Breast Reconstruction in the NHSE Restoration and Recovery phase of Covid-19 Pandemic at QVH

This document must be read in the context of wider health economic challenges, the sharing of limited surgical, anaesthetic & PPE resources and its implications at a regional/local level.

Introduction

The Queen Victoria Hospital NHS Trust is the South East England regional centre for breast microvascular reconstructions, known as free flap breast reconstruction. It serves breast cancer units in Kent, Sussex and Surrey. The repertoire of reconstructions include abdominal-based free flaps such as free DIEP (Deep Inferior Epigastric Perforator) flaps and MS-TRAM (Muscle-sparing Transverse Rectus Abdominis Myocutaneous) flaps; and Medial thigh-based flaps such as TUG (Transverse Upper Gracilis) or its variations.

Reconstructive surgery can be performed at the same time as a mastectomy (immediate breast reconstruction), or after all treatment has been completed (delayed breast reconstruction). Free-flap procedures are also used to improve outcomes for patients who have suboptimal clinical outcomes following other types of reconstruction, and are the treatment of choice for breast reconstruction following radiotherapy. We continue to manage an increasing demand for bilateral reconstruction at the same operation as a risk-reducing mastectomy for patients who have a genetic predisposition to breast cancer, such as the BRCA gene.

With increasing frequency, free bi-pedicled DIEP flaps (where the vessels from both sides of the abdomen are re-attached to chest vessels), and two-in-one TUG flaps (placing both TUG flaps into one breast), are used in complex reconstructive situations to enable larger reconstructions to be successfully performed.

QVH consultants have also been using thigh flaps with different patterns of skin such as DUG and LUG flaps. Tailoring flaps to the individual thigh maximises the available tissue, and increases the number of women who are able to benefit from reconstruction using their own tissues.

With a fully holistic approach to our patients' reconstructive journeys, there is also work underway to look at "prehabilitation" services. These have been developed in association with "Revive", at the time of "show & tell" Restore sessions. These are designed to enhance patients physical and emotional well-being before surgery, with the aim of improving post-operative outcomes. Particular focus has been given to weight loss, nutrition, diet and exercise.

Breast reconstruction after mastectomy using free tissue transfer – flap survival and outcomes

The gold standard for breast reconstruction after mastectomy is 'free flap' surgery as described above. These techniques have high patient satisfaction and longevity. It is

important we not only monitor our success in terms of clinical outcome but also how the woman feels throughout her reconstructive journey with patient reported outcome measures (PROM).

Clinical outcomes include length of stay, emergency returns to theatre, unplanned readmissions to hospital and PROMs patient feedback. Any reconstructive failures or complications are reviewed in monthly breast team meetings to identify learning, and further improve the service with optimised learning points and multidisciplinary team engagement.

In 2019, the QVH Breast reconstruction team were reviewed and visited by the Getting It Right First Time (GIRFT) team. QVH were able to demonstrate a high-volume autologous breast reconstruction service with short inpatient stays, and low failure rates in comparison to our peers. The "global" insight that the GIRFT review provided has enabled QVH to improve the collection of out of hospital complication data from across the region.

Over the last year, 355 free-flap breast reconstructions were performed for 294 women. 44% of these cases were immediate reconstructions, performed at the same time as mastectomies. The total failure rate was 0.6%. During this period, the mean length of stay for QVH free-flap breast reconstruction patients was 3.6 nights. 18% of women were discharged after two nights, 38% after 3 nights, 22% after 4 nights and 13% after a 5-night post-operative inpatient stay.

Since the introduction of enhanced recovery after surgery (ERAS), the post-operative length of stay has decreased from 5 to 3.6 days. Factors that may predict early discharge include BMI, length of the surgery, ASA grade and drain output.

QVH is the one of the high volume centres for breast microvascular reconstructions in the UK with excellent results as evidenced in the First report of the UK National Flap Registry, published in Dec 2019 [1].

	Target	Benchmark	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20
Breast reconstruction after mastectomy using free tissue transfer - flap survival	100%	95-98% (published literature); 98% (BAPRAS 2009)	98.94%	100%	99.6%	100%	99.3%	99.7%	99.4%

BAPRAS: British Association of Plastic Reconstructive and aesthetic surgeons

Pre-Covid success rates and efficiency may not be achievable. Any surgery that is undertaken should be subject to ongoing audit.
Patients must be made aware that outcomes may not be as good as pre-Covid.

Breast Reconstruction and the Global Covid-19 pandemic in 2020

It has been expected that demand for immediate and delayed free-flap breast reconstruction will continue to rise. Over the last year, the Trust has worked hard to streamline pathways for immediate and delayed breast reconstruction to improve compliance with Referral to Treatment (RTT) targets.

With the onset of the Global COVID-19 pandemic, breast reconstruction at QVH had been halted in line with the guidelines published by Association of Breast Surgery [2] and the joint statement on Surgical prioritisation during coronavirus pandemic issued by the four surgical Royal Colleges [3].

Association of Breast Surgery have since released a further statement on 25 May 2020 [7] which instructs units to commence work on an operations manual involving all stakeholders and to ensure that breast reconstruction can be delivered safely. This should include robust pathways for patients who develop complications.

Significant changes to all aspects of the UK economy including healthcare occurred with the introduction of a national lockdown to suppress the spread of COVID-19. This has resulted in significant disruption to elective cancer services in the UK. Oncological surgery is currently limited to a small number of patients for whom non-surgical therapies are of limited value, and currently, breast reconstruction in the UK has been halted.

QVH has been designated a *COVID-protected* cancer hub, and arrangements made for provision of surgery for breast cancer patients from across Kent, Surrey & Sussex. **This means that women, who under normal circumstances, would have had immediate reconstruction (mastectomy and breast free microvascular flap), have been treated with mastectomy alone. These patients are being added to the waiting list for breast reconstruction which will be performed sometime in the future.** A "recovery plan" for the QVH breast-reconstruction service is currently being devised to ensure that we are able to treat patients as efficiently as possible once the situation improves.

The waiting time for delayed breast microsurgical reconstructions was 12 months, at the timepoint when all breast reconstructions were stopped. This waiting list is expected to increase significantly.

Breast Reconstruction stratification in the Restoration and Recovery phase of Covid-19

As the regional *Covid-protected* Cancer hub, microvascular reconstruction has continued at QVH for Head and Neck oncology, as these represent a group in the Priority 2 level (surgery deferred up to 4 weeks). Screening includes self-isolation for 7 days and preop Covid swab test (RT-PCR).

With Head & Neck microvascular reconstructions as precedence, it is logical that breast microvascular reconstruction is undertaken once the curve of the pandemic starts to flatten. The key issue is the balance of benefit for our breast reconstruction patients vs. risk of adverse outcomes, including death, from covid infection .

We aim to re-introduce breast reconstruction in a specified group of highly selected low Covid-risk patients. Once the results have demonstrated that this is safe in a controlled environment, the patient group can be extended.

Specific local factors relating to resumption of free-flap reconstruction for breast patients at QVH include the following and are in line with the RCOA guidance on re-starting planned surgery [4]:

- Demonstrable low complication & failure rate for this surgery
- The QVH ERAS pathway does not require patients to be nursed post-operatively in ITU or HDU and are nursed in a designated Enhanced Recovery Area (EHRA with 1nurse: 2-3 patients) making this cost-effective
- There is no competition for other higher priority cancers at QVH, allowing capacity to resume breast reconstructive practice
- Covid-19 patients are not admitted for treatment at QVH. The site has been designated a *Covid-protected* cancer hub for the region, reducing covid cross-infection to patients admitted for surgery. Resumption of breast reconstruction at QVH will not adversely impact management of Covid-19 positive patients being treated in the region.

Any proposed surgery has to discussed with the patient and should include the benefit of reconstructive surgery vs. 'material' risk of acquiring Covid-19 during the reconstructive process, resulting in adverse outcomes and complications, including death. This discussion has to be part of the informed consent process and documented in the medical notes.

Surgical prioritisation and pathway

Initial Patient Group: It is proposed that initial reconstructions will be performed in patients who meet the following criteria.

- Pre-menopausal patients and/or under 60 years of age diagnosed with breast cancer requiring unilateral mastectomy (immediate unilateral reconstruction)
- BMI less than 32
- ASA 1 / 2
- All patients discussed in MDT which *includes an anaesthetist*

On referral, the patient is sent a breast reconstruction pack (QVH booklet and DVD). She is then seen for consultation at QVH, with Pre-assessment and MRA abdominal wall for DIEP perforators performed on the same day in a one-stop visit to QVH.

***Extended groups*:** Reconstruction will then be offered to patients with other breast pathologies requiring therapeutic mastectomy and immediate reconstruction, risk-reducing mastectomies, symptomatic patients requiring revision of reconstruction to autologous, and finally to patients requiring delayed reconstruction.

Safety and management of balance of risk vs. benefit in the reconstructive process is paramount. In the long-term, we aim to safely and sequentially return to breast cancer reconstruction using QVH long-standing pre-Covid protocols and patient demographics.

Screening and pathway

Pre-op

- Minimise face-to-face contact through use of Virtual clinics, Electronic information, Video consultations.
- Clinic visit, Imaging for pre-op-planning and Pre-assessment combined.
- **Self-isolation for 14 days [**5]
- RT-PCR preop test when patient added to WL test (possible home-test): If *positive*, surgery is postponed. This allows for optimal and efficient use of major case operating lists with alternative case(s) scheduled into that slot, and to cover the incubation period.
- RT-PCR t preop test when patient added to WL test: If *negative*, continue self-isolation for the 14 days specified period
- 2nd RT-PCR swab test 48-72 hours pre-op
- Specific Covid Co-Consent form: to be used in conjunction with separate procedure-specific surgical Consent form applying Montgomery principles [6].

If 2nd RT-PCR test (48-72 hrs preop) is *negative*, proceed with surgery.

If 2nd RT-PCR test is *positive*, surgery is deferred with the patient self-isolating for a further 14 days minimum, and decision to proceed with surgery following two negative RT-PCR tests. It has been demonstrated that *infective* viral shedding can occur until day 8. RT-PCR is repeated twice to ensure there is no activity and to account for the possibility of one false negative swab, and establish this as a benchmark of best practice.

For mixed Priority 2/4 patients (i.e. immediate breast reconstructions where the reconstructive element is priority 4), a pre-operative *positive* swab would necessitate an open and frank discussion with the patient and a decision to treat the breast cancer with *no* reconstruction is advisable.

In South Korea, surgery is postponed until RT-PCR swab turns negative. A pre-op positive patient is admitted to a Covid treatment hospital/centre (patient does not go home for isolation) and treated until *negative* conversion. The patient returns to the non-covid hospital, tested at the time of, scheduling the operation and again day before

admission. The time period is approximately 7-14 days after first negative swab test. This may not be feasible in the UK setting.

The goal is to minimize the possibility of any Covid+ve patients being admitted to hospital.

Personnel

- Staff screening using tests that detect the presence of virus (LAMP+/- RT-PCR): at regular intervals is key to minimise the risk of in-hospital spread from asymptomatic or pre-symptomatic staff. At QVH, staff will be risk-stratified and regular testing may range from daily to every week.
- Rigorous in-house contact-tracing, to minimise risk of transmission from staff to patients and staff to staff.
- Visiting surgeons screened for the presence of virus in line with the above.
- Minimise number of staff in contact with individual patient.

Intra-op

- Two-consultant operating for major cases to reduce operating time to an average of 4-5 hours for free flaps (breast recon), instead of 6-7 hours.
- With two consultant teams, it is advisable to have a 3rd consultant with the requisite skills on standby, in the event of one surgeon testing positive pre-operatively.
- Reduce in-theatre circulating personnel with appropriately planned teams.
- All in theatre personnel to wear appropriate PPE.

Postop

- RT-PCR swab test to detect the presence of virus at discharge.
- Where practical, patients to self-isolate after major surgery for 14 days [6].
- First postop dressing clinic visit at 10-14 days + a further RT-PCR test.
- Minimise face to face follow-up visits. Virtual / remote follow-ups.

Positive postoperative RT-PCR swab at Discharge

- Duty of candour- patient informed.
- Track and trace all staff in contact with a positive patient.
- Self-isolation of the relevant staff for 7-14 days according to local guidance.
- RT-PCR swab test for staff members prior to returning to work and monitoring with LAMP swab test on return to work.

  When a discharge RT-PCR swab test is positive, and preop RT-PCR test is negative, the preop *negative test does not preclude the presence of Covid-19 infection*. The patient may have had a (i) *False negative* preop RT-PCR test due to *inadequate material* on the swab or *low viral load* in asymptomatic or

pre-symptomatic patients. Or (ii) patient has *hospital-acquired Covid*. This can be minimised by extensive and regular staff testing.

Postoperative test at discharge is advisable, as this has been established as best practice internationally, eg. South Korea where elective surgery has continued during the pandemic. The second purpose of postoperative Covid test at discharge is, in a positive patient, to permit measures to be put in place for safe self-isolation and adequate care during recovery from surgery. Furthermore, it is the hospital's ethical responsibility to consider the societal implications regarding discharging a patient with covid into the wider community.

In addition to staff self-isolation for 7-14 days after contact with a covid positive patient, consideration should also be given to disinfection of the ward, operating theatres, other patients notified and scheduled surgical patients given the choice to defer their surgery (South Korea).

Conversely, track and trace all patients who have been exposed to positive staff members.

Conclusion

As clinicians, the decision for individual patients offered surgery is a balance between undergoing surgery for breast cancer and immediate reconstruction to minimise hospital episodes vs. the risk of poor outcome from Covid-19 exposure and infection. Undertaking surgery in a designated *Covid-protected* cancer centre, with rigorous pre-operative screening of patients and staff will help to considerably reduce the risk of Covid-19 transmission.

References

[1] First report of UK National Flap Registry

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[2] Association of Breast Surgery statement 27 April 2020

https://associationofbreastsurgery.org.uk/media/252026/abs-statement-270420.pdf

[3] Clinical guide to surgical prioritisation during the coronavirus pandemic

https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/C0221-specialty-guide-surgical-prioritisation-v1.pdf

[4] RCOA : restarting planned surgery 1 May 2020 : https://static1.squarespace.com/static/5e6613a1dc75b87df82b78e1/t/5eac2a173d65cd27933fca88/1588341272367/Restarting-Planned-Surgery.pdf

[5] Surgical College and Associations: Guidelines for Pre-operative Covid-19 testing for elective cancer surgery 13 May 20: https://www.rcsed.ac.uk/media/681195/guidelines-for-pre-operative-covid-19-testing-for-elective-cancer-surgery-1305202.pdf

[6] Covid Co-Consent form.

[7] Association of Breast Surgery statement 25 May 2020 https://associationofbreastsurgery.org.uk/media/296474/may-abs-statement-final-250520.pdf

Useful website (s):

https://icmanaesthesiacovid-19.org/clinical-guidance