post-mastectomy rehabilitation, which improves quality of life.

Keywords: Breast cancer, External breast prosthesis, Adhesive breast prosthesis

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Marmara Medical Journal 2008;21(2);133-145

FRANSA DA MASTEKTOMİZE OLAN HASTALARDA 'SİLİMA DİRECT' İSİMLİ ADHESİVE PROTEZİN DEĞERLENDİRMESİ

ÖZET

Amaç: Meme kanseri, kadınlarda en sık görülen malin hastalıktır. Meme kaybı, kadın için travmatize eden bir olaydır, bu yüzden, cerrahi veya cerrahi olmayan rekonstrüksiyon hayat kalitesini arttırabilir. Bu çalışmada iki farklı adheziv meme protezi modeli ile hastaların memnuniyet derecesini değerlendirmek ve daha önce giyilmiş modellerle karşılaştırmayı amaçladık.

Materyal ve Metot: Bu iki protezden birini kullanan 240 kadına bir sorgulama formu yollandı.154 sorgulama formu geri gönderildi. 41 tanesi araştırmaya uygun değildi. Öğelerin çoğunun değerlendirilmesinde Sözel Değerlendirme Ölçeği (SDÖ) esas alındı.

Bulgular: 4.5 yıllık protezsiz dönemden sonra, kadınlar 'Silima direct' protezinin her iki modelini de 2 yıla yakın giydiler. Ortalama SDÖ puanları 5 üzerinden ikiden biraz fazla olması itibariyle pozitifti. Daha hafif olan model daha iyi puanlar aldı. Hafif modeli kullanan hastaların %73,6'sı en azından "tatmin olmuşlardı", buna karşılık normal ağırlıklı olanla ise bu oran %58,3'dü. Daha önce giyilen Amoena adheziv ve diğer protezlere göre, Silima direct ve özellikle hafif modeli tüm kriterlerde daha iyi olarak değerlendirildi.

Sonuç: Eksternal meme protezi, post mastektomi rehabilitasyonunda çok değerli bir yöntemdir ve hayat kalitesini artırabilir.

Anahtar Kelimeler: Meme kanseri, Meme protezi, Adheziv protez

INTRODUCTION

Despite intensive efforts and remarkable progress in diagnostics and therapy, Mammary Carcinoma is one of the most important health problems world-wide; from the early recognition to the rehabilitation its management binds a substantial portion of resources of the health service. According to an estimate by the institute for Robert Koch (conditions February 2006) approximately 206,000 women get cancer per year in Germany. Mammary Carcinoma thereby represents the most frequent malignant tumor illness in women: currently, in Germany, about 59,000 women get breast cancer annually, and since 1980 the number of these cases has nearly doubled[1]. Mammary Carcinoma is responsible for 28.8% of all new cancer cases and 17.3% of all cancer deaths in women[1]. The mean age of illness is 63.5 years[2]. Theoretically, for every healthy woman, the risk of getting breast-cancer until 74 years old is about 8%[3].

However, ablatio mammae is still, even today, frequently the only surgical therapy option in advanced cases, in multimorbid cases or in elderly patients – with considerable, predominantly socioeconomically determined, regional variations. In addition, the indications for mastectomy may include, for example, the refusal of the patient to undergo the obligatory radiation therapy after the removal of the tumor[4]. Technically breast-conserving therapy is possible in about 70% of all breast cancer patients[5,] and in principle, this proportion can in principle be regarded as rising, through improved methods of early recognition and systemic treatment[6]. Overall the aim of the mammary centers in Germany, is to reach over 80% for breast-conserving surgery. The West German Breast Centre which is directed towards this aim, has conducted benchmarking studies that have shown that the average proportion of radically mastectomized patients still stands at ~35%, with considerable differences among individual centers; an estimated 15,000 to 25,000 ablations are currently being performed in Germany each year [http://www.brustcentrum.de/wbc/default.aspx].

This intervention is extraordinarily damaging for the patient concerned, not only physically but particularly also from a psychological point of view. Due to the very great aesthetic and symbolic significance of the female breast, which far exceeds its biological

function as lactation organ[8], its loss is extremely traumatic. Primary reconstruction using autologous tissue or an expander is successful in only ~15% of the patients. For rehabilitation, three different procedures are used:

• Surgical fitting of an implant
• Surgical reconstruction with autologous tissue
• Fitting of an external prosthesis.

Apart from the surgical possibilities, in principle, the method of treatment determined by technical and surgical feasibility but chiefly by the wishes of the patient. Mainly younger women with elevated socio-economic status and intensive leisure activities tend to choose surgical reconstruction[9], while reasons for the choice of prosthesis are the fear of further surgical intervention, misgivings concerning the quality of the cosmetic results, a higher age and a stable accepting familial background (particularly, the relationship with the partner)[10].

For the external fitting, two different systems are available:

• Non-adhesive prostheses, which are carried in a special bra with sewn-in flap; or
• Adhesive prostheses, which are either (one-part) placed directly on the skin or fixed to the skin with the help of an adhesive pad (two-parts).

Prostheses should fulfill the following fundamental constructional requirements[11]:
• similarity with the natural breast regarding size, form, weight and consistency
vodorless, kind to the skin, easily cleaned
• durability
• fits without puling or friction
• good heat exchange
• natural behavior in moving property

Further development of these systems is naturally dependent on the feedback from fitted patients concerning comfort during wearing, ease of handling and improvement of the body image. This means a continuous communication between manufacturers, distributors and patients.

Aim of the study

The study used a random sample of mastectomized patients, who had been fitted with various prostheses over a period of 2–5 years and who currently used self-adhesive prostheses. Self-adhesive prostheses were represented by two 'Silima direct' models that differed from each other in weight: a normal-weight full-gel prosthesis (model 66373), and a 30%-lighter three-layered variant (model 66377) both from Thämert, Großburgwedel, Germany.

In the present study, communication-based quality control was carried out and the reliability of the product was examined, by evaluations based on the following issues:

• whether the patients perceive differences between the prostheses when worn;
• how the patients rate the two most recently worn versions of the self-adhesive prostheses (by asking the patients who had used other products); and
• whether the lighter model is rated differently from the normal weight version.

MATERIAL AND METHOD

For privacy and data security reasons, the names and addresses of the patients were with hold by the medical houses in France. The questionnaires were by Thämert France to 12 medical houses in France, and they were invited to participate. Each medical house accepted to send the questionnaires to 20 patients who had been provided with "Silima direct".

154 (64.2%) questionnaires were returned to the medical houses, and for the evaluation of the data these questionnaires were sent to Clinics for Physical Medicine and Rehabilitation, Medical University Hannover. Of the 154 questionnaires 27 (17.5%) were not completely filled out, 12 questionnaires (7.8%) contained inconsistent answers (e.g. at the beginning the patients mentions that she used no other prosthesis before, then she claims that she feels better with this new one). Two patients had used other prosthesis models (model 66320 and/or 66387)

subjected to this study. Finally, in all 113 questionnaires remained for further analyses.

Prostheses

73 of the patients (64.6%) tested the light model 66377 (in short 377) (Figure I A), 40 patients (35.4%) tested the heavier one-layered model 66373 (in short 373). The basic construction of the two models is similar: each is attached to the thorax wall by a removable adhesive pad, which is coated on both sides with medical silicone adhesive; the inner side of the prosthesis is shaped in such a way that it can only be fixed when it fits exactly in the anatomically correct position. Model 377 consisted of both normal and light silicone, in contrast to the model 373 consisting of completely normal silicone.

Questionnaire

The questionnaire was reviewed by an expert commission. Most items were rated on a verbal scale (VRS), and the questions were chosen with regard to comparability with published results[5,8,11-19]. In order to obtain a comparison between different models, particular aspects of comfort and the ease of handling were noted.

Statistics

StatView 4,5 (SAS of institutes, Cary, numerical control) was used for the statistic evaluation of the data. Since VRS evaluation of the items involves interval-scaled variables, these were treated as continuous; they were described by mean value values, standard deviation and the 95% confidence interval. The description of the discrete variables proceeded in form of frequency distribution of individual categories. Statistical group comparison was performed by Mann-Whitney U-test or Chi-square test, and the correlations between continuous variables were investigated by linear regression; the significance level was fixed at $p<0.05$.

RESULTS

The patient profiles of the two groups were comparable except in terms of weight or BMI; the wearers of the lighter model 377 had on average a BMI that was about 2 points higher. After an average interval of 4.5 years between operation and fitting, the prostheses of both groups were – with wide scatter – worn for a mean of just under 2 years.

Evaluation of the Prostheses

The experiences with both models were mainly positive; the average VRS scores were slightly above 2 out of 5 points, i.e. signifying a "good" rating. In most aspects, the model 373 was judged as positive as the model 377; except for the weight (the difference was not clearly evident). According to 80% of the model 377 testers, and to only 63% of the testers, the weight of the prosthesis was ranked as appropriate. The feeling on skin scored better with model 377, around 0.4 points (Table II).

The patients typically wore the prosthesis for 8 or more hours per day, 4–5 days a week. The use and care of the prosthesis were consistently judged positively; in addition, model 377 possessed a significant advantage with an average of 2.4 points, whereas the score for model 373 was "neutral". The adhesive pads have a life of 6–7 months, and the prosthesis was to be cleaned every other day.

The reported satisfaction of the patients was high overall, which means that most of them would probably select the same model again. Model 377 had a slight but significant advantage ($p<0.05$, Table IV). It is worth noting that 'adhesion to the body' scored one-half of a point better with model 377 than with model 373. Since the adhesion system is identical in the two models, this difference in score is attributable solely to the difference in weight between the two prostheses (Table III).

The proportion of 'satisfied' and 'very satisfied' patients was about 75% for the weight-reduced model 377, but in contrast it was only 49% for the traditional model 373; 43% of the patients rated model 373 as only 'moderately satisfactory' (Figure II).

Comparison with earlier prostheses involved only 40 patients who had earlier worn a non-

adhesive prosthesis. A further 35 patients who had worn adhesive prostheses produced by another manufacturer were not taken into consideration in this regard, since information about the construction of the prostheses worn earlier was too vague to allow a rational comparison to be drawn.

Experiences with the adhesive prostheses were generally rated 'better', with the light prosthesis (66377) scoring clearly and in part significantly better in this comparison with non-adhesive earlier models than did the heavier full-gel prosthesis 66373 (Table V).

The difference between the two adhesive models was particularly clear in the assessment of the weight (a difference of 0.95 points), the feeling on the skin (a difference of 0.93 points) and the item 'dependability in public' (a difference of 0.80 points), where in each case nearly a whole scoring category lay between the two models; in these categories, model 66373 represented only a very marginal improvement on the earlier, non-adhesive model, whereas the improvement was clear for model 66377 (Table V).

Overall satisfaction had on the whole also clearly improved in comparison with the non-adhesive earlier model, with model 66377 being distinctly preferred by the patients. 61.9% of the patients were 'more satisfied' or 'very satisfied' with model 66377, but only 50.0% with model 66373. Clearly dissatisfied patients were absent from the group with model 66377, but amounted to 8.3% of the patients with model 66373 (Figure II).

None of the independent variables (age, weight, BMI, duration of wearing, interval between operation and fitting with Silima direct, bra or cup size, and previous fitting with other prostheses) exerted any quantitatively appreciable or statistically significant influence on the satisfaction of the patients.

Table I: Body measures and wearing time¥

	Whole group	Model 377 (n=73)	Model 373 (n=40)	Significance
Age (Years)	58.6±10.1 56.6-60.7	59.0±10.9 56.4-61.5	57.8±8.5 54.9-60.7	p=0.585
Height (cm)	163.0±6.1 161.6-163.9	163.5±6.4 162.0-165.0	161.4±4.6 159.8-163.0	p=0.076
Weight (kg)	63.6±10.3 61.6-65.6	65.9±10.6 63.4-68.4	59.1±8.1 56.4±61.9	p<0.01
BMI	24.0±3.5 23.3-24.6	24.6±3.6 23.8-25.5	22.7±3.1 21.7-23.7	p<0.01
Trial perid of the prosthesis (Months)	21.9±22.1 17.6-26.1	19.4±18.3 15.0-23.7	27.1±28.1 17.3-36.9	p=0.096
Period between OP and care with "Silima direct" (Months)	55.4±80.5 39.9-71.0	52.7±76.4 34.7-70.8	61.1±89.5 29.9-92.3	p=0.620

Table II: Experiences with the "Silima direct"

	Item	Whole group	Model (n=73) 377	Model (n=40) 373	Significance
2.1	Complaints in shoulder-neck-region?‡				
	Yes	32.5	29.3	38.9	p=0.428
	No	67.5	70.7	61.1	
	… since use of "Silima direct"…‡				
	ameliorated	30.9	28.2	37.5	p=0.669
	unchanged	67.3	69.2	62.5	
	worsened	1.8	2.6	0.0	
2.2	Complaints in back-lumbar-region?‡				
	Yes	22.2	19.4	27.8	p=0.461
	No	77.8	80.6	72.2	
	… since use of "Silima direct"…‡				
	ameliorated	17.9	24.0	7.1	p=0.372
	unchanged	82.1	76.0	92.9	
	worsened	0.0	0.0	0.0	
2.3	Sports with the prosthesis‡				
	Yes	64.3	60.0	73.0	p=0.255
	No	35.7	40.0	27.0	
2.4	Lymph edema before use of "Silima direct"? ‡				
	Yes	28.4	30.1	25.0	p=0.737
	No	71.6	69.9	75.0	
2.5	Weight of "Silima direct": ‡				
	too light	0.9	1.4	0.0	p=0.091
	adequate	75.7	80.8	63.9	
	too heavy	23.4	17.8	36.1	
2.6	Symmetry of the upper body¥ (from 1="very good" to 5="never correct")	2.06±0.84 1.911-2.22	2.11±0.89 1.90-2.31	1.97±0.74 1.72-2.22	p=0.427
2.7	Feeling on the skin¥ (from 1="very comfortable" to 5="very uncomfortable")	2.39±0.82 2.23-2.55	2.23±0.86 2.06-2.47	2.63±0.69 2.39-2.87	**p<0.05**
2.8	Safety in publicity¥ (from 1="very safe" to 5="never safe")	2.09±0.94 1.91-2.26	2.05±0.96 1.83-2.27	2.16±0.90 1.86-2.46	p=0.565
2.9	„Forget" the prosthesis¥ (from 1="almost always" to 5="almost never")	2.26±1.21 2.03-2.49	2.23±1.25 1.94-2.51	2.33±1.15 1.95-2.72	p=0.666
2.10	Change in the quality of the life¥ (from 1="great improvement" to 5="evident worsening")	2.35±0.75 2.21-2.50	2.30±0.83 2.11-2.50	2.44±0.56 2.26-2.63	p=0.369

Table III: Evaluation of the use and care.

Item		Whole group	Model 377 (n=73)	Model 373 (n=40)	Significance
3.1	Application¥ (from 1=very good" to 5="very complicated")	2.18±0.93 2.01-2.36	2.12±0.94 1.91-2.34	2.31±0.90 2.01-2.62	p=0.312
3.2	Adhesion on the body ¥ (from 1=very good" to 5="highly insufficient")	2.60±1.16 2.38-2.837	2.43±1.08 2.17-2.70	2.94±1.25 2.50-3.38	**p<0.05**
3.3	Wearing time (days per week) ¥	4.62±2.42 4.12-5.11	4.65±2.38 4.05-5.25	4.55±2.53 3.62-5.48	p=0.848
3.4	Wearing time (hours/day)‡				
	less than 2	9.0	6.0	15.2	
	about 2	5.0	4.5	6.1	
	about 4	5.0	6.0	3.0	p=0.428
	about 6	13.0	16.4	6.1	
	about 8	15.0	11.9	21.2	
	over 8	53.0	55.2	48.5	
3.5	Adhesion pad replaced after… (Months) ¥	6.73±6.30 4.95-8.50	7.22±7.27 4.60-9.84	5.90±4.24 3.85-7.94	p=0.473
3.5	Cleaning … times per week¥	3.51±2.18 3.08-3.93	3.42±2.15 2.90-3.94	3.67±2.24 2.91-4.43	p=0.584
3.7	Cleaning practice ‡				
	easy	91.5	94.3	86.1	p=0.288
	difficult	8.5	5.7	13.9	

Table IV: Satisfaction with the prostheses.

Item		Whole group	Model 377 (n=73)	Model 373 (n=40)	Significance
4.1	General satisfaction ¥ (from 1="very satisfied" to 5="very dissatisfied")	2.28±0.86 2.11-2.44	2.13±0.86 1.92-2.33	2.57±0.80 2.30-2.84	**p<0.05**
4.2	Would use the "Silima direct" again¥ (from 1="for sure " to 5="not sure")	2.23±1.28 1.98-2.47	2.08±1.24 1.79-2.38	2.53±1.31 2.07-2.99	p=0.093

¥ mean value ± standard deviation, 95%-confidence interval for the average value

Table V: Experience with the 'Silima direct' in comparison with non-adhesive prostheses previously worn.

Item	Whole group (n=40)	Model 377 (n=24)	Model 373 (n=16)	Significance
Sports with the prosthesis?‡				
improved	60.0	66.7	50.0	
unchanged	28.0	13.3	50.0	p=0.076
worsened	12.0	20.0	0.0	
Lymph edema‡				
improved	27.3	37.5	0.0	p=0.580
unchanged	72.7	62.5	100.0	
worsened	0.0	0.0	0.0	
Weight¥				
(from 1="much comfortable" to 5="much uncomfortable")	2.28±1.00 1.94-2.62	1.91±0.87 1.52-2.29	2.86±0.95 2.31-3.41	**p<0.01**
Symmetry of the upper body¥ (from 1="much better" to 5="much worsened")	2.32±0.96 2.00-2.63	2.17±0.96 1.76-2.57	2.57±0.94 2.03-3.11	p=0.215
Feeling on the skin¥ (from 1="more comfortable" to 5="more uncomfortable")	2.21±1.01 1.82-2.59	2.00±1.00 1.52-2.48	2.60±0.97 1.91-3.29	p=0.132
Safety in publicity¥ (from 1="great progression" to 5="much diminishment")	2.32±1.16 1.94-2.71	2.00±1.16 1.49-2.51	2.80±1.01 2.24-3.36	**p<0.05**
„Forget" the prosthesis¥ (from 1="great improvement" to 5="evident worsening")	2.22±0.96 1.90-2.55	2.00±0.95 1.59-2.41	2.62±0.87 2.09-3.14	p=0.064
Change in the quality of the life¥ (from 1="great improvement" to 5="evident worsening")	2.17±0.86 1.88-2.47	2.09±0.90 1.70-2.48	2.33±0.78 1.84-2.83	p=0.428

¥ mean value ± standard deviation, 95%-confidence interval for the average value; ‡ Portion into % 5: Experiences with the Silima does not direct compared with before carried responsible prostheses

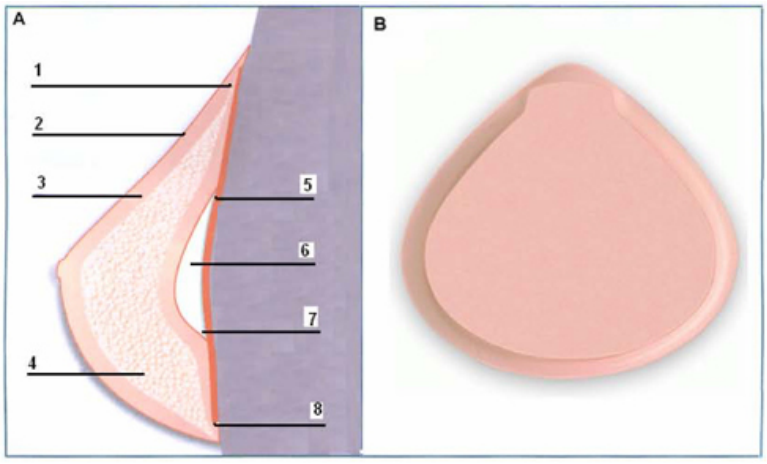

Figure I: A: Half schematic sectional view of the "Silima direct", model 66377. (1) Flat moulding of the adhesive pads in the upper region, (2) Matte outer layer, (3) Normal-Silicone, (4) Light silicone core, (5) Adhesive pad for the safe placement of the prosthesis, (6) Cavity for the natural swinging vibration property, (7) Non-adhesive region of the adhesive pad for optimal fit (8) Specially shaped inner surface for precise positioning of the adhesive pad. B: Removable adhesive pad and prosthesis, view from the thorax side.

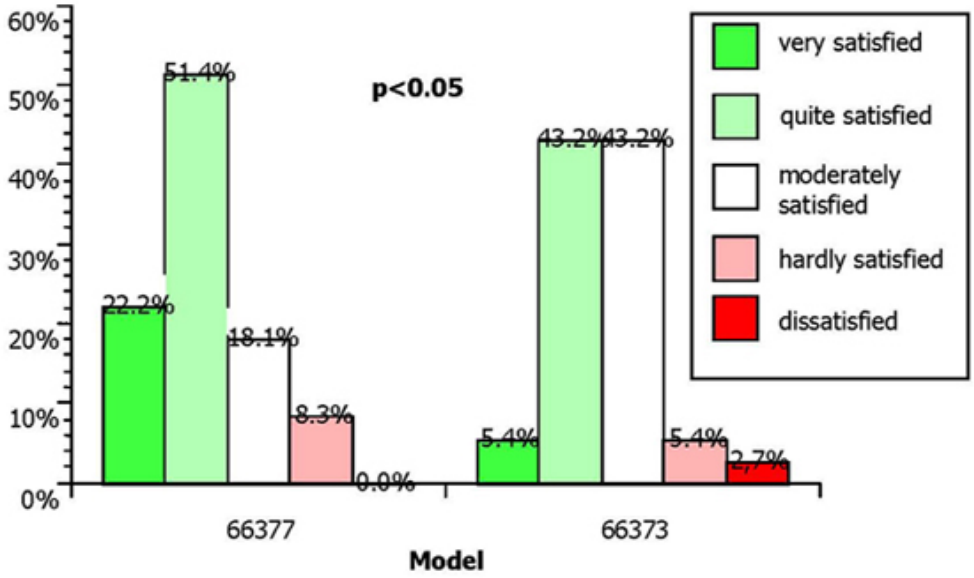

Figure II: Proportion of the scores of satisfaction as related to the prosthesis model.

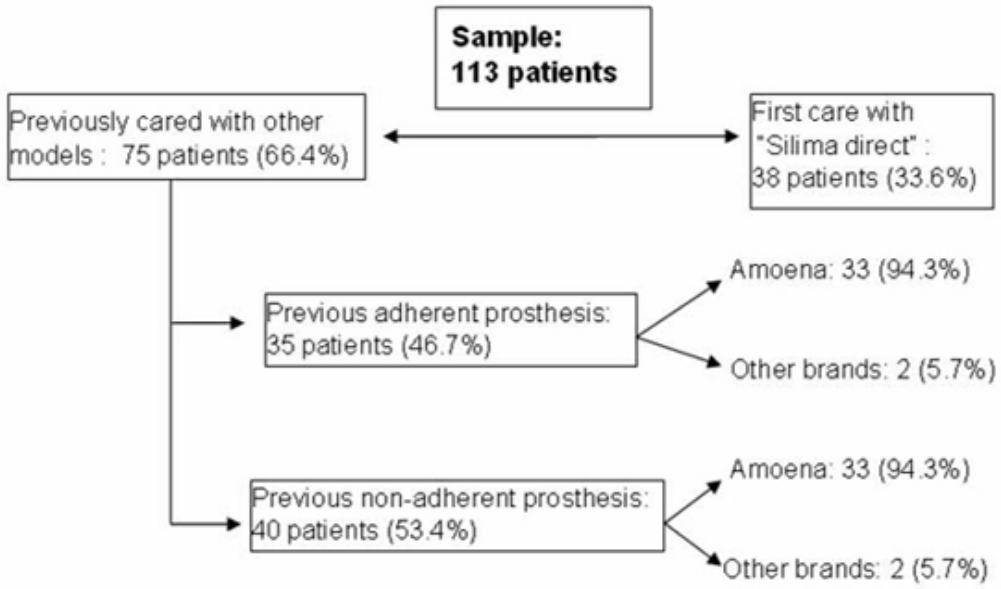

Figure III: Distribution of patients who had used prostheses models other than "Silima direct".

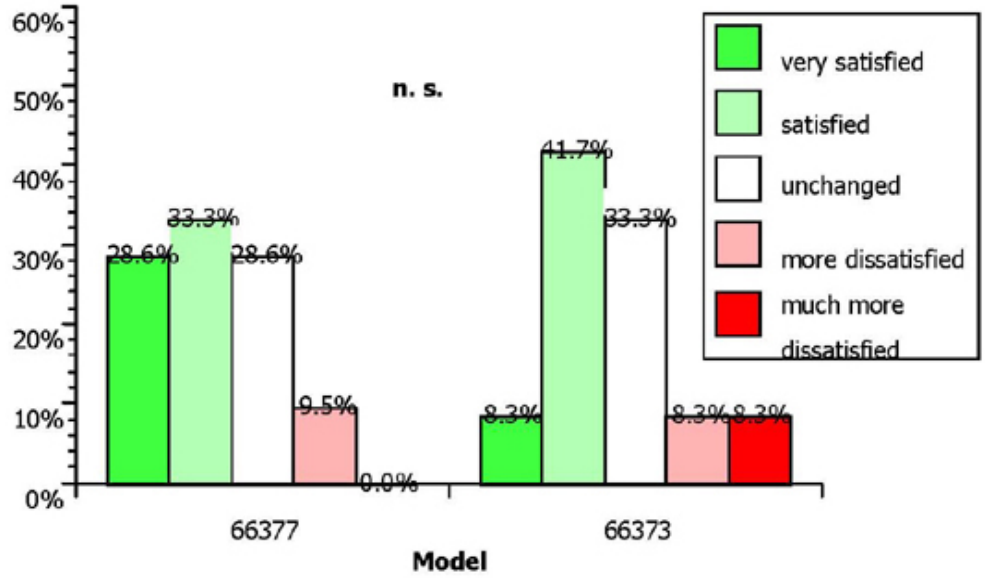

Figure IV: Proportions of the evaluations of the satisfaction with the two models of the "Silima direct" in comparison with a previously carried not responsible prosthesis (n=40)

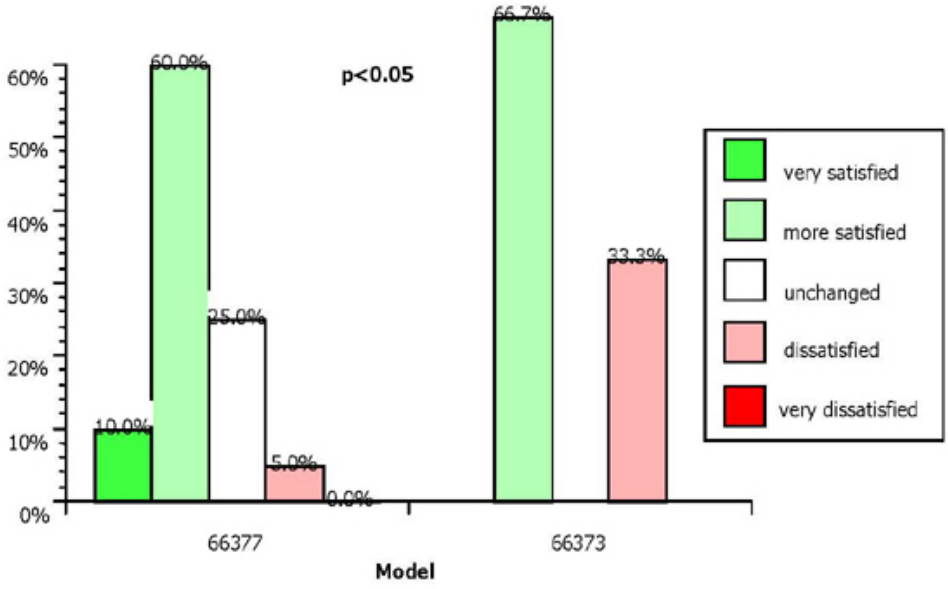

Figure V: Proportions of the evaluations of the satisfaction with the "Silima direct" comparison with the Amoena adhesive prosthesis (n=33)

DISCUSSION

In the present study, it could be shown that the development of the "Silima direct" prosthesis targeting reduction in weight has raised the satisfaction of the patients with an adhesive prosthesis significantly. Also, compared with the formerly used prostheses by other manufacturers, the improvement has been clearly obtained and proved to be better. Therefore, for women who decide against a surgical reconstruction after mastectomy, sufficient non-invasive rehabilitation options are available, which permits prominent improvement in the quality of life permitting daily activities in the public. It is worth noting that the overall satisfaction of the patients with the reduced-weight model 66377 corresponds almost exactly to that reported by McCormick et al. (1989) for patients after radiation therapy and a subsequent breast-conserving operation; also, the proportion of patients in that study who 'forgot' the affected breast during daily activities was no higher than in the present investigation[20]. Also, in direct comparisons of women who had undergone a surgical reconstruction with those who had been fitted with prostheses there were no conclusive[8,17] or lasting[21] differences with respect to body image and psychological sensitivities. Nissen et al. (2001) described even a stronger adverse psychological effect[22] in patients after reconstruction due to the disappointments about their aesthetic expectations from the operation[23]. The very question of psychological damage to the patient through the mastectomy itself is debatable[8]; however, it seems certain that fitting with an adhesive prosthesis is judged overall as positive from the point of view of the patients[8,11]. This is fully supported by the results of the present investigation, especially for the lighter 'Silima direct' model. A more strongly adverse effect among patients under 65 years old, on which Korvenoja et al. (1998) had based a general recommendation for surgical reconstruction for this age group[14,] was not supported by the results of the present study.

In an investigation by Thijs-Boer et al. a cross-over comparison between adhesive and non-adhesive prostheses showed a clear advantage for the adhesive prosthesis. Although in the first treatment phase, the patients scored both systems the same (positively), after the change-over between the two study groups the patients who at first had worn an adhesive prosthesis were subsequently markedly less satisfied with the non-adhesive model[19].

It is necessary to consider whether fitting with a new model will be scored positively as a result of a self-fulfilling expectation; however, two results suggest that this is not the case: The middle stretcher duration of the prosthesis usedØ at present amounted to altogether scarcely 2 and for the lighter model 66377 over 1.5 years, so that such an effect would have itself already "used up". Secondly, there was not a systematic negative correlation between satisfaction and stretcher duration, also not in the sense of a trend (Spearman' s R=0.09; p=0.371).

Compared with the earlier prostheses, which had been previously investigated, the results of the present study demonstrate a substantial progress. For example, in an investigation of an adhesive prosthesis manufactured by the Amoena company, Münsted et al. (1998),[5,] reported problems with the adhesive function in 50% of the cases; in the present investigation such problems were mentioned by only 21.8% of the total number of patients and only 16.4% of those fitted with the reduced-weight Silima direct model (66377). Adhesive function is one of the substantial criteria that determine the satisfaction of the patients with a self-adhesive prosthesis[15].

If such positive results are to be achieved, the development of a well thought-out service must be supported by individualized and expert on-the-spot guidance by the staff of the clinics. As well as tests of morphological requirements for the customizing of an adhesive prosthesis – e.g. the absence of marked unevenness in the surface profile, perhaps after removal of the M. pectoralis

major – and other factors that impede the fixing of the prosthesis by means of an adhesive system (e.g. frequent outbreaks of sweating in menopausal patients, problems with digital dexterity in arthritis or dislike of seeing and disturbing the scar[13]), it is imperative that the patient be informed about the advantages and disadvantages of different models; the results reported by Roberts et al. establish the key function of the person entrusted with fitting and advising the patient if prosthetic care is to have optimum results[18].

The result of the present investigation shows in addition – in terms of the difference between the two variants of the 'Silima direct', 373 and 377, and also the contrast with earlier used models from other manufacturers – the substantial improvement of the construction that has been developed as a result of the dialogue between manufacturer, breast clinic and patients. From the patterns emerging from evaluations it can be deduced that the parameters like weight, kindness to the skin and adhesion have an extremely prominent role[15,16,] and that this has led to a very satisfactory overall finding for the reduced-weight model. Also, these attributes were scored negatively in earlier investigations of adhesive prostheses[5,13].

In weighing up the various methods of rehabilitation, an advantage of the adhesive prosthesis is that further surgical procedures and, where necessary, the implantation of allogenous material can be avoided. On the one hand, the fear and concerns about additional operations are one of the main reasons of women to reject the surgical reconstruction[7,10]. Besides, even still today, the controversy about possible unfavorable effects of silicon-based breast implants on health could not be fully excluded[24-27].

Thereby, avoidance of surgical breast reconstruction is a proper decision for many patients; since there are primary concerns about aesthetic-surgical measures[7,] it is particularly important to reach a 'strategic' decision about the later method of rehabilitation before the mastectomy takes place[10]. Therefore, informing the patients about the possibilities of adhesive prosthesis options and their specific advantages and disadvantages compared with the operational reconstruction, should be a regular component of the interdisciplinary care for the patients with mammary carcinoma.

CONCLUSION

For many patients, wearing an adhesive prosthesis is a very valuable rehabilitation method after mastectomy and it can considerably increase the quality of life. At present available models can be very differently evaluated; with the personal advice and selection of appropriate prosthesis models a high measure of quality of life can be recovered for many women. The development of the weight-reduced model 66377 "Silima direct" is also welcomed by the users in France, and in comparison with the earlier products, this prosthesis is considered as an improvement. This suggests not only the fact that all surveyed women would purchase one of these prostheses in the future, but also their choice will certainly be the lighter model, 66377 from the "Silima direct" series.

The further developments in external prostheses should be based on the opinions of the patients; the comparison between traditional non-adhesive and adhesive models, as well as between normal-weight and reduced-weight models, clearly shows that the further progress is to be achieved by this means.

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