



Long-term Follow-up and Trends in Breast Augmentation in 527 Transgender Women and Nonbinary Individuals: A 30-year experience in Amsterdam



Isha Sijben^{a,b}, Floyd W. Timmermans^{a,b}, Oren Lapid^c, Mark-Bram Bouman^{a,b}, Wouter B. van der Sluis^{a,b,*}

^a Center of Expertise on Gender Dysphoria, Amsterdam University Medical Center, location VUmc, Amsterdam, the Netherlands

^b Department of Plastic, Reconstructive and Hand Surgery, Amsterdam University Medical Center, location VUmc, Amsterdam, the Netherlands

^c Department of Plastic, Reconstructive and Hand Surgery, Amsterdam University Medical Center, location AMC, Amsterdam, the Netherlands

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* Corresponding author: Wouter B. van der Sluis MD PhD. Department of Plastic, Reconstructive and Hand Surgery, Amsterdam University Medical Center, location VUmc, De Boelelaan 1117, 1081 HV, Amsterdam, The Netherlands. *E-mail address:* w.vandersluis@vumc.nl (W.B. van der Sluis).

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underwent breast augmentation and genital gender-affirming surgery in one-stage. Reoperations due to short-term complications were infrequent (hematoma (0.4%) or infection (0.4%)). Reoperations due to long-term complications comprised: implant rupture (5.7%), capsular contracture (4.9%), aesthetic problems (3.8%), low-grade infection (0.4%), or seroma (0.6%). In total, 2.5% of individuals requested larger implants. After performing the literature search and manuscript screening, 9 out of 115 identified studies were included for review. Follow-up time ranged from 30 days to 5.5 years. Reported complications requiring reoperation were capsular contraction (range 0.0-5.6%), asymmetry (3.6%), hematoma (range 0.0-2.9%), infection (range 0.0-0.9%) and implant rupture (0.7%),

Conclusion: Implant-based breast augmentation is a safe procedure in transgender individuals. \bigcirc 2021 British Association of Plastic, Reconstructive and Aesthetic Surgeons. Published by Elsevier Ltd. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/)

Introduction

The reported prevalence of transgender and nonbinary people seeking medical and surgical care increased in the past decades.¹ This trend is also observed in The Netherlands.² Gender-affirming surgical procedures in transgender women and transfeminine spectrum nonbinary individuals comprise breast augmentation (top surgery), orchiectomy, gender-confirming-vulvoplasty or vaginoplasty (bottom surgery), and other feminizing procedures, such as facial gender-confirming surgery and chondrolaryngoplasty.

Before any gender-affirming surgical procedure is performed, transgender women and nonbinary individuals have to meet criteria set by the World Professional Association for Transgender Health (WPATH). These include persistent and well-documented gender dysphoria, legal ability to provide informed consent, being of legal adult age, and other medical or mental problems, if present, should be well controlled. Breasts are associated with femininity and may therefore be an important aspect for some transgender women and nonbinary individuals. Feminizing hormone therapy often only results in moderate breast growth.⁴ Therefore, some individuals may opt for surgical breast augmentation to achieve a satisfactory result. Generally, it is recommended to be on feminizing hormone therapy for at least one year before opting for breast augmentation surgery.³ Satisfaction with breasts, psychological well-being, and sexual well-being are known to improve after breast augmentation in this population.⁵

Currently, information on long-term follow-up of transgender women who underwent breast augmentation is scarce.⁶ Large-volume studies, especially with long followup times, are lacking. The aim of this study is to provide information and long-term follow-up of implant-based breast augmentation in transgender women and nonbinary individuals. An up-to-date overview of relevant literature on this subject is also provided.

Methods

Design

All transgender women and nonbinary individuals who underwent breast augmentation with or without genital

gender-affirming surgery (gGAS) from January 1990 to January 2020 were identified from the hospital registry. Some included individuals were described in earlier studies.⁷⁻⁹

Time path analysis

Individuals who underwent both gGAS and breast augmentation, either at our or another institution, were included for time path analysis. They were classified as: augmentation first, gGAS first or augmentation, and gGAS in one stage.

Surgical outcomes

For the retrospective analyses on surgical outcomes, only transgender women and nonbinary individuals who underwent primary breast augmentation at our center were included. The following data were recorded:

- Individual demographics: age at implantation, body mass index, medical history (hypertension, diabetes mellitus, HIV), history of smoking, and alcohol abuse.
- Surgical characteristics: incision site, implant pocket location.
- Implant characteristics: brand, size.
- Date of breast augmentation and gGAS.
- Complications or other reasons requiring reoperation.
- Implant survival: time to explantation of implant.
- Clinical follow-up, defined as the time between breast augmentation and the last visit at our transgender clinic.

Setting

The Amsterdam University Medical Center, location VUmc is the largest gender surgery center in the Netherlands with a high-volume presentation of transgender and nonbinary individuals who wish to undergo gender-affirmative treatment. It is the only hospital in the Netherlands which provides the full range of surgical procedures for both transgender men and women. Consequently, the majority of transgender individuals in The Netherlands receive their treatment at our center.²

Follow-up protocol

After breast augmentation with an uncomplicated course, individuals are discharged the day after surgery. A scheduled postoperative visit is planned two and six weeks after surgery or on indication, depending on the occurrence of postoperative complications. Long-term complications were diagnosed 'only on presentation of a complaint' at the outpatient clinic. Generally, individuals follow multiple (medical and surgical) simultaneous treatment trajectories at the plastic surgery department and different transgender specialties in our hospital, which allows for a long clinical follow-up time.

Literature search

A systematic literature search was performed in MEDLINE on all available literature on breast augmentations in transgender women and nonbinary individuals. The search was performed in November 2020. Studies reporting clinical outcomes and/ or revision surgery were included. Exclusion criteria were case-reports and studies reporting cancer as clinical outcomes. No restrictions were imposed with regard to publication date. The search string consisted of the following search terms:

- (Mammaplasty[MESH] OR 'breast implantation'[MESH] OR 'breast implants'[MESH] OR breast augmentation) AND ('Transgender Persons'[mesh] OR 'gender dysphoria'[mesh] OR transgender* or transsexual* or trans-sexual*).

All full-texts of identified manuscripts were screened by two authors (IS, WvdS) for eligibility.

Statistical analyses

All statistical analyses were performed using IBM SPSS software Version 26.0 (IBM Corp., Armonk, N.Y.). Descriptive statistics were calculated for all variables. Continuous Gaussian variables were presented as means and standard deviations (SD), continuous non-Gaussian variables as medians and Q1-Q3 interquartile ranges (IQR). Categorical data were presented as frequencies and percentages. The Kruskal-Wallis test was performed to assess change of implant size over periods of ten years and the Mann-Whitney U test for independent observations to compare median implant size. Breast implants survival outcomes were presented as Kaplan-Meier curves. The censored outcomes are defined as the last visit or lost to follow-up of participants. The endpoint is explantation of implants. P-values of < 0.05 were considered significant.

Results

Study population

A flow chart of study participation is presented in Figure 1. A total of 1388 individuals underwent gGAS in the study time period (1328 vaginoplasty, 17 no-depth vaginoplasty,

| Table 1 Demographics of included individu | lais. | | |
|--|----------------------------------|--|--|
| Demographic | Value | | |
| Total number of included individuals, n (%) | 527 (100) | | |
| History of vaginoplasty | 507 (96.2) | | |
| History of no-depth vaginoplasty | 3 (0.6) | | |
| History of orchiectomy | 2 (0.4) | | |
| No history of gGAS | 15 (2.8) | | |
| Median age breast augmentation (y); IQR | 35; 27-45 | | |
| Mean BMI at surgery (kg/m2) \pm SD | $\textbf{23.3} \pm \textbf{3.5}$ | | |
| Pocket, n (%) | | | |
| Subglandular | 372 (70.6) | | |
| Dual plane | 139 (26.4) | | |
| Subpectoral | 15 (2.8) | | |
| Unknown | 1 (0.2) | | |
| Incision, n (%) | | | |
| IMF | 494 (93.7) | | |
| Axillary | 27 (5.1) | | |
| Periareolar | 1 (0.2) | | |
| Unknown | 5 (0.9) | | |
| Documented history of intoxications, n (%) | | | |
| Alcohol abuse | 26 (4.9) | | |
| Smoking | 269 (51.0) | | |
| Co-morbidity, n (%) | | | |
| Hypertension | 47 (8.9) | | |
| Diabetes Mellitus | 18 (3.4) | | |
| HIV | 25 (4.7) | | |
| Median clinical follow-up (y); IQR | 11.2; 3.3-17.5 | | |
| IMF = Inframammary fold, BMI = Body gGAS = genital gender-affirming surgery | mass index, | | |

43 orchiectomy), of whom 653 (47%) underwent breast augmentation. These individuals were included for time path analysis. With exclusion of 141 individuals who underwent breast augmentation elsewhere, and inclusion of fifteen individuals who underwent breast augmentation without a form of gGAS, a total of 527 individuals were included for surgical outcome and trend analyses. All gGAS procedures were performed in our center, except for one genderconfirming vulvoplasty and two vaginoplasty procedures. Individual demographics are presented in Table 1.

Trends in time path: breast augmentation and gGAS

An overview illustrating the chronological order of surgical procedures in included individuals is presented in the online-only Supplementary Data 1. The overview of the time path also included transgender women and nonbinary individuals who underwent breast augmentation or gGAS elsewhere (Figure 1). In total, 653 transgender women and nonbinary individuals underwent both breast augmentation and gGAS (vaginoplasty n=647, genderconfirming-vulvoplasty n=4, or orchiectomy n=2) between January 1990 and January 2020. Of 653 included individuals, 85 (13%) underwent gGAS before, 417 (64%) in the same session and 150 (23%) after breast augmentation. The median time between augmentation and gGAS was 16.4 months (IQR 10.9 - 27.6) and the median time between



Figure 1 Flow chart of study participants and corresponding analyses.

surgeries in those undergoing breast augmentation after gGAS was 20.4 months (IQR 8.6 - 39.9). Whereas breast augmentation and gGAS in the same session was the most prevalent in earlier years, a trend is observed toward undergoing breast augmentation at a later stage then gGAS.

Trends in implant-based breast augmentation

In total, 527 transgender women and nonbinary individuals underwent primary breast augmentation in the study time period in our center. The number of performed breast augmentation procedures over the years is presented in Figure 2.

- Trends in implant size

The median implant size was 290cc (IQR 230 - 340). The median implant size used during the last decade increased significantly as compared to median implant size reported in 1990 - 1999 (median difference + 100cc, P < 0.001) and 2000 - 2009 (median difference + 123cc, P < 0.001) (Figure 3).

- Trends in implant brands

The brands of the breast implants used in our center changed over the past decades (online-only Supplementary Data 2). In the 1990s, frequently used brands were: Mentor/Siltex, Nagor, and PIP. Later on, the majority of breast augmentations were performed with the brand Allergan (McGhan, Inamed, CUI, Inspira, and Natrelle). Currently, predominantly Motiva is used.

- Implant Pocket

Breast implant pockets were subglandular (n= 372 (70.6%)), subpectoral (n= 15 (2.8%)), or dual plane (n= 139 (26.4%)). Between 1991 and 2007, the subglandular pocket was more common. After 2007, the majority of implants were placed in the dual plane pocket (online-only Supplementary Data 3).

Complications and implant survival

An overview of complications requiring reoperation is presented in Table 2. Short-term complications were uncommon and comprised infection (2/527, 0.4%) or hematoma (2/527, 0.4%). Long-term complications comprised mainly capsular contracture (26/527, 4.9%, after a mean time of 6.8 ± 4.7 years) and implant rupture (30/527, 5.7%, after a mean time of 12.9 \pm 6.5 years). Implant survival, defined as 'the original breast implant that was in place at the time of follow-up', is presented in Figure 4. In 141 of 150



Figure 2 Number of transgender women and nonbinary individuals who underwent breast augmentation in our center per year. In the time period 2006-2016, breast augmentation was not reimbursed by public medical insurance companies.



Figure 3 Median implant size per year. In the time period 1990-1999, a median implant size of 275 cc was used, in the time period 2000-2009, 252 cc, and in the time period 2010-2019, 375cc.

individuals, the first time of explantation was also the first reoperation. No distinction was made between explantation of one or both breast implants within one individual.

Breast implant-associated anaplastic large-cell lymphoma

Anaplastic large-cell lymphoma (ALCL) was diagnosed in one transgender woman, which has been published elsewhere.¹¹

ALCL was diagnosed after a long trajectory of multiple reoperations and different prostheses.

Regret

During the study time period, five (0.9%) of 527 people who underwent breast augmentation developed transitional regret, of which three opted for implant explantation. One person underwent explantation of implants due to rupture,

| Table 2 | Clinical | outcomes o | f breast | augmentation | in 527 | 7 included | individuals. |
|---------|----------|------------|----------|--------------|--------|------------|--------------|
| | | | | | | | |

| | First reoperation | Mean time to reoperation |
|---|-------------------|------------------------------|
| | N (%) | years \pm SD |
| Short-term complications (<3 months) | | |
| Hematoma, for which retake to theater | 2 (0.4%) | Day: 1; 3 |
| Infection, for which explantation | 2 (0.4%) | Day: 7; 11 |
| Long-term complications (>3 months) | | |
| Rupture | 30 (5.7%) | 12.9 (±6.5) |
| Capsular contracture | 26 (4.9%) | 6.8 (±4.7) |
| For which capsulectomy | 7 (1.3%) | 2.5 (±1.8) |
| For which implant exchange | 19 (3.6%) | 9.2 (±5.3) |
| Excessive seroma, for which explantation | 3 (0.6%) | 0.6 (months: 2.6, 7.7, 12.9) |
| Low-grade infection, for which explantation | 2 (0.4%) | 11.0 (±2.6) |
| Aesthetic problems* | 20 (3.8%) | 4.8 (±4.6) |
| For which reoperation | 7 (1.3%) | 1.5 (±2.8) |
| For which implant exchange | 13 (2.5%) | 6.6 (±4.8) |
| Other reasons | | |
| PIP recall** | 52 (9.9%) | 11.7 (±1.3) |
| Request larger size | 13 (2.5%) | 5.0 (±5.9) |
| Request for explantation*** | 8 (1.5%) | 9.5 (±7.6) |

* Aesthetic problems: dislocation, malposition, asymmetry, rippling, cleavage tenting, or double bubble sign of implants.

** PIP implants were at risk for rupture¹⁰.

*** Transition regret, neck and shoulder problems, health complaints they attributed to implants, temporary explantation due to family who did not accept transition



Survival Functions

Figure 4 Survival of breast implant, as depicted per brand. The survival analysis included the following brands: Motiva, Mentor/Siltex, Allergan (Inamed/ McGhan/ CUI/ Inspira/ Natrelle), Nagor, PIP, and others (Dow corning, Silimed, and unknown). Implant rupture occurred in the following brands: Inamed (n= 5), McGhan (n= 1), PIP (n= 6), Nagor (n= 3), Mentor (n= 14), or unknown (n= 2).

before the date of regret. One person did not yet undergo explantation at time of analysis.

Literature search

A total of 115 studies were identified. After full-text screening, a total of nine studies on surgical outcomes and/ or revision of breast augmentation in transgender women and nonbinary individuals were included. Most studies on this subject were of retrospective design. An overview is presented in Table 3. Follow-up time ranged from 30 days to 5.5 years. The reported complications requiring reoperation were: capsular contraction (range 0.0-5.6%), asymmetry (3.6%), hematoma (range 0.0-2.9%), infection (range 0.0-0.9%), striae distensae (0.7%), implant rupture (0.7%), abscess (0.4%), scarring (0.0%), hypersensitivity (0.0%), and numbness (0.0%). Studies reporting satisfaction of breast augmentation in transgender women and non-binary individuals used different kind of patient-reported outcome measurements (PROMs).

Discussion

In this article, trends, outcomes and long-term follow-up of transgender women and nonbinary individuals, who underwent primary breast augmentation, are presented. Short-term complications were scarce and consisted of hematoma or infection, both in 0.4% of cases. Implant rupture (5.7%) and capsular contracture (4.9%) were the most common long-term complications. Thirteen (2.5%) transgender women and nonbinary individuals underwent revision breast augmentation due to a request for larger implants.

In current literature, the reoperation rate after breast augmentation in the described population ranges from 0% to 18%. However, great variation exists in reported clinical follow-up times and upheld definition of complications.^{5-9,12-15} The prevalence of capsular contracture requiring reoperation ranges from 0.0% to 5.6%. Implant rupture was reported in one study in 0.7% of included individuals. The maximum reported follow-up was 5.5 years (Table 3). This could, at least partially, explain the higher rate of capsular contracture and rupture observed in our study when compared to other studies, since reoperations due to capsular contracture occurred after a mean time of 6.8 years and reoperations due to implant rupture occurred after a mean time of 12.9 years.

Cuccolo et al. compared short-term complications of breast augmentation in cis- and transgender women. The reoperation rates were low in both.¹³ Similar to studies published in the transfeminine population, studies reporting on postoperative complications after breast augmentation in ciswomen are variable in follow-up time and upheld definitions of complications.¹³ Short-term complications requiring reoperation was infrequent in our study as well as in literature of ciswomen.^{16,17} Long-term complication rates requiring reoperation defined as capsular contracture and rupture were lower in ciswomen, although their follow-up time was shorter.¹⁸⁻²⁰

The number of performed breast augmentations per year varied over the past decades. A decrease was observed in

the period 2007-2016. An explanation for this decrease is most likely due to our national public medical insurance companies halting the reimbursement of breast augmentations between 2006 and 2016 (online-only Supplementary Data 4). The authorization of reimbursing by public medical insurance companies remained valid for one year, which explains the decrease after 2006. This underlines the fact that insurance reimbursement policy may affect the accessibility to surgical care of transgender individuals.

A shift in surgical timing of gGAS and breast augmentation was observed. In the 1980's, breast augmentation was performed either during or after the gGAS procedure.⁹ In that time period, breast augmentation was rarely performed before or without the prospect of a vaginoplasty procedure, which may be a reflection of a more binary (surgical) gender view.²¹ For some time now, it has been possible for the individual to choose for top surgery- with or without bottom surgery, in the order of their preference.

The aforementioned study of Kanhai et al. reported a trend of increasing implant size over the years.⁹ This over-time increase of implant sizes has also been observed in a study by Fakin et al..¹² Our data supports this observation as well. Thirteen (2.5%) transgender women and nonbinary individuals underwent reoperation following the request for larger implants. Three of these individuals were mentioned the same study cohort (1979 - 1997) performed at our center earlier. In that cohort, eleven (5.5%) of 201 transgender women and nonbinary individuals requested larger implants.⁹ The decrease in transgender women and nonbinary individuals requesting reoperations for larger implants could be explained by the increase of average implant size over the past decades, as well as the historically variable reimbursement policies by public medical health insurance companies.

In practice, larger implant sizes are generally associated with wider based implants. These two implant characteristics, in our experience, results in a more harmonious result in relation to the broader chest seen in transgender women. Resulting, the choice for larger, wide-based implants allows for both cleavage formation and more appropriate nipple positioning on the breast. The lessons taught by our experience throughout the years have emphasized the necessity of informed decision-making on implant characteristics and proper expectation management to achieve patient satisfaction.

Unfortunately, known studies reporting satisfaction of breast augmentation in transgender women and nonbinary individuals used different kinds of PROMs. The existing BREAST-Q was not developed to cater to the needs of transgender people.²² An all-encompassing transgender-specific PROM is still being developed, which will also specifically address breast augmentation outcomes.²³

Strengths of this study comprise the study population size with long-term clinical follow-up. Limitations of this study comprise the lack of patient-reported outcomes, which was however mentioned in a recent study by our colleagues⁴, and the retrospective nature of the study. For our systematic review, only the MEDLINE database was used. Therefore, the absence of multiple search methods is a limitation. Different implant dimensions available over the years and different surgeons performing augmentations in this single-center study may contribute to a certain

| Authors | Year | Ν | gGAS before, during or after augmentation | Implant size | Complications | Request larger size | Satisfaction measurement and outcome | Follow-up |
|------------------------------|------|-----|---|---|---|------------------------|--|----------------------------------|
| Kanhai et al. ⁷ * | 1999 | 201 | NR | Increased from mean 165 to 287 cc | Reoperation n=21 (10.4%): n= 11 (5.5 %) Capsular contraction n= 11 (5.5%) not specified | NR | NR | NR |
| Kanhai et al. ⁸ * | 2000 | 107 | During (n=85) Before (n=22) | Mean 258 cc Range 130-450 | NR | n= 17 (16%) | Semi-structured, self-developed, non-validated questionnaire 75% satisfied, 25% dissatisfied: majority about breast size (too small), other reasons were pain and aesthetic problems. | 5.5 years (range 1.3-17) |
| Kanhai et al. ⁹ * | 2001 | 201 | During (n=159) Before (n=42) | Mean 255 cc Range 120-450 | NR | n= 11 (5.5%) | NR | Mean 3.8y Range 0.04-16) |
| Weigert et al. ⁵ | 2013 | 35 | Before | Mean 327 \pm 61 cc | No complications or reoperations | NR | BREAST-Q satisfaction with breasts, sexual well-being, and psychosocial well-being improved significantly at 4 and 12 months after surgery | Median 20.7 Range 12.0 - 39.6 |
| Fakin et al. ¹² | 2019 | 138 | NR | $\begin{array}{c} 1995\text{-}1999\\ 221\pm 44\\ 2000\text{-}2004\\ 250\pm 49cc\\ 2005\text{-}2010\\ 348\pm 113\\ 2011\text{-}2016\\ 363\pm 97\ cc\\ \end{array}$ | Reoperation $n= 12$ (18%): n= 5 (3.6%) Asymmetry n= 4 (2.9%) Capsular contracture n= 1 (0.7%) Striae distensae n= 1 (0.7%) Hematoma n= 1 (0.7%) Rupture | n= 13 (9.4%) | Retrospective chart review and subjective extrapolation of satisfaction. Very satisfied: 67%, satisfied: 15%, neither satisfied nor dissatisfied: 2%, dissatisfied: 15%, very dissatisfied: 2% | Median 4.6y Range 2.0-13.3 |
| | | | | | | | (co | ntinued on next page) |

 Table 3
 Overview of literature on surgical outcomes of breast augmentation in transgender women and non-binary individuals

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| Authors | Year | Ν | gGAS before, during or after augmentation | Implant size | Complications | Request larger size | Satisfaction measurement and outcome | Follow-up |
|---------------------------------|------|-----|---|--|---|------------------------|---|------------------------------|
| Miller et al. ⁶ | 2019 | 34 | NR | Mean 520 cc (range 350-700) | n= 1 (2.9%) Hematoma (reoperation) n= 1 (2.9%) Infection n= 2 (5.9%) Extrusion n= 1 (2.9%) Excessive scarring n= 1 (2.9%) Asymmetry | NR | Self-developed, non-validated questionnaire 93% was happier and more satisfied with their chest. 100% reported improvement in their gender dysphoria and expressed they would choose to undergo the operation again. 25% expressed the wish for revisionary surgery after augmentation | Mean 15.9m Range 0.5-38.7 |
| Cuccolo et al. ¹³ | 2019 | 280 | NR | NR | n= 3 (1.1%) Hematoma n= 1 (0.4%) Abscess | NR | NR | 30 days |
| Chatterjee et al. ¹⁴ | 2020 | 111 | Before | n=14 180-300cc n=76 300-400cc n=21 400-550cc | n= 12 (10.8%) Capsular contracture, for which reoperation in one individual n= 1 (0.9%) Infection n= 11 (9.9%) Poor scarring | n= 2 (1.8%) | NR | NR |
| Coon et al. ¹⁵ | 2020 | 36 | NR | 530 ± 76 | n= 1 hematoma (2.8%) n= 2 capsular contraction (grade 3) (5.6%) | NR | Self-developed, non-validated questionnaire Results: improvement in psychosocial well-being and high satisfaction rate with overall cosmetic result (79% very satisfied and 21% moderately satisfied) | Mean 6m range 0- 22 |

*= Overlap of included individuals can be expected in these same-author studies

amount of intervention bias with regard to the trend of increased implant sizes observed

Conclusion

The incidence of short- and long-term complications after implant-based breast augmentation in transgender women and nonbinary individuals is acceptable. The procedure may be regarded as safe. Over the years, implant size, brand, pocket, and medical reimbursements have changed.

Conflict of Interest

None declared.

Funding

None.

Ethical Approval

The study protocol was assessed and approved by the Ethical Review Board of the Amsterdam University Medical Center, location VU University Medical Center, and is registered under METC 2014322.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.bjps.2021.03. 107.

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