

Accordion: A Useful and Workable Classification of Complications After Breast Reconstructive Surgery

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Accordion : une classification utile et réalisable des complications après une chirurgie mammaire reconstructive

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Abstract

Background: The aim of this study was to evaluate whether Accordion Severity Grading System can serve as a tool for classification, and severity assessment in reporting postoperative complications after breast reconstructive surgery. **Methods:** A retrospective analysis covered 88 breast reconstruction surgeries following mastectomy and prophylactic breast amputation with simultaneous reconstruction conducted from January 2015 to December 2017. All registered postoperative complications were evaluated using the Accordion Severity Grading System. The time horizon selected was 6 weeks after surgery. **Results:** Eightytwo adverse events which met the criteria for complications according to the Accordion classification were observed in 53.4% (n = 47) of the patients. The highest percentage of complications was observed in the group where reconstruction involved using autologous tissues (pedicled transverse rectus abdominis myocutaneous), which were associated with 77.4% risk of complications. In patients with combined methods (latissimus dorsi + prosthesis), complications occurred in half of the cases (51.4%). In patients who underwent reconstructive procedures with artificial materials (expander/prosthesis), complications occurred in 20% of cases. A high γ correlation coefficient of 0.7 (P < .001) was observed between the Accordion degree assigned to the patient and the length of hospital stay. A moderately strong correlation was found between the degree of Accordion system and rehospitalization rate (r = 0.54; P < .0001) and cost of hospital care (r = 0.65; P < .001). **Discussion:** Based upon the presented study, Accordion Severity Grading System is a workable, intuitive and universal scale for classifying and assessing the severity of postoperative complications and may be recommended for documenting complications in breast reconstructive procedures.

Résumé

Historique : La présente étude visait à établir si le système de classement de la gravité Accordion peut servir d'outil de classification et d'évaluation de la gravité pour signaler les complications postopératoires après une chirurgie mammaire reconstructive. **Méthodologie :** Les chercheurs ont effectué l'analyse rétrospective de 88 chirurgies de reconstruction mammaire après une mastectomie et une amputation mammaire prophylactique accompagnée d'une reconstruction simultanée, effectuées entre janvier 2015 et décembre 2017. Ils ont évalué toutes les complications postopératoires consignées au moyen du système de classement de la gravité Accordion. L'horizon prévisionnel était de six semaines après l'opération. **Résultats :** Les chercheurs ont observé 82 événements indésirables qui respectaient les critères de complications chez 53,4 % (n = 47) des patients d'après le classement Accordion. Le plus fort pourcentage de complications était observé dans le groupe chez qui la reconstruction était effectuée avec des tissus autologues (le muscle grand droit abdominal pédiculé musculocutané), qui était associé à un risque de complications de 77,4 %. Lorsque les méthodes étaient combinées (grand dorsal + prothèse), des complications se produisaient dans la moitié des cas (51,4 %). Les patients chez qui l'intervention reconstructive était effectuée à l'aide de matériau artificiel (extenseurs et prothèse) présentaient des complications dans 20 % des cas. Les chercheurs ont observé un fort coefficient de

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corrélation γ de 0,7 (P < 0.001) entre le degré Accordion attribué au patient et la durée du séjour hospitalier. Ils ont constaté une corrélation modérément forte entre le degré du système Accordion, le taux de réhospitalisation (r = 0.54; P < 0.0001) et le coût des soins hospitaliers (r = 0.65; P < 0.001). **Discussion :** D'après la présente étude, le système de classement de la gravité Accordion est une échelle universelle applicable et intuitive pour classer et évaluer la gravité des complications postopératoires. Il peut être recommandé pour consigner les complications lors d'interventions de reconstruction mammaire.

Keywords

breast reconstruction, complications, Accordion classification

Introduction

Postoperative complications are a key parameter in assessing the results of surgical procedures. So far, no uniform, standardized system of their classification has been developed. In the literature, complications are usually divided based on their type (bleeding, postoperative wound infection, etc) or broadly defined severity (light, medium, and severe). The need for a more objective system leads to the development of T92 classification in Toronto in 1992¹ and its later modifications—Clavien-Dindo² and Accordion Severity Grading System (ASGS).³

As intended by the creators of the Accordion system, not all adverse events occurring in the postoperative period should be deemed complications. They are divided into complications, sequelae of a procedure, and failure to cure. Accordion is a 4-or 6-grade scale, thanks to which it can be adapted to the needs of a study. The 6-grade scale separates severe complications into 3 different grades. This allows for more transparent research in the case of procedures with a higher risk of serious complications.

The Postoperative Morbidity Index (PMI) is an Accordion-based method of estimating the burden of complications for a given procedure.⁵ By assigning weight of complications as a measurable numerical value for each of the 6 grades of the extended Accordion scale, a method for quantifying the severity of postoperative complications was developed. Dividing the total burden of all complications in a given population, subjected to one procedure, by the number of patients allows to calculate PMI, and thus gives the procedure a numerical value of this burden (presented in the range from 0 to 1, eg, 0.145).

Methods

We conducted a retrospective analysis of patients undergoing delayed breast reconstruction and prophylactic breast amputation with simultaneous reconstruction from 2015 to 2017 at the Department of Plastic Surgery of tertiary care centre. The study protocol was approved by an Independent Bioethics Commission for Research. Electronic and paper documentation was the basis for developing an Excel 2007 (Microsoft) database of patients. The database contained basic information on the characteristics of patients, data on comorbidities, type of surgery, cost of hospital care, and all adverse events which occurred in the postoperative period as well as data on treatment and subsequent follow-up at the outpatient clinic. The definitions of complications were based on the The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP)

dictionary⁶ and the Common Terminology Criteria for Adverse Events (CTCAE v5.0).⁷ The time of postoperative complication is within 6 weeks from the date of surgery.

All recorded postoperative complications were evaluated independently by 2 researchers and assigned an appropriate degree according to the contracted and expanded version of the Accordion system. The compliance rate of the assignment by 2 researchers was 92.05%. All discrepancies between the 2 reviewers were discussed, checked, and reevaluated by the team. In the next step, all patients were assigned to the appropriate group on the Accordion system, by the highest ranking complication if there was more than 1. In women who underwent more than one breast reconstruction procedure, each procedure was considered as a separate event.

The total weight of complications for the different reconstruction methods (autologous, combined, alloplastic) was derived by summing the burden of the most severe complications in every patient. Postoperative Morbidity Index was calculated by dividing the total weight of complications by the number of patients undergoing the procedure. The PMI indicates the mean weight of the procedure for all patients, regardless of whether they had a complication or not. A PMI of zero would indicate that no patient had postoperative complications, while a PMI of 1.000 would indicate that each procedure performed was fatal.

$$PMI = \frac{\sum_{k=1}^{n} a}{n}$$

n, number of patients in the sample; a, burden of the most severe complication that occurred in each patient.

The mean burden of patients with complications was calculated by dividing the total weight of complications by the number of patients who developed a complication. This value shows the severity of the procedure in patients with a complication. In other words, it indicates the expected severity of the complication, if it does occur.

Statistical analyses were conducted with the use of tools available in the STATISTICA 13.1 (TIBCO Software), Spearman correlation test was used and P < .05 was considered statistically significant.

Results

In the years 2015 to 2017, 81 women underwent 88 breast reconstruction surgeries at the department of origin of this study. The range of surgical techniques encompassed

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Table I	Distribution (of All Registered	1 Complications	in the Accordion	Contracted and	Expanded Scale
I able I		OI VII IVESISCELE	i Combilications		i Contracted and	LADAHUEU SCAIE.

			Contracted					Expanded					
Complication		n	ı	2	3	4	I	2	3	4	5	6	
Surgical site complications	Superficial SSI (Surgical side infection)	3	0	3	0	0	0	3	0	0	0	0	
	Deep SSI	4	0	0	4	0	0	0	0	4	0	0	
	Tissue venous congestion	5	5	0	0	0	5	0	0	0	0	0	
	Wound dehiscence	3	2	- 1	0	0	2	I	0	0	0	0	
	Skin edge necrosis	9	5	0	4	0	5	0	3	- 1	0	0	
	Flap necrosis	8	2	0	6	0	2	0	2	4	0	0	
	seroma	9	9	0	0	0	9	0	0	0	0	0	
	Hematoma	5	4	0	- 1	0	4	0	0	I	0	0	
	Haemorrhage	14	0	14	0	0	0	14	0	0	0	0	
Systemic complications	Constipation	2	2	0	0	0	2	0	0	0	0	0	
,	Hypouresis	2	2	0	0	0	2	0	0	0	0	0	
	Urinary retention	1	- 1	0	0	0	1	0	0	0	0	0	
	Electrolyte imbalance	6	6	0	0	0	6	0	0	0	0	0	
	pneumonia	5	- 1	4	0	0	1	4	0	0	0	0	
	Fever	5	4	ı	0	0	4	- 1	0	0	0	0	
	Pulmonary embolism	i	0	0	Ĺ	0	0	0	0	0	i	0	
	Total	82	43	23	16	0	43	23	5	10	İ	0	

reconstruction using autologous abdominal tissues—pTRAM (pedicled transverse rectus abdominis myocutaneous flap; n = 31), including flaps with additional microsurgical anastomosis of the lower epigastric vessels with the thoracic vessels—pTRAM supercharged (n = 22), reconstructions with LD flap (pedicled latissimus dorsi flap) with silicone prosthesis (n = 37), tissue expander implantation (n = 6), and final prosthesis (n = 14), including one procedure in which the implant was covered with synthetic titanium mesh. In 78 cases, delayed reconstruction surgery was performed after complete mastectomy due to cancer, and in 10 cases, prophylactic breast amputation surgery was performed in breast cancer susceptibility gene (BRCA) gene carriers and involved simultaneous reconstruction. All procedures were conducted by an experienced surgical team under the supervision of the senior author. The mean age of patients was 51 \pm 9.91 years, average body mass index 27 \pm 4.26, and the average length of hospital stay (LOS) was 7.62 ± 7.2 days. The time of hospitalization was the total number of days of all hospital stays of a patient, including those related to the treatment of complications.

Complications by Type

In total, we observed 82 adverse events which met the Accordion complication criteria in 53.4% (n = 47) of patients. A single complication was observed in 23.86% (n = 21) patients, 2 complications occurred in 21.59% (n = 19), 3 in 6.82% (n = 6), and only 1 patient had 5 complications simultaneously. In almost half of the cases (46.59%; n = 41), no complications were observed within 6 weeks of surgery. In the contracted Accordion classification, 15 (17%) patients were qualified as the first grade, 16 (18.2%) as the third grade. No patient died. On the expanded scale, 15 (17%) patients were qualified as the first grade, 16 (18.2%) as

the second grade, 5 (5.7%) as the third grade, 10 (12.5%) as the fourth grade, and 1 (1.1%) as the fifth grade. It should be noted that the first and second grades of the contracted and the expanded versions do not differ, while the highest (the fourth in the contracted version and the sixth in the expanded version) correspond to the death of the patient.

Seroma (n = 9; 10.98% of all complications) was the most common type of grade 1 complication. The most common reason for which patients were assigned to the group of grade 2 complications was bleeding requiring the transfusion of blood products (n = 14; 17.07%). On the contracted scale, the most common grade 3 complication was flap necrosis (n = 6; 7. 32%). On the expanded scale, the most common type of grade 3 complication was skin edge necrosis (n = 3; 3.66%). Flap necrosis (n = 4; 4.88%) and deep wound infection (n = 4; 4.88%), resulting in the need for reoperation of the patient under general anaesthesia, were main reason for which patients were classified as grade 4 complications on the expanded scale. In the studied group of patients, there was only 1 grade 5 complication, in the form of pulmonary embolism requiring a stay in the intensive care unit (ICU). The classification and distribution of all registered complications in the Accordion contracted and expanded scale is presented in Table 1.

Autologous Versus Implant

In terms of the reconstruction technique used, the highest percentage of complications was observed in the group post reconstruction with autologous tissues (pTRAM), which had a 77.4% risk of complications. This group of patients also had the highest percentage of severe complications (37.5% of all complications were classified as severe; n=9). Complications occurred in half of the cases (51.4%) which involved using combined methods (LD + prosthesis). In patients who underwent

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Table 2. Distribution of Complications Classified According to the Accordion System Depending on the Type of Reconstruction Used, With a Detailed Breakdown into Specific Methods and Time of Performance.^a

		Autologous methods		Combine	d methods	Alloplastic methods			
Accordion Severity Grading		pTRAM n ¹ = 9	pTRAM superch. n ¹ = 22	LD n ¹ = 28	Prophylactic amputation + LD n ¹ = 9	Tissue expander $n^{I} = 6$	Prosthesis $n^1 = 13$	$\begin{array}{c} \text{Prophylactic} \\ \text{amputation} + \\ \text{prosthesis} + \text{titanium} \\ \text{mesh} \\ \text{n}^{\text{I}} = \text{I} \end{array}$	
Contracted	Non	3	4	17	I	4	12	-	
Accordion	- 1	-	7	4	3	-	I	-	
Classification	2	2	6	4	3	I	-	-	
	3	4	5	3	2	I	-	Į	
	4	-	-	-	-	-	-	-	
Expanded	Non	3	4	17	I	4	12	-	
Accordion	- 1	-	7	4	3	-	1	-	
Classification	2	2	6	4	3	I	-	-	
	3	-	3	-	1	I	-	-	
	4	3	2	3	1	-	-	1	
	5	I	-	-	-	-	-	-	
	6	-	-	-	-	-	-	-	
% of complications		$66.7 (n^2 = 6)$	$81.8 (n^2 = 18)$	39.3 $(n^2 = 11)^2$) 88.9 $(n^2 = 8)$	$33.3 (n^2 = 2)$	$7.7 (n^2 = 1)$	$100 (n^2 = 1)$	
Total weight of complications ^b			7.75		.36		34	, ,	
PMI ^b		0.	250	0.	145	0.0)67		
Mean burden of patients with complications ^b			322		282		335		

Abbreviations: LD, latissimus dorsi; PMI, Postoperative Morbidity Index; pTRAM, pedicled transverse rectus abdominis myocutaneous.

Table 3. Average Total Time of Hospitalization of Patients Depending on Accordion Grade and Treatment Cost Ratio of Patients Without Complications to Patients With Different Grades of Complications.

Contracted Accordion system	Average total number of days of hospitalization	Average cost ratio	Expanded Accordion system	Average total number of days of hospitalization	Average cost ratio
No complications	4.46	I	No complications	4.46	I
1	6.13	1.2	i	6.13	1.2
2	7.75	1.4	2	7.75	1.4
3	17	2.5	3	7	1.3
4	-	-	4	22.2	3
			5	15	2.8
			6	-	

implant-based reconstructions (expander/prosthesis), complications occurred in 20% of cases. The distribution of patients classified by the type of surgery performed is presented in Table 2. Complications were most frequently observed in the group of patients who underwent prophylactic subcutaneous mastectomy due to BRCA mutation with simultaneous reconstruction with a prosthesis coated with titanium mesh (100%; n=1) and a prosthesis covered with latissimus dorsi (88.9%; n=8). Delayed breast reconstruction with autologous tissues—a pTRAM flap—was associated with 66.7% (n=6) risk of developing complications, which increased to 81.8% for pTRAM flaps with additional microsurgical anastomosis

(n = 18). The relatively lowest risk of developing complications in the group of procedures which involved the use of autologous tissues was associated with transposition of latissimus dorsi muscle (39.3%; n = 11). Reconstruction procedures involving tissue expander and final prosthesis were associated with 33.3% (n = 2) and 7.7% (n = 1) risk of developing complications, respectively.

Postoperative Morbidity Index

The total burden of complications in the entire group was 14.45 points, of which minor complications, accounting for one-third

^aTotal weight burden, PMI, and mean burden of patients with complications calculated for different types of reconstructive methods (autologous, combined, and alloplastic). n¹, number of procedures carried out; n², number of procedures with complication.

^bBased on Porembka et al (2010).⁵

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of all observed complications, were responsible only for 11.4% of the burden (1.65 points). In contrast, severe complications, accounting also for one-third of all complications, were responsible for 60% of the total burden (8.64 points). Calculations of *total burden*, PMI and *mean burden of patients with complications*, categorized by different methods of breast reconstruction (autologous, combined, and alloplastic) are presented in Table 2.

Length and Cost of Hospital Stay

The mean hospitalization time was 7.62 + 7.2 days. We calculated the correlation between the Accordion grade assigned to the patient and the LOS. A high γ 0.7 correlation coefficient (P < .001) was obtained for both the contracted and the expanded versions. In the contracted version, patients with grade 1, 2, and 3 complications statistically spent 1.67, 3.29, and 12.54 more days on average in the hospital, respectively, compared to average hospitalization time of patients who had no complications (4.46 days). In the expanded version, grades 1, 2, 3, 4, and 5 were associated with 1.67, 3.29, 2.54, 17.74, and 10.54 days more, respectively. Table 3 shows the average total time of hospitalization depending on the Accordion grade as well as an average treatment cost ratio of patients with complications to patients without complications. The analysis of Spearman's rank correlation coefficient showed a positive dependence between the incidence and severity of complications and the cost of hospital care (r = 0.65; P < .001).

Readmission rate due to complications with ASGS was compared with the use of Spearman rank correlation, showing a moderately strong correlation (r=0.54; P<.0001) in both the contracted and the expanded version.

Discussion

Despite the fact that hundreds of thousands of surgical procedures are performed everyday in the world, there is no agreement as to what actually constitutes a complication. Attempting to define complications as a negative result or any deviation from the normal postoperative course leaves considerable room for interpretation. The lack of an unambiguous definition and universally accepted system of classification of postoperative complications makes it difficult to adequately interpret the results.

An ideal classification system should be simple, intuitive, objective, universal, and repeatable. Until now, the Accordion classification system has been used mainly in general surgery, 8-10 urology, 11 and gynaecology. 12-17 Although the Accordion system has not been studied for application in breast reconstruction surgery before, it was successfully adapted for the needs of plastic surgery in carpal tunnel surgery. 18 Noszczyk also proposes to use the discussed scale in aesthetic surgery procedures. 19,20

The presented work is the first published report on the use of the Accordion system to assess the results and classify postoperative complications of breast reconstructive surgery. This scale can be universally applicable as a tool which can be adapted to any type of surgery rather than a specific complication. In the course of treatment, not all complications and adverse events which occurred after the surgery are always accurately documented. The actions taken to correct these events are more consistently reported. Because the Accordion system classifies complications on the basis of interventions, it works well in retrospective studies involving documentation analysis. Even if there is no description of a complication, it is not only possible to deduce its occurrence from the course of treatment but also to classify it.

In our study, complications were recorded in 53.4% of cases. What should be noted is the heterogeneity of the examined group in terms of the magnitude of procedures. Breast reconstruction with expanders or implants significantly differs from pedicled or free-flap reconstructions. More complex and longer procedures are associated with a higher risk of complications. In addition, each type of surgery is associated with a different profile of complications. For example, deep tissue infection in reconstructive procedures with synthetic prostheses is most often associated with necessary reoperation and removal of the implant, while in the case of flap infection, conservative antibiotic therapy may be attempted. The heterogeneity of the procedures in the study provides material for the analysis of Accordion system used in different types of reconstructive operations. Nevertheless, it can also be a bias due to the small cohort of patients.

The greatest risk of developing complications was associated with breast amputation with simultaneous LD flap reconstruction (88.9%) and reconstruction surgery with a pTRAM flap with microsurgical anastomosis (81.8%). The lowest incidence of postoperative complications was recorded in the case of procedures with the use of tissue expander (33.3%) and final prosthesis (7.7%). These results coincide with presented in the relevant literature.²¹ A significant proportion of complications are mild (first grade in ASGS). They accounted for more than half of all registered complications (52.4\%; n = 43). However, only 15 (17%) patients had only one such complication and they were classified as the group of patients with mild complications. In our opinion, grade 1 complications are an important factor which underlies a high total percentage of complications. They usually do not require immediate and complicated therapy, but they affect the overall postoperative course. A definite downside of the Accordion system is the omission of milder complications if a patient has more than one complication. Only the most severe complication is taken into account, thus neglecting the impact of the others on the duration of hospitalization and the cost of patient care. This limitation is also acknowledged by other authors who recommend the use of system.²² In our study, as many as 26 (29.5%) surgical procedures were associated with more than one complication.

In the study population, the PMI was 0.250 for autologous reconstructions, 0.067 for implant-based reconstructions, and 0.145 for combined methods. This means that the greatest risk of postoperative complications or their more severe course was related to pTRAM procedures, and the lowest to alloplastic reconstructions. Postoperative Morbidity Index calculations

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are consistent with the analyses presented earlier. The PMI index veritably reflects the risk of complications associated with a given procedure. Additional information provided by the presented calculations is the mean burden of patients with complications, which was 0.322 for autologous reconstructions, 0.335 for alloplastic, and 0.282 for combined reconstructions. It tells us how severe the complications associated with a given surgical procedure will be, if they occur. This indicates that in patients who have undergone reconstruction with an implant, the risk of developing complications is relatively small compared to other surgical techniques (PMI = 0.067); however, if they do occur, they have a heavy weight, comparable to that in the autologous reconstruction group (0.322 vs 0.335). These patients can expect a severe course of complications. On the other hand, patients who underwent LD reconstruction had a moderate risk of developing complications (PMI = 0.145) compared to other reconstructive techniques, and the burden of complications was lower compared to other procedures (0.282). Presented results reflect the significant impact of higher grade complications. Although mild and moderate complications accounted for two-thirds of all complications in the entire group, they were responsible for only 40% of the total burden. In turn, severe complications were responsible for 60% of the burden.

In their work, Strasberg and Hall present PMI results for various procedures in general surgery. Some procedures, such as inguinal hernia surgery (PMI = 0.005) or appendectomy (PMI = 0.031), despite the generally low PMI, and thus a low risk of developing complications and their severe course, showed a high *burden in patients with complications* (0.345 for hernias and 0.365 for appendectomy). This could be concluded that while these procedures for the general population are rather safe and have low surgical risk, when complications do occur, they might be potentially severe. The correction of carpal tunnel syndrome is associated with a PMI of 0.014 with a *burden of patients with complications* of 0.122. ¹⁸

Postoperative Morbidity Index, and the burden of patients with complications, is a simple and fast way of assessing the risk of complications and their burden in a given procedures, without the need to perform complex calculations. As a result, both can be easily used in everyday surgical practice to reliably determine to what extent patients undergoing a given procedure might expect a certain frequency of complications, and how much those complications will be burdensome for the patient. Therefore, the PMI seems to be a good tool for comparing one's own results and complications between procedures in a given centre. Consequently, it may facilitate the patient's decision to undergo reconstructive surgery and the preferred surgical technique.

The LOS is a widely used criterion for assessing treatment results. The presented study showed a high correlation between the Accordion grade and LOS. Severity grading also was in correlation with the cost of hospitalization, showing more than 3 times higher cost of care in patients with grade 4 complications (extended Accordion) compared to patients without complications. Therefore, Accordion system can be a useful tool in

analysing the correlation of the severity of postoperative complications with LOS and the cost of patient care.

In the study, 18\% of patients were classified as cases of severe complications. This corresponds to 3 on the contracted scale and 3 to 5 on an expanded scale. It is a considerable part of the study group, and the range of the severity of these complications is significant. This group includes patients who needed, among the others: minor necrotic tissue removal under local anaesthesia, reoperation with the removal of the entire flap or its part, removal of the prosthesis due to deep tissue infection, and ICU admission due to pulmonary embolism. In our opinion, this group of complications is too heterogeneous and needs to be divided in a more detailed manner. Pulmonary embolism is a far more severe complication than partial flap necrosis. What is more, we observed a significant difference between grade 3 and grade 4 of expanded classification in relation to LOS (7 vs 22.2 days) and cost (1.3 vs 3 times higher compared to patients with no complications). These observations along with the benefits of calculating PMI (designed only for expanded version) led us to proposing the extended version for analysis of complications after breast reconstruction surgery. The contracted version of Accordion may be more appropriate for studies where severe complications are less frequent.

Increasing the quality of patient care through constant evaluation and improvement of surgical techniques should be a standard practice. It is rather unlikely that a system for assessing postoperative complications could be completely devoid of subjectivity, however, we should strive to maximize its objectivity. The choice of treatment in the event of a postoperative complication will always be the responsibility of the surgeon. The use of the Accordion system based on interventions in the classification of complications can help in more reliable and authentic assessment. The Accordion system is an easy, intuitive and universal system for classifying and assessing the severity of postoperative complications and can be recommended for documenting complications in breast reconstruction procedures.

Authors' Note

Reprints will not be ordered. Study was approved by Independent Bioethics Committee for Scientific Research at Medical University of Gdańsk, approval number NKBBN/260/2019. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5). Informed consent was obtained from all patients for being included in the study.

Declaration of Conflicting Interests

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