The Use of Six Sigma to Assess Two Prostheses for Immediate Breast Reconstruction

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Abstract. Breast reconstruction is fundamental and urgent for patients in order to avoid future psychological and physical issues. That's why immediate breast reconstruction has been requested increasingly in the last years. In this study two prosthesis with different structures and properties were compared according the aesthetic appearance (BREAST-Q© was employed) and five complications (seroma, hematoma, infections, dehiscence and red breast syndrome). The overall population was composed by 56 patients: 24 received a Tutomesh prosthesis and 32 received a Surgimend prosthesis. The DMAIC (define, measure, analyse, improve and control) cycle was implemented as a problem-solving strategy of the Six Sigma to compare the prostheses. While statistically significant difference between the two groups wasn't found according to the overall BREAST-Q© (p-value = 0.674), the number of complications of the two groups resulted statistically different (p-value of chi-square test less than 0.001). Although it is not possible to understand from this study the reasons of the differences between the complications, this research proved that Surgimend and Tutomesh prostheses can be both implanted safely for immediate breast reconstruction since the higher costs of Surgimend could be neutralized with its lower hospitalization compared to Tutomesh.

Keywords: Six Sigma · DMAIC · Immediate breast reconstruction

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1 Introduction

Breast reconstruction helps patients in long-terms psychological and physical issues when proposed by physicians as an immediate procedure [1, 2]. As a result, the request for immediate breast reconstruction (IBR) has rapidly grown over the last decades [3]. In the United States, almost two thirds of the nearly 90,000 annual implants for breast reconstructions were performed using dermal scaffolds [4, 5]. IBR with biological scaffolds allows a better prosthesis placement and a good aesthetic outcome without compromising the oncological safety [6]. Moreover, these devices seem to improve the lower pole expansion and lateral projection [7]. Using acellular dermal matrix (ADM) refines the inframammary and lateral mammary fold definition and decreases capsular contracture rates. It is both a protective device against radiation damages and helpful in the correction of secondary breast shape deformity [8, 9]. Biological devices have a higher amount of collagen promoting faster tissue healing and provide scaffolding for the regeneration of surrounding tissues [10]. Despite having well-reported advantages, employing biological meshes showed that several complications (seroma, hematoma, skin flap necrosis, wound dehiscence, capsular contracture, and adverse radiotherapy-related effects) could still occur [11].

Using dermal matrix has become popular in several surgical fields and for many reasons [12], choosing IBR offers many advantages (facility to direct-to-implant reconstruction, the improvement of inframammary and lateral mammary fold definition, and a decrease of capsular contracture rate) [13]. The most important advantage, originating from a three-dimensional acellular collagen structure, is that it aids an inducement for fibroblasts attraction and a promotion for their replication. Mesh tissue integration, by reparative processes of fibrosis and angiogenesis, follows the three-dimensional collagen structure as a scaffold for the ingrowth of patient's own tissue. Nevertheless, ADM works as a tissue reinforcement and an anatomical support for the inframammary and lateral fold. ADM facilitates surgical procedures when more covering tissue is needed and comparing to an autologous reconstruction (both for the microsurgical flaps and the fascia flaps of the anterior serratus muscle), it requires shorter operative times, eliminates donor site morbidity promoting more rapid convalescence [14].

Six Sigma (SS) was created by Motorola in 1987 to produce higher quality products at a lower cost. Quality has been seen in two sides: the potential and the actual. The former was the known maximum possible value added per unit of input, the latter was the current value added per unit of input [15]. This concept was first applied in healthcare by the Commonwealth Health Corporation and gave a huge profit, improved radiology throughput by 33% and decreased costs per radiology procedure by 21.5% [16]. Antony et al. reviewed all the applications of SS in healthcare, explaining its evolution in terms of space and geography, the benefits, critical success factors and challenges in its application and the top 5 tools used in DMAIC (define, measure, analyse, improve, control) problem-solving strategy [17]. Researchers have used it in combination with other methodologies [18, 19] and applied it in healthcare for different reasons: reducing hospital stay in hip and knee surgery [20–22], analysing the introduction of new clinical pathways in femur surgery [23, 24]. Recently, Polanski et al.

employed SS to compare treatment-dependent outcome data of deep brain stimulation of the subthalamic nucleus in patients with Parkinson's disease [25].

Colwell et al. asserted that Single Stage Breast Reconstruction (SSBR) after a nipple-sparing mastectomy could give a low complication rate if the patient is correctly selected with or without the use of a mesh [26]. Atiyeh et al. showed that an SSBR with no mesh could be done safely and the results are correlated to the quality and quantity of the tissues after mastectomy [27, 28]. We can assert that some authors described the late occurrence of complications using a variety of ADMs in breast reconstruction with an average of 73 days and a range of 9–895 days [29].

The aim of this study is to perform a retrospective analysis on aesthetic appearance and complications between two groups of patients who underwent immediate breast reconstruction at the Policlinic of University "L. Vanvitelli": in one group a direct implant for breast reconstruction with Tutomesh prosthesis was performed (Bovine Pericardium collagen membrane) while in the other group Surgimend prosthesis (fetal bovine acellular dermal matrix) was employed.

2 Materials and Methods

The number of surgical procedures performed by the hospital "Vanvitelli" is around 7000 per year. The 5% of them is related to plastic surgery while the 40% of plastic surgery is represented by the IBR. In this research the Tutomesh group (24 patients) was compared with the SurgiMend Group (32 patients) in a retrospective review of a single centre experience (Policlinic of University L. Vanvitelli), in a period of 4 years (from 2012 to 2016), for a total of 56 surgeries. Surgeries included oncological subcutaneous (skin or skin/nipple spearing) mastectomies only. Delays or other types of reconstruction (synthetic mesh) were excluded from the study. Written informed consent was acquired for every patient and local ethical committee gave its approval.

DMAIC cycle was applied to conduct the analysis. It is a problem-solving strategy of SS allowing to tackle quality issue with a five steps approach:

1. Defining the problem and a critical to quality (CTQ);
2. Measuring the CTQ;
3. Analysing the process (eventually with a root cause analysis);
4. Improving the process through a corrective action;
5. Controlling the results.

First, a project charter was written to define all the points of the research project (Table 1). The team who took part of the research was made up of a mix of biomedical and managerial engineers and surgeons.

The BREAST-Q© is a PRO instrument designed to evaluate outcomes among women undergoing different types of breast surgery [30]. There are currently 4 BREAST-Q© modules (i.e., Augmentation, Reduction/Mastopexy, Mastectomy, Reconstruction), each of them comprises multiple scales; the values haven't got a unit of measurement. The conceptual framework of the BREAST-Q© comprises the following 2 overarching themes (or domains): HR-QOL and patient satisfaction. Domain 1 (HR-QOL) comprises 3 subdomains: physical, psychosocial, and sexual well-being. Domain 2 (patient satisfaction) also comprises 3 subdomains: satisfaction with breasts,

Table 1. Project charter.

Project title Using SS to compare two prostheses	
Problem statement Identifying the best prothesis according to the total Q Breast score and the postoperative complications	Objective statement Analysing the clinical data to answer to the problem statement
Critical to quality The CTQ is the overall Q Breast score	
In scope 1. Prosthetization of the breast 2. Policlinic of University "L. Vanvitelli"	Out of scope 1. All the other interventions 2. All the other prostheses 3. All other structures

satisfaction with overall outcome, and satisfaction with care; indeed, body image is a key issue in breast surgery and is considered across multiple. BREAST-Q© scale was developed to examine specific aspects of HR-QOL and patient satisfaction. Each BREAST-Q© scale is composed of a series of items (or questions) that evaluate a unidimensional construct; the items composing each scale reflect a clinically relevant hierarchy. Each module of the BREAST-Q© has both preoperative and postoperative versions. The postoperative version includes all the preoperative items in addition to items that address unique postoperative issues (e.g., scars). The preoperative and postoperative scales are linked psychometrically to measure change.

The aim of the project was defined as "Identifying the best prothesis between the Tutomesh and the Surgimend according to the total BREAST-Q© (by analysing the sum of domains 1 and 2 considering the postoperative phase) score and the postoperative complications".

After the define phase, some measurements were performed on the dataset and the data were represented graphically to better understand their distributions (Fig. 1). The mean BREAST-Q© scores were 280.67 and 279.63, respectively for Tutomesh and Surgimend groups.

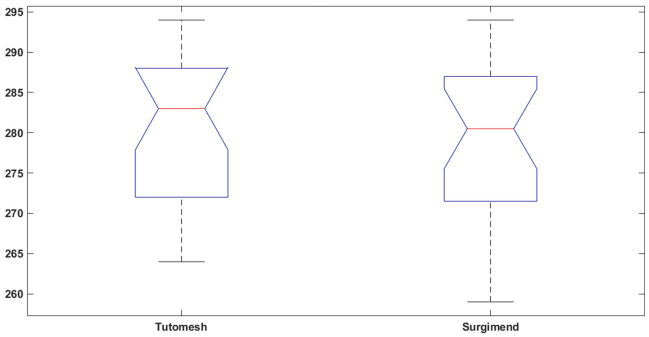

Fig. 1. Comparative boxplot for the BREAST-Q© score of Tutomesh and Surgimend prostheses.

Then, the analyse phase consisted in analysing the causes that lead surgeons to employ a new kind of prosthesis: the structure of the new one, described in the improve phase, is the main cause.

On the one hand, Surgimend derives from fetal bovine dermal collagen. It has valuable mechanical properties and is rich in type III collagen, which may help in healing tissues and preventing scarring. It shouldn't provoke an acute or chronic foreign body inflammatory response; it would remove the possibility of a degeneration of the implant site. Furthermore, its microporous matrix is rapidly revascularized, which, in turn, may support tissue building and healing for prolonged reinforcement. It is the first biological mesh with fenestration which should allow a fluid accumulation around the implant to drain into the surrounding tissue [11–14].

On the other hand, Tutomesh is an avital, acellular, xenogenic collagen membrane made from bovine pericardium. According to the manufacturer, Tutomesh is made up of the 92% of native collagen type I. This collagen lets it maintain its three-dimensional structure and be extremely resistant to tensile forces. This ADM, similarly to Surgimend, allows the in-growth of vessels and fibroblasts, thereby being gradually replaced by patient's own tissue. Very little data exist in this area [11–14].

Finally, in the control phase the statistical tests to compare the groups were defined: first, a normality test was performed to understand whether using parametric or non-parametric test. Then, two sample independent test and chi square for demographical reasons were performed. All the tests were performed by using IBM SPSS v. 25 software.

3 Results

The Kolmogorov Smirnov and the Shapiro Wilk tests for normality showed a p-value of 0.20 and 0.07, respectively, allowing to treat the data as normally distributed. Therefore, t tests were computed to compare the groups. Table 2 shows the comparison between the total BREAST-Q© scores of each prosthesis group.

Table 2. Statistical comparison between the total BREAST-Q© score of the prostheses

Variable	Category	Tutomesh	Surgimend	p-value
Overall		280.67 ± 9.37	279.63 ± 8.94	0.674
Seroma	Yes	282.33 ± 7.15	280.00	0.775
	No	280.11 ± 10.12	279.61 ± 9.08	0.86
Hematoma	Yes	275.50 ± 0.71	NA	NA
	No	281.14 ± 9.66	279.63 ± 8.94	0.557
Infections	Yes	280.50 ± 7.78	NA	NA
	No	280.68 ± 9.66	279.63 ± 8.94	0.681
Dehiscence	Yes	276.00	NA	NA
	No	280.87 ± 9.53	279.63 ± 8.94	0.622
Red Breast Syndrome	Yes	275.50 ± 0.71	NA	NA
	No	281.14 ± 9.66	279.63 ± 8.94	0.591

No statistically significant difference was found between the BREAST-Q© score of the two groups. Table 3 shows the results of a chi square with a 5% of uncertainty level in order to understand the different frequencies of complications in each prosthesis group.

Table 3. Demographic study to evaluate the number of complications

Variable	Category	N Tutomesh	N Surgimend	p-value
Overall complications	Yes	13	1	<0.001
	No	107	159	
Seroma	Yes	6	1	0.014
	No	18	31	
Hematomas	Yes	2	0	0.096
	No	22	32	
Infections	Yes	2	0	0.096
	No	22	32	
Dehiscence	Yes	1	0	0.244
	No	23	32	
Red Breast Syndrome	Yes	2	0	0.096
	No	22	32	

The demographic study (Table 3) showed a statistically significant difference in the number of Seromas (p-value = 0.014) and almost significant differences in the number of hematomas, infections, red breast syndromes (p-value = 0.096). Finally, the overall number of complications was 13 for the Tutomesh group and 1 for the Surgimend group, thus obtaining an extremely statistically significant difference between two groups.

4 Discussion and Conclusion

First, the data of two groups of patients undergoing IBR were collected. They received Tutomesh (24 patients) and Surgimend (32 patients) prostheses. Their overall BREAST-Q© scores were analysed according to some variables: Seroma, Hematomas, Infections, Dehiscence and red breast syndrome. Moreover, the number of complications was investigated per each group.

Regarding the aesthetic outcome, both devices reached an equivalent high result. It probably happens because tissue integration seems to give a natural breast shape that helps women to accept it, or at least this is what appears to come from the questionnaire that each woman was given. Unfortunately, we don't have any technical judgment method (in terms of three-dimensional structure, type of ADM, decellularization method, fibrosis grading, etc.) to explain why Tutomesh had a higher rate of postoperative complications.

According to our experience, the use of an ADM rather than another one is influenced by various factors. Firstly, from availability and costs: within our structure, Tutomesh is more easily accessible than Surgimend; moreover, Surgimend is also much more expensive than Tutomesh. However, we found both greater comfort from a technical point of view when using Surgimend, and fewer post-operative complications. Greater manageability, fewer complications and, consequently, lower re-hospitalization rates could offset the higher costs.

In our study, the analysis showed a higher postoperative complication rate with the use of the Tutomesh device. We believe that identifying the causes of complications is challenging (it could be due to surgical technique, type of mesh used for reconstructions, mesh itself or selection of patients).

There is in literature a lack of works analysing ADM's complications with a longer follow-up (years) [31]. Prolonging the time of follow-up may be interesting to evaluate the overall outcomes and significant both for clinicians and patients.

In conclusion, both devices could be used safely equivalently for IBR. After this work, a cost-benefit analysis could be performed to relate the economic advantage of a minor price (Tutomesh) with the minor number of complications (Surgimend).

Conflict of Interests. The authors declare they have no conflict of interests.

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