



Lean DIEP flap surgery: saving time and reducing complications

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Received: 17 March 2021 / Accepted: 14 May 2021 / Published online: 7 June 2021

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Abstract

Background The number of performed deep inferior epigastric perforator (DIEP) flaps for post-mastectomy breast reconstructions (PMBR) has shown a dramatic increase over the past decade. As this increased demand requires a higher proportion of operative capacities worldwide, there is a need for increased efficiency. Introduction of lean strategies might form a solution. Therefore, the purpose of this study was to assess the effects and outcomes of practising lean strategies in DIEP flap surgery over six years by analysing operation time and complications.

Methods In this retrospective cohort study, all patients who underwent a DIEP flap for PMBR between January 2013 and May 2019 were included. Patient- and surgery related characteristics were collected. Duration of surgery and complication rates were compared.

Results A total of 170 DIEP flaps for PMBR were performed in 139 patients. DIEP flaps were performed in an immediate (8 patients) or delayed (131 patients) setting. Mean operating time was 329 minutes for unilateral and 554 minutes for bilateral DIEP flap reconstruction. Over time, operating time decreased 19% in the unilateral, and 17.1% in the bilateral series. Also, more additional procedures during the initial DIEP flap procedure were performed over time. Total flap loss was seen in 1.2% of the cases. While surgical time decreased, the number of major complications decreased 9.3% in the unilateral and 20% in the bilateral series.

Conclusions Using lean strategies can safely reduce surgical time in DIEP flap breast reconstructions, while achieving, a reduction of complications.

Level of evidence: Level IV, risk/prognostic study.

Keywords DIEP flap · Autologous breast reconstruction · Duration of surgery · Lean

Introduction

An increasing amount of post-mastectomy breast reconstruction (PMBR) is performed worldwide [1]. Autologous reconstructions have shown to have superior results regarding patients' satisfaction compared to implant-based reconstructions [2–4]. Additionally, an increasing awareness of the benefits of autologous breast reconstruction among patients leads to a rise in a number of autologous reconstructive procedures. Of autologous reconstruction procedures, the deep inferior epigastric perforator (DIEP) flap has become the gold standard. It is the most frequently used option for autologous breast reconstruction these days [4]. Consequently, this increased popularity leads to a higher demand on the capacity of hospitals and surgeons, as autologous PMBR procedures typically take longer than other types of breast reconstruction (e.g. implant-based reconstructions) [1, 5].

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In order to keep up with this increasing demand successfully, optimizing pre- and postoperative care and refining operation techniques are paramount to improve the DIEP flap reconstructions. One way of increasing efficiency while maintaining safety is the implementation of lean working strategies, a technique that has been successfully utilized by other sectors and was developed by Toyota and was popularized as the Toyota lean production system [6]. Lean strategies are founded upon two pillars: one, it combines a continuous improvement cycle in a kind and friendly environment for personnel, and two, it identifies a number of focus areas to improve — overburden, inconsistency and waste. Waste is defined in eight categories: overproduction, waiting time, waste of transportation, waste of processing, excess inventory, waste of movement, waste of making defective products and waste of underutilized personnel. Previous literature underlines that utilization of the lean method while also gaining experience with a particular procedure results in decreased operating time and potentially better postoperative outcomes with less complications [7–10].

An important step of lean includes the identification and reduction of all non-vital steps in a process. In the case of flap surgery, this could, for example, include optimization of preoperative planning techniques such as using CT-angiogram. This supports preoperative planning which decreases operating time [9]. Moreover, performing more simultaneous procedures, i.e. direct nipple reconstruction and/or contralateral symmetrizing procedures, can result in a reduction of the number of surgeries needed and thus time needed to finish the complete reconstruction [11]. Consequently, this can decrease patients' psychological stress and days of sick leave from work [7]. In our hospital, lean strategies were gradually implemented since the introduction of DIEP flap surgery in 2013. The purpose of this study was to retrospectively assess the effects and outcomes of practising lean strategies in DIEP flap surgery by analysing operation time and complications over time from a general, non-teaching hospitals perspective.

Methods

Population and data collection

In this retrospective study, all patients who underwent unilateral or bilateral DIEP flap for PMBR between January 2013 and May 2019 were included. Indications for surgery included (a history of) breast cancer or prophylactic mastectomy. DIEP flaps were performed either immediate or delayed (with or without previous pre-expansion with a tissue expander or reconstruction with an implant). Other flaps for autologous breast reconstruction, such as tensor fascia lata (TFL) and profunda artery perforator (PAP) flaps, were

excluded. Additionally, the local hospital protocol excludes women who actively smoke and women with a body mass index (BMI) over 35. This study was approved by the regional medical ethics committee.

Patients' medical records were reviewed for patient and surgical characteristics, and data were collected and stored in IBM SPSS® Statistics (version 24.0) in a pseudonymous manner. Patient characteristics included comorbidities, BMI, smoking status, radiotherapy, previously received oncological therapy and history of breast surgery and breast reconstruction.

Surgical data on the DIEP flap procedure were collected. Data included the number of surgeons per procedure, duration of surgery and simultaneous additional reconstructive procedures during surgery. The duration of surgery was calculated from the time of incision to the finish of the procedure and was expressed in minutes.

Postoperative data included duration of hospital stay, second operation and consultation of a medical specialist. Hospital stay was calculated in days from admission until discharge. Patients were admitted at the day of surgery.

Short-term postoperative complications were retrieved from medical records up to 30 days postoperatively. The Clavien-Dindo classification was used for categorizing complications [12]. A complication was defined as any complication at the recipient or donor site including wound dehiscence, seroma, infection, fat necrosis, re-exploration, partial flap loss and total flap loss. Major complications include total flap loss, partial flap loss and compromised flap. Partial flap loss was defined as partial necrosis of the flap, which requires reoperation for debridement with or without redistribution. Compromised flap refers to a compromised circulation of the perforator with successful revision after re-exploration under general anaesthesia.

Lean protocol

All DIEP flaps were performed in a non-academic, single community hospital with a dedicated team of plastic surgeons and nurses. In all cases, one surgeon (HAR) took part in the surgical team, sometimes accompanied by one other (varying) plastic surgeon. The case series starts at the start of an autologous breast reconstruction program, so all patients that underwent a DIEP flap were included since the start of this program. Treatment protocol changed over time in adherence to the lean strategies. Gradually, different items of the lean methods were introduced since 2013. The key components of the current protocol are outlined in Table 1.

Statistical analysis

Descriptive statistics were used to report the baseline characteristics of the study. Mean values with standard

Table 1 Parts of the ZGT lean protocol for DIEP flap surgery

Examples of our lean approach of DIEP flap surgery

Preoperative

- Preparation of patients: 30 min consultations at the plastic surgeon to show a standard PowerPoint with principles, examples of outcomes, complications and the treatment protocol
- Imaging: CT-angiogram for perforator selection and planning of the dissection. Stop doing pencil Doppler or duplex investigations

Anaesthesia

- Standardizes preparation between induction and incision:
 - Stop preoperative discussion on positioning by introduction of a rapid patient positioning system using specific wrapping and head support system
 - Minimize use of opioids, only short working anaesthetics
 - Inotropics as requirements without discussion
 - Insertion of a urinary catheter
 - Injection of surgical sites with 0.2% ropivacaine with 1 mg of adrenaline in 200 cc
- Antibiotics: 2-g cefazolin
- Antithrombotics: low-molecular-weight heparin (Dalteparin 2500 IE) at start surgery

Surgical

- Aim to keep only vital surgical steps and dissection, aim to reduce movement, handling and instrument changes
- Reduction number of surgical instruments
- Use of automatic vascular clippers (Liga clip multiple clip applier)
- Developing algorithms for most frequent choices made during surgery:
 - Perforator selection
 - When to remove a rib for IMA dissection
 - When to clip a side branch
 - When to redo an anastomosis
- Standardized perforator dissection:
 - First the abdominoplasty and raising the flap except for a focused area surrounding the perforators
 - The superficial inferior epigastric vein (SIEV) is routinely clipped at 1 cm
 - Dissection of the perforator in a focused manner, preferably two perforators
 - Introduction of algorithm for clipping side branches
 - Put a microsurgical clamp on one of the two concomitant veins to test the venous status of one vein anastomosis
- Standardized internal mammary artery (IMA) dissection:
 - Split the pectoralis major (PM) muscle over the widest intercostal space
 - Remove rim of rib if space too narrow or vein too small
- Standardized microsurgical protocol:
 - Standard positioning of suction system
 - Presternal position of the flap, leaving room for both hands to do the anastomosis
 - Use of a venous coupler, aiming for > 2.5 mm diameter
 - Redoing the anastomosis; in case any member of the team, including nurses, is in doubt on patency
 - Reduce the role of the assisting surgeon, the microsurgeon should do as much as he/she can by himself/herself

Postoperative

- Removal of urinary catheter at the operating theatre or in the recovery room
- Flap monitoring:
 - Clinical evaluation of the colour
 - Capillary refill
 - Temperature
 - Handheld Doppler
- Antibiotics: 2-g cefazolin continued until 24 h postoperatively
- Antithrombotics:
 - Low-molecular-weight heparin 6-h postoperative (Dalteparine 2500 IE) till 6 weeks postoperatively (Dalteparin 5000 IE)

Table 1 (continued)

Examples of our lean approach of DIEP flap surgery

- Compression stocking from surgery till discharge from the hospital
- Rapid removal of intravenous lines and drains
- Active mobilization of the patient on day 0
- Out of bed policy for patients on day 0 or 1 with support of physiotherapy
- Active involvement nursing staff in rapid mobilization strategies
- The patient should shower as soon as possible
- One day postoperative determination of lab values: Hb, Ht and electrolytes

deviation (SD) were used for continuous variables with a normal distribution. Frequencies and percentages were used for categorical variables. To compare operating time and complications over time in the unilateral and bilateral cases, respectively, two (independent) groups were created. All subsequent patients were divided in two equal groups based on chronological order, 2013–2017 and 2017–2019 (54 patients in each group for the unilateral cases and 15 patients in each group for the bilateral cases). The means for operating time and hospital stay were compared by the independent sample T-test. The Chi-square test was used to compare postoperative complications. All statistical analyses were performed with statistical software SPSS (version 24.0, IBM Corp., Armonk, NY). A two-sided p -value less than 0.05 was considered statistically significant.

Results

Patient characteristics

From January 2013 to May 2019, 170 DIEP flaps were performed in 139 patients. All DIEP flaps were performed in patients with a history of breast cancer. Prior to the DIEP flap reconstruction, 46.8% received radiotherapy. The mean age was 52 years (SD 8), and the mean body mass index (BMI) was 27 (SD 3). All patient characteristics for the total and for the two subgroups are presented in detail in Table 2.

Surgical data

Unilateral reconstructions were performed in 108 patients and bilateral reconstructions in 31 patients. Of all DIEP flap reconstructions, 94.2% were delayed breast reconstructions. In 53.2% of the delayed procedures, the breast was pre-expanded with a tissue expander or previously reconstructed with an implant. Over time, an increasing number of simultaneous procedures was performed (e.g. nipple reconstruction), from none of the cases in 2013–2014 compared to 87.5% of the cases in 2018–2019. All operative details are shown in Table 3.

Table 2 Patient characteristics

| | Unilateral | Bilateral | Total |
|------------------------|------------|------------|------------|
| Patients (n) | 108 | 31 | 139 |
| DIEP flaps (n) | 108 | 62 | 170 |
| Mean age, y (SD) | 51.6 (8.2) | 45.7 (8.6) | 50.3 (8.6) |
| Mean BMI (SD) | 26.8 (3.2) | 27.7 (3.7) | 27.0 (3.3) |
| Smoking, % (n) | 2.8 (3) | 0 (0) | 2.2 (3) |
| Hypertension, % (n) | 14.8 (16) | 0 (0) | 11.5 (16) |
| Diabetes, % (n) | 1.9 (2) | 0 (0) | 1.4 (2) |
| Abdominal scar, % (n) | 9.3 (10) | 9.7 (3) | 9.4 (13) |
| Radiotherapy, % (n) | 47.2 (50) | 48.4 (15) | 46.8 (65) |
| Chemotherapy, % (n) | 49.1 (53) | 45.2 (14) | 48.2 (67) |
| Hormone therapy, % (n) | 43.5 (47) | 38.7 (12) | 42.4 (59) |

The mean duration of surgery was 329 min for unilateral reconstruction and 554 min for bilateral reconstruction. With the increase in the number of additional procedures, a statistically significant decrease of operating time over the years was observed when comparing all subsequent patients in two equal groups (2013–2017 and 2017–2019). This applies to the unilateral as well as the bilateral DIEP flap reconstruction (unilateral, 357 versus 300 min, $p=0.000$; bilateral, 596 versus 509 min, $p=0.024$). Figures 1 and 2 illustrate this decrease in operating time for unilateral and bilateral DIEP flaps over time.

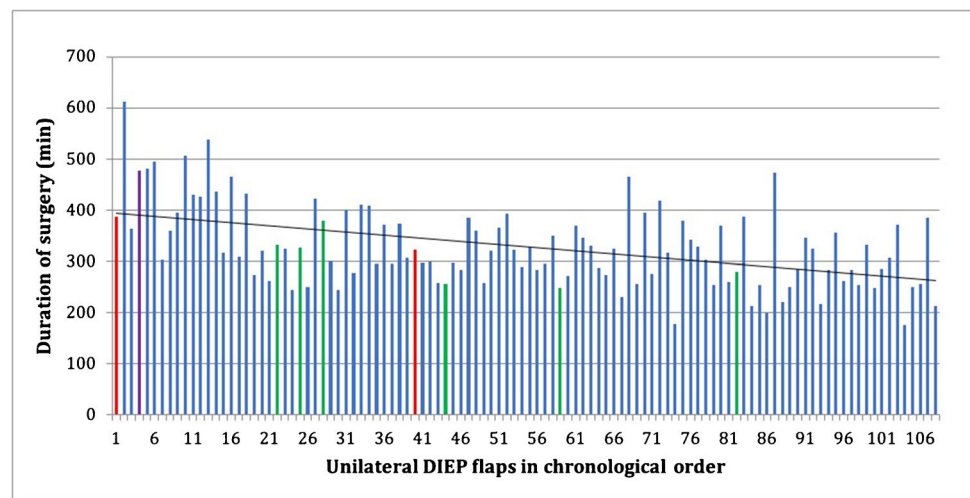
Postoperative complications

When using the Clavien-Dindo classification for postoperative complications, this study shows that most complications were categorized as Grade 1 (Table 4). Life-threatening complications (Grade 4) and mortality (Grade 5) did not occur. Both total and partial flap loss occurred in two patients (1.2% and 1.2%, respectively, of all flaps). A compromised flap was seen in nine flaps (5.3%). Grade 3b complication, involving reoperation in theatre, occurred in 12.9% (18 patients). Figures 1 and 2 show that most major complications occurred in the first half of the reconstructions.

Table 3 Operative details

| | Unilateral | Bilateral | Total |
|---|------------|-----------|------------|
| Patients (n) | 108 | 31 | 139 |
| DIEP flaps (n) | 108 | 62 | 170 |
| Preoperative | | | |
| Pre-expansion, % (n) | | | |
| Non pre-expansion | 49.1 (53) | 38.7 (12) | 46.8 (65) |
| Tissue expander | 40.7 (44) | 45.2 (14) | 41.7 (58) |
| Implant | 10.2 (11) | 16.1 (5) | 11.5 (16) |
| Timing of DIEP reconstruction, % (n) | | | |
| Immediate | 0.9 (1) | 22.6 (7) | 5.8 (8) |
| Delayed | 99.1 (107) | 77.4 (24) | 94.2 (131) |
| Peri-operative | | | |
| Mean number of surgeons (SD) | 1.7 (0.5) | 1.8 (0.4) | 1.7 (0.5) |
| Mean duration of surgery (SD) | 329 (80) | 554 (108) | 379 (128) |
| Additional elements to DIEP flap, % (n) | | | |
| Total | 21.3 (23) | 3.2 (1) | 17.3 (24) |
| Breast reduction/mastopexy | 9.3 (10) | 0 (0) | 7.2 (10) |
| Nipple reconstruction | 6.5 (7) | 3.2 (1) | 5.8 (8) |
| Other | 5.6 (6) | 0 (0) | 4.3 (6) |
| Postoperative | | | |
| Mean duration of hospital stay, days (SD) | 5.8 (1.7) | 6.9 (1.9) | 6.1 (1.8) |
| Second operation, % (n) | 50.9 (55) | 51.6 (16) | 51.1 (71) |
| Medical consultation, % (n) | 6.5 (7) | 9.7 (3) | 7.2 (10) |

Fig. 1 Unilateral DIEP flap. The duration of surgery per patient in chronological order. The red colour represents total flap loss, the purple colour represents partial flap loss, and the green colour represents a compromised flap with successful revision. The black line illustrates the trend of the duration of surgery



Univariable analysis was performed to explore a possible association of surgical time on the major complication rate (Grade 3b). A decrease of major complications over the years was observed for the unilateral and bilateral DIEP flap reconstructions when comparing all subsequent patients in two equal groups (2013–2017 and 2017–2019). For the unilateral DIEP flap reconstructions, the complication rate decreased from 16.7 to 7.4%, $p=0.118$. Bilateral DIEP flap reconstructions show a decrease from 26.7 to 6.7%, $p=0.165$.

Postoperative management

The mean hospital stay was 5.8 days for unilateral and 6.9 days for bilateral DIEP flap reconstructions. A statistically significant decrease of hospital stay was observed over the years when comparing all subsequent patients in two equal groups (2013–2017 and 2017–2019). This applies to the unilateral as well as the bilateral DIEP flap reconstruction (unilateral, 6.5 versus 5.1 days $p=0.000$; bilateral, 7.7 versus 6.1 days $p=0.022$).

Fig. 2 Bilateral DIEP flap. The duration of surgery per patient in chronological order. The purple colour represents partial flap loss, and the green colour represents a compromised flap with successful revision. The black line illustrates the trend of the duration of surgery

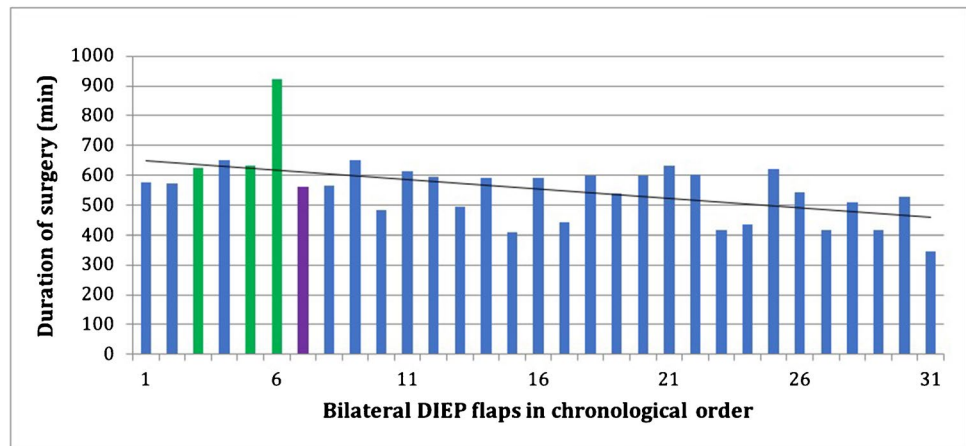


Table 4 Complications categorized according to the Clavien-Dindo classification

| | Unilateral | Bilateral | Total |
|-------------------------------------|------------|-----------|-----------|
| Patients (n) | 108 | 31 | 139 |
| DIEP flaps (n) | 108 | 62 | 170 |
| Clavien-Dindo classification, % (n) | | | |
| Grade 1 | 22.2 (24) | 38.7 (12) | 25.9 (36) |
| Grade 2 | 13.0 (14) | 16.1 (5) | 13.7 (19) |
| Grade 3 | | | |
| a | 1.9 (2) | 0 (0) | 1.4 (2) |
| b | 12.0 (13) | 16.1 (5) | 12.9 (18) |
| Grade 4 | | | |
| a | 0 (0) | 0 (0) | 0 (0) |
| b | 0 (0) | 0 (0) | 0 (0) |
| Grade 5 | 0 (0) | 0 (0) | 0 (0) |

In 51.1% of all patients, more elective surgeries (i.e. touch-ups) were performed after the DIEP flap reconstruction, varying from nipple reconstruction and scar revision to more complex operations, such as redistribution of the DIEP flap tissue and lipofilling (Table 5).

Discussion

Today, the DIEP flap is considered an excellent option for breast reconstruction with superior outcome in terms of PROMs when compared to implant-based reconstruction [4]. From 2013 to 2018, the number of DIEP flap reconstruction performed in our community hospital has increased with 68%. The national numbers in the Netherlands confirm this phenomenon with a nearly 72% increase in the number of procedures over the past 6 years [13]. The increasing demand for breast reconstructive surgery calls for a reduction of surgical time and subsequent costs, possibly

Table 5 Second operation

| | Unilateral | Bilateral | Total |
|-----------------------------------|------------|-----------|-----------|
| Second operation, % (n) | | | |
| Total | 51.9 (56) | 51.6 (16) | 51.1 (71) |
| Redistribution DIEP | 13.0 (14) | 16.1 (5) | 13.7 (19) |
| Contralateral reduction/pexy | 20.4 (22) | 3.2 (1) | 16.5 (23) |
| Reduction DIEP flap | 7.4 (8) | 9.7 (3) | 8.6 (12) |
| Lipofilling DIEP flap | 12.0 (13) | 9.7 (3) | 11.5 (16) |
| Lipofilling contralateral mam-mae | 0.9 (1) | 0 (0) | 0.7 (1) |
| Reduction skin DIEP flap | 7.4 (8) | 16.1 (5) | 9.4 (13) |
| Excision dog-ear donor site | 13.9 (15) | 16.1 (5) | 14.4 (20) |
| Excision dog-ear DIEP flap | 7.4 (8) | 3.2 (1) | 6.5 (9) |
| Scar revision DIEP flap | 1.9 (2) | 3.2 (1) | 2.2 (3) |
| Scar revision donor site | 4.6 (5) | 6.5 (2) | 5.0 (7) |
| Nipple reconstruction | 33.3 (36) | 22.6 (7) | 30.9 (43) |
| Fat necrosis | 2.8 (3) | 19.4 (6) | 6.5 (9) |
| Other | 2.8 (3) | 12.9 (4) | 10.1 (14) |

by focussing on higher surgical efficiency and reduction of number of procedures during a lifetime. However, one might be concerned that increasing efficiency and speed in surgery could lead to higher complication rates. Fortunately, this study showed the contrary: while surgical time decreased significantly in our practice during the time lean strategies where implemented, complication rates also decreased.

The results of this study should be interpreted while considering its strengths and limitations. First, this study is limited by the fact that the subjects cannot be stratified in to a lean and non-lean group for comparison, as all strategies were implemented gradually since 2013. This gradual implementation makes it difficult to examine the pure effect of the specific lean elements. Additionally, a true causal relation between implementation of lean strategies and complication rates could not be proven, as this correlation

was not corrected for other factors that were not measured (i.e. increased surgical experience over time, preoperative reconstruction status). Although we could not differentiate the effect of the different lean elements, we did see a simultaneous decrease in complications and surgical time. This implies a positive effect of the introduction of various parts of lean strategy that might also have sped up the learning curve. The fact that all DIEP flap reconstructions were performed in one centre by one surgeon strengthens this study as it ensures continuity in learning curve and surgical techniques. Also, even though the range in follow-up time is wide, the minimum follow-up of 8 months postoperatively in this study is considered sufficient.

Various elements of the lean strategy affect surgical time differently (Table 1). First, clear preoperative imaging, using CT-angiogram, supports planning of the dissection, which reduces surgical time. Second, anaesthesia has no direct impact on the surgical time, although, if the induction of anaesthesia goes well, the procedure can be started with a clear mind and the patient spend less time in the operating room. Thirds, all elements of the surgical steps influence surgical time. In this context, the most important element is to reduce all non-vital steps during the procedure. Last, postoperative elements predominantly affect postoperative hospital stay. By improving peri-operative protocols, hospital stay can be drastically reduced.

The significant reduction in surgical time in DIEP flap reconstruction found in this study meets the results of peers. In 2011, Acosta et al. reported a significant improvement in operation time (438 min to 248 min) over a 9-year period, after introducing lean strategies [9]. More recently, Bodin et al. showed that in unilateral series, their time of surgery decreased progressively from 415 to 233 min [8].

One might hypothesize an increase in major complications as surgical time is reduced. However, the results of this study show that the reduction in operative time did not result in an increase in major, nor minor complications. In fact, a statistically significant correlation was seen between the decrease in surgical time and the decrease in major complication rates. An obvious confounding factor that was not taken into account could be found in a growing experience of the surgical team over time. It is known from previous literature that a higher number of complications occur shortly after introducing a new program and that a subsequent decrease follows as experience grows [1, 5, 7, 8, 14]. For DIEP flap surgery in particular, Bodin et al. showed a revision rate of 50% for the first ten unilateral cases, followed by a rapid decrease to 6% for the following cases [8]. Also Basic et al. showed a decrease in complications such as total flap loss, partial flap loss and fat necrosis. This is in line with the results of our study (i.e. 1.2% flap loss) [7].

To finalize the reconstruction, additional operations (i.e. touch-ups) were performed. In this study, 51% of patients

underwent one or more additional interventions to achieve a satisfactory end result. Literature on the number of additional operations is limited and difficult to compare, as most studies focus on reinterventions for complications rather than reinterventions for improvement of aesthetic results. Damen et al. performed 1.4 additional procedures per patient after a DIEP flap breast reconstruction [11], and Enajat et al. performed an average of 1.06 additional interventions per patient [15]. An important goal of surgery in line with lean principles is to aim for a ‘final product’ at once. This meant that we started doing simultaneous procedures in the last 2 years of the cohort, such as nipple reconstruction at the DIEP site or breast reductions in the contralateral side. By increasing the number of simultaneous procedures during DIEP flap reconstruction, we aim to decrease the number of additional surgeries performed in a patient’s lifetime, increasing satisfaction while decreasing costs for society and health care [16, 17].

The mean duration of hospital stay was 5.8 days for unilateral and 6.9 days for bilateral DIEP flap reconstructions. As mentioned, a continuous improvement cycle supports continuous improvement of protocols and procedures. This means that we expect that hospital stay will decrease further in the near future with the introduction of new measures. Previous literature already showed that enhanced recovery after surgery (ERAS) protocols significantly decreases the length of hospital stay and improves surgical outcomes (complications, hospital readmission, and mortality) [18]. This is in line with the experience that improved anaesthetic care reduces nausea, which is a major factor in reducing recovery time.

Conclusions

By acquiring experience with DIEP flap reconstruction while introducing a combination of lean methods and improving surgical techniques, this study showed that the duration of surgery can be significantly shortened while decreasing complication rates. Improving quality and efficiency in patient selection, preoperative imaging, operation room preparation, anaesthetic care, team composition and surgical techniques increases the confidence of the surgical team resulting in less stress during surgery. This can translate into superior outcomes, more cases and less complications. Optimizing peri-operative care (i.e. through introduction of lean elements), while growing experience with reconstructive surgical techniques, results in a decreased surgical time while reducing major and minor complications.

Acknowledgements Anaesthetists (A.J. Jansen; A.F. van der Meer), nurse practitioner (C. van Zuuren), theatre staff (P. Kammerman, T. Kruiper, R. Leis-Dorenbusch, M. Dosoe, M. Postmus-Folkes, G.

Kouwenhoven-Voortman, R. van Ommen-Schipper, A. Aaldering, B. van der Horst), and nursing staff.

Declarations

Ethics approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This study was approved by the regional Medical Ethics Committee, registration no.: K20-15.

Informed consent Informed consent was obtained from all individual participants included in the study.

Patient consent Patients signed informed consent regarding publishing their data.

Conflict of interest Juliette E.D. Jacobs, Nikki Beudeker, Claudia A. Bargon, Sabine Siesling, Narda Hendriks-Brouwer, Oliver T. Zöphel, Ute Schmidbauer, Yvonne C.M.M. Smulders, Johan G. Wijbenga, and Hinne A. Rakhorst declare no conflict of interest. The authors alone are responsible for the content and writing of the paper.

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