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| **CRITICALLY APPRAISED TOPIC** |

**FOCUSED CLINICAL QUESTION**

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| For a transgender patient planning to undergo gender affirming surgery, will a comprehensive exercise plan and physical therapy intervention pre- and post-surgery result in more efficient and effective recovery? |

**AUTHOR**

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**CLINICAL SCENARIO**

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| The patient is a 30-year-old transgender female who is planning on scheduling her gender-affirming vaginoplasty surgery sometime in the next 3 months. She works full-time doing mainly office work for a fermentation company, which occasionally requires heavy lifting. Due to limited coverage from her health insurance, the money she has saved barely cover the procedure itself. She inquires at the surgeon’s office about an exercise program that she can begin now in order to help her recover from her surgery faster and get back to work as soon as possible, and is referred to pelvic floor physical therapy. She lives a mainly sedentary life outside of work, but is highly motivated to increase her physical activity in preparation for surgery.  There is limited research in this area and many transgender patients face barriers to healthcare including not knowing where to go, and who is safe to talk to.1,2 Not only do I want be an accessible and clearly inclusive provider, I also want to her recover as quickly as possible, and spend the least amount of money. Therefore, I would like to know if pelvic floor physical therapy interventions pre and post-surgery will be effective in strengthening and recovery, helping her return to work and prior level of function after surgery as soon as possible. |

**SUMMARY OF SEARCH**

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| Eight studies met the inclusion and exclusion criteria established prior to the search. These included 1 RCT, 3 cohort studies, 1 case series, 1 cross sectional study and 2 qualitative analysis.   * There is a high incidence of pelvic floor dysfunction in transgender female patients, prior to vaginoplasty, in which a screening by a physical therapist prior to surgery can lead to reduced symptoms and an improved quality of life.3 * In addition to physical dysfunction, this patient population has a high prevalence of depression, anxiety and poor mental health, and tend not to seek out healthcare due to fear of discrimination. A lack of knowledge regarding health issues in the transgender population leads to poorer overall care.1,2,4 * Seeking a pelvic floor physical therapist before gender-affirming vaginoplasty has been found to be beneficial, as therapists can both identify and resolve pelvic floor issues prior to and following surgery that may otherwise go undetected and untreated.3,5,6 * Pelvic organ prolapse, bowel and bladder complications and impaired sexual functioning are all common issues following vaginoplasty, that can be addressed by a pelvic floor physical therapist.6–8 * Overall, there is a paucity of high-quality evidence regarding physical therapy for the transgender population for gender-affirming surgery (or otherwise). The evidence that does exist is generally low-level evidence of moderate to poor methodological quality, limiting the applicability of the findings to clinical practice. |

**CLINICAL BOTTOM LINE**

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| Taking into consideration the limitations of the evidence found, referring this patient to a pelvic floor physical therapist who is knowledgeable about transgender health issues and inclusively-minded would be a major consideration for their rehabilitation. Secondly, preoperative pelvic floor physical therapy beginning at least 2 months prior to surgery can reduce pelvic floor dysfunction symptoms and identify areas that could encumber postop rehabilitation. Following surgery, at least 3 months of therapy is shown to have desirable outcomes, particularly when paired with preop therapy as well. |

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| ***This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor*** |

**SEARCH STRATEGY**

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| **Terms used to guide the search strategy** | | | |
| **P**atient/Client Group | **I**ntervention (or Assessment) | **C**omparison | **O**utcome(s) |
| “Transgender”  “Trans”  “intersex”  “non-binary”  “gender affirming surgery”  “vaginoplasty”  “top surgery”  “breast augmentation” | “Physical therapy”  “physio”  “physiotherapy”  “prehab-ilitation”  “rehabilitation”  “pelvic floor therapy”  “pelvic floor exercise” | No PT treatment | “Post-surgery recovery”  “recovery time”  “patient reported quality of life”  “patient reported function” |

**Final search strategy (history):**

*Show your final search strategy (full history) from PubMed. Indicate which “line” you chose as the final search strategy.*

1. Trans OR Transgender OR intersex OR non-binary
2. “Gender affirming surgery”
3. Vaginoplasty
4. top surgery OR breast augmentation
5. “physical therapy” OR physiotherapy OR rehabilitation ~~OR prehabilitation~~
6. “pelvic floor therapy” OR “pelvic floor exercise”
7. Recovery OR “post-surgery recovery” OR “recovery time”
8. #1 AND #2 AND (#5 OR #6)
9. **#1 AND (#2 OR #3 OR #4) AND (#5 OR #6)**
10. #1 AND (#2 OR #3 OR #4) AND (#5 OR #6) AND #7

*In the table below, show how many results you got from your search from each database you searched.*

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| **Databases and Sites Searched** | **Number of results** | **Limits applied, revised number of results (if applicable)** |
| **PubMed**  **CINHAL**  **Embase**  **Web of Science** | **133**  **61**  **25**  **122** | English, and published from 2010-2020 decreased the results to 92  Reduced to 55 with published in 2010-2020  N/A  Reduced to 110 when looking for publications 2010-2020 |

## INCLUSION and EXCLUSION CRITERIA

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| **Inclusion Criteria** |
| * any non-gender conforming/gender variance patient population * all ages of patient * Include lesser performed surgeries such as ‘metoidioplasty’ and ‘phalloplasty’ * qualitative research * randomized control trials * patient reported outcomes regarding quality of life and function |
| **Exclusion Criteria** |
| * Not published in English * Published prior to 2000 |

**RESULTS OF SEARCH**

**Summary of articles retrieved that met inclusion and exclusion criteria**

*For each article being considered for inclusion in the CAT, score for methodological quality on an appropriate scale, categorize the level of evidence, indicate whether the relevance of the study PICO to your PICO is high/mod/low, and note the study design (e.g., RCT, systematic review, case study).*

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| **Author (Year)** | **Risk of bias (quality score)\*** | **Level of Evidence\*\*** | **Relevance** | **Study design** |
| **Jiang et al. (2019)**5 | **Downs & Black 17/29** | **Level 4** | **High** | **Retrospective case series** |
| **Manrique et al. (2019)**3 | **Downs & Black**  **21/29** | **Level 3** | **High** | **Retrospective cohort study** |
| **Canner et al. (2018)**4 | **Downs & Black**  **18/29** | **Level 3** | **Low** | **Observational study**  **(Retrospective cohort study)** |
| **Ross & Setchell (2019)**2 | **JBI Critical Appraisal of Qualitative Research**  **9/10** | **Level 5** | **Moderate** | **Qualitative design** |
| **De Cuypere et al. (2004)**7 | **Downs & Black**  **15/29** | **Level 2b** | **Low** | **Longitudinal cohort study** |
| **Kuhn (2011)**8 | **Downs & Black**  **17/29** | **Level 4** | **Moderate** | **Cross-sectional study** |
| **Snelgrove et al. (2012)**1 | **JBI Critical Appraisal of Qualitative Research**  **9/10** | **Level 5** | **Low** | **Qualitative analysis** |
| **Pauls et al. (2014)**6 | **PEDro – 6/11** | **Level 1b** | **Moderate** | **RCT** |

\*Indicate tool name and score

\*\*Use Portney & Watkins Table 16.1 (2009); if downgraded, indicate reason why

**BEST EVIDENCE**

The following 2 studies were identified as the ‘best’ evidence and selected for critical appraisal. Rationale for selecting these studies were:

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| * **Manrique OJ, Adabi K, Huang TC-T, et al. Assessment of Pelvic Floor Anatomy for Male-to-Female Vaginoplasty and the Role of Physical Therapy on Functional and Patient-Reported Outcomes. *Ann Plast Surg*. 2019;82(6):661-666. doi:10.1097/SAP.0000000000001680** * Level 3 evidence, which I know in the grand scheme of things is not great, but is on the higher end of what I’ve found relating to my topic, with a relatively high Downs and Black score of 21/29; This study directly addresses all aspects of my PICO question. It also looks at both preoperative physical therapy as well as postoperative physical therapy and the outcomes that they had in the transgender patient population. * **Jiang DD, Gallagher S, Burchill L, Berli J, Dugi D. Implementation of a Pelvic Floor Physical Therapy Program for Transgender Women Undergoing Gender-Affirming Vaginoplasty. *Obstet Gynecol*. 2019;133(5):1003-1011. doi:10.1097/AOG.0000000000003236** * This is another study that is highly relevant to my PICO question despite lower level of evidence and a moderate methodological quality (17/29 on the Downs and Black scare). Again, this study looked at both preoperative and postoperative physical therapy intervention and the associated outcomes. Though relevant, this study was notably weaker than the first, with a lack of validated outcome measures. Despite this, the authors were able to demonstrate the impact that a physical therapy program can have post gender affirming surgery and also implicates the need for further studies. |

**SUMMARY OF BEST EVIDENCE**

**(1) Description and appraisal of “Assessment of Pelvic Floor Anatomy for Male-to-Female Vaginoplasty and the Role of Physical Therapy on Functional and Patient-Reported Outcomes by Manrique OJ, Adabi K, Huang TC-T, et al., 2019**

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| **Aim/Objective of the Study/Systematic Review:** |
| The aim of this study was to examine the incidence of pelvic floor dysfunction in transgender females undergoing vaginoplasty, prior to surgery and evaluating the progression of these symptoms following the surgery with the use of standardized patient-reported outcome measures. It is looking at the role of physical therapy within these circumstances and how it can be used as treatment as well as its effectiveness in improving long-term outcomes in this patient population. |
| **Study Design**  [e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]  Note: For systematic review, use headings ‘search strategy’, ‘selection criteria’, ‘methods’ etc. For qualitative studies, identify data collection/analyses methods. |
| This is a retrospective cohort study that looked at 40 patients undergoing a male to female transition with a gender-affirming vaginoplasty, over the course of 2 years. A physical therapist took each patient’s history and performed a physical examination pre-operatively. Following this assessment, an individualized comprehensive treatment plan was developed in order to address the findings of the exam, including components of patient education, manual therapy, therapeutic exercises and neuromuscular re-education. A home exercise component was also included and patients were seen by a physical therapist for an average of 6 months with 2-4 appointments prior to their surgery and re-evaluated at a mean of 3.4 weeks following the vaginoplasty. They continued therapy for an average of 13 months following surgery with 3-5 appointments.  Patient demographics, their history with hormonal therapy and comorbidities were compared among those who presented with symptoms as well as those who never developed symptoms. The severity of symptoms was assessed by standardized outcome measures, the Pelvic Floor Distress Inventory (PFDI-20) and the Pelvic Floor Dysfunction Index. Patients completed these assessments with every physical therapy session, pre-operatively and post-operatively.  The Wilcoxon rank sum test was used to compare continuous variables and the Fisher exact test was used to compare nonparametric variables between the symptomatic and non-symptomatic groups. In looking at multicategory data Fisher (2 x n) evaluated the associations between variables and outcomes with P<.05 considered statistically significant. |
| **Setting**  [e.g., locations such as hospital, community; rural; metropolitan; country] |
| This study took place in a multidisciplinary transgender clinic and Manrique is a surgeon practicing at the Mayo Clinic in Rochester, MN. |
| **Participants**  [N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]  Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article. |
| Participants in this study were a group of 40 patients that were scheduled to undergo a gender-affirming vaginoplasty between July 2016 and July 2018. The mean ago of this group was 40.7 years and spanned from 19 to 72 years old. The mean BMI was 27.1 kg/m2 and comorbidities within the group include 4 patients with diabetes and 6 patients with hypertension. They were all seen by a physical therapist for a preoperative assessment for symptoms of pelvic floor dysfunction. All patients had initiated hormone therapy an average of 2.2 years prior to their initial physical therapy assessment. After the initial physical therapy assessment, 31 of the 40 patients were determined to be symptomatic of pelvic floor dysfunction and 9 were non-symptomatic. Compliance was high with in this group, with 2 patients who opted out, one after the therapist assessment and one after surgery, and only 2 patients who had completed 1 less appointment than recommended by the therapist initially. |
| **Intervention Investigated**  [Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* |
| As a cohort study, there was no true control group in this study, though there were 5 total patients who remained non-symptomatic of pelvic floor distress throughout the study and did not receive physical therapy treatment. |
| *Experimental* |
| As a retrospective cohort study there was no true experimental group but the procedure of the study is outlined below.  Preoperatively, the 40 patients were examined by a physical therapist and a thorough history was taken. Following this assessment, 31 patients were determined to be symptomatic of pelvic floor distress and 9 were non-symptomatic. One patient with symptoms of distress opted out of preoperative physical therapy as it triggered her gender dysphoria. For the remaining 30, an individualized treatment plan was created considering the information from the exam findings, for the symptomatic patients. This plan consisted of patient education focusing on bladder training or retraining, sexual health and lifestyle modifications, as well as manual therapy of soft tissue that reduced muscle spasms and fascial tightness. The plans also included therapeutic exercises to help target coordination of the lumbopelvic muscles as well as lumbar stabilization and hip strengthening. Exercises that focused on respiration, kinetic awareness and postural training were also taught to patients, to be incorporated into a home exercise program. Lastly, the treatment plan had a neuromuscular re-education component where patients learned how to appropriately contract and relax pelvic floor muscles voluntarily and involuntarily, with visual, tactile and auditory feedback in order to improve pelvic floor muscle awareness, neuromotor control and appropriate lumbopelvic activation. Patients went to physical therapy for a minimum of 6 months prior to their surgery. They went for between 2-4 appointments in this timeframe  The non-symptomatic patients upon the physical therapist assessment in the study did not perform therapy prior to their surgery.  All patients had follow-ups at an average of 3.4 weeks after their surgery, and reported outcomes were assessed every 2-3 months with PFIQ-7 and PFDI-20 outcome measures. One patient with symptoms prior to surgery opted out of therapy at this time, and one patient who was previously non-symptomatic began having symptoms following surgery. The patients who developed pelvic floor distress symptoms following surgery began pelvic floor physical therapy for an average of 13.2 months, with similar techniques employed as the preoperative therapy treatment plans. Patients were seen for 3-5 appointments in this timeframe. |
| **Outcome Measures**  [Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| The two outcome measures used in this study are the Pelvic Floor Distress Inventory (PFDI-20) and the Pelvic Floor Dysfunction Index (PFIQ-7). These both have been standardized for pelvic floor dysfunction and widely cited in literature supporting their use.  At the initial assessment by the physical therapist, only the 6 item Urinary Distress Inventory (UDI-6) and 8 item Colorectal Anal Distress Index (CRAD-8) components of the PFDI-20 were administered as the third section, the 6 item Pelvic Organ Prolapse Distress Inventory is specific to female pelvic and vaginal anatomy. All three components of the PFDI-20 were completed post-operatively. Scale scores for each component were determined by taking the mean value of all answered items (possible value from 0 to 4) within a section and then multiplying by 25 to obtain the scale score (possible range 0-100). A summary score was obtained by adding the scores from the 3 components together (possible range 0-300).  The PFIQ-7 was completed postoperatively in order to assess the impact of pelvic floor dysfunction on daily living, assessing patient symptoms and how much they affect their activities, relationships and feelings over the past 3 months. It is broken down into bladder/urine, bowel/rectum and vagina/pelvis and how each affect chores, physical activities, entertainment activities, travel, social activities, emotional health and feelings of frustration. All items used the response scale of 0= not at all, 1=somewhat, 2= moderately, 3 = quite a bit. To find the scale score, the mean of each section is calculated (possible range 0-21), multiplied by 100 and then divided by 3. Then the 3 scale scores are added together for the total score (possible range 0-300). |
| **Main Findings**  [Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. You may summarize results in a table but you must explain the results with some narrative.] |
| **Preoperative**: There was a high incidence of pelvic floor dysfunction as 77.5% of participants reported symptoms in the initial evaluation by the physical therapist. The mean score of the PFDI-20, without the Pelvic Organ Prolapse component was 162.4/300 (range 152-173) with a mean score of 91.3 on the UDI-6 section (range 84-99) and a mean score of 71.1 on the CRAD-8 section (range 68-74). In a comparison of patients who were symptomatic vs. asymptomatic, it was determined that the mean age in those with symptoms was higher than in those without, with P<0.01.  When both the UDI-6 and CRAD-8 were administered again 2 months prior to surgery, a significant reduction in symptoms were seen with physical therapy, with P<0.01. Five patients (16.1%) reported complete resolution of their symptoms, and all others reported some amount of improvement. The mean of UDI-6 scores dropped to 60.4 (range 58-63) and the mean of CRAD-8 scores dropped to 65.6 (range 54-67).  **Postoperative:** Following surgery one participant in the non-symptomatic group began reporting symptoms of pelvic floor distress. This patient was 12 years older than the mean age (40.7 years) and had a history of diabetes and hypertension. Overall, mean PFDI-20 scores increased after surgery from 120 (range 110-129) to 129.2 (range 127-134) with a change from 60.8 (range 59-63) mean score of the UDI-6 to a mean score of 62.1 (range 58-63) and a change of a mean score of 66.1 (range 54-68) on the CRAD-8 to a mean score of 66.9 (range 65-69). None of the immediate changes from preoperative scores to postoperative scores were considered significant.  At a 6 month follow up after surgery a significant reduction of symptoms on the PFDI-20 was seen with P<0.01. UDI-6 scores dropped to 54.8 (range 53-55, P<0.01) and 63.3 (range 62-65) in the CRAD-8 component. Eight patients (26.7%) reported complete resolution of their symptoms and all patients reported some amount of improvement.  The PFIQ-7 also showed a drop in scores from 112.4 (range 108-114) to 103 (range 101-104) signifying patients’ symptoms were having less impact on their daily lives.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | Initial Preop Exam | 2 mo. prior to surgery | 1 mo. prior to surgery | 1 mo. post-surgery | 6 mo. post-surgery | | **UDI-6** mean scores | 91.3 | 60.4 | 60.8 | 62.1 | 54.8 | | **CRAD-8** mean scores | 71.1 | 65.6 | 66.1 | 66.9 | 63.3 | |
| **Original Authors’ Conclusions**  [Paraphrase as required. If providing a direct quote, add page number] |
| There is a high incidence of pelvic floor dysfunction in patients prior to gender-affirming surgery, indicating that pre-operative assessment of the pelvic floor is crucial to improving post-surgical outcomes. Additionally, in these patients with pelvic floor dysfunction, physical therapy can “significantly improve symptoms both prior to and after surgery.” (p.665) |
| **Critical Appraisal** |
| **Validity**  [Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.] |
| **Internal Validity**: Downs & Black, 21/29  This score on the Downs & Black scale indicates a relatively high internal validity, as this was a well-structured cohort study.  **Weaknesses**: Limitations of this study include the small sample size and inconsistent use of outcome measures throughout the study. Manrique et al., mention the absence of appropriate outcome measures to use in this population as many pelvic floor dysfunction questionnaires mention vaginal anatomy, which pre-surgery does not relate to this population. With only 2 assessments appropriate for this population, it limits the data that is able to be collected. Along these lines, an outcome measure that look deeper into the psychosocial issues, such as gender dysphoria, that could play a role in pelvic floor dysfunction within this population would also be useful in future studies. Lastly, longer follow-up time after surgery could also be beneficial in order to see the long-lasting effects of physical therapy.  **Strengths**: As previously mentioned, this study had high compliance with the participants with a low drop-out rate and consistent attendance to physical therapy sessions. Despite the few number of physical therapy sessions over the 6 months pre- and post-operatively, improvement was seen due to patient compliance with their home exercise program. Additionally, throughout the study, patients were evaluated on a regular basis at similar times in their surgical journeys.  **External Validity**: Due to its small sample size, and resulting small power, the external validity of this study is lower as it may not be applicable to a wider range of patients. |
| **Interpretation of Results**  [This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.] |
| The first issue seen with this study is that 3 participants seem to disappear from the results. It began with 9 non-symptomatic patients and by the post-operative assessment, there are 6 non-symptomatic patients with no mention of if 3 opted out, didn’t go through with the surgery or something else entirely. Additionally, as this study had a small sample size, it decreases the statistical power of the study and increases the likelihood of a Type II error skewing the results. As many of the participants had pelvic floor dysfunction to begin with (double what was previously reported in literature for the overall patient population), this could very well have been the case here.  All that being said, due to the complete lack of research on transgender health care, there is definite value to this study, as it did find significant improvement in pelvic floor dysfunction with the addition of physical therapy to the patients’ care. It is unclear if any of these participants knew of their impaired pelvic floor before the initial physical therapy assessment, again showing the value of pelvic floor therapy in this population. |
| **Applicability of Study Results**  [Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.] |
| Though this is Level 3 research as a retrospective cohort study and there is a small sample size, this study is applicable to this clinical question as it looks at pelvic floor health both prior to and after gender-affirming surgery and found that physical therapy significantly improved dysfunction in both cases. Additionally, the finding that only one patient, of older age and with diabetes and hypertension showed symptoms of pelvic floor dysfunction after surgery indicates that vaginoplasty itself does not necessarily result in pelvic floor dysfunction. Pelvic floor therapy would be a practical and feasible intervention to pursue before vaginoplasty, in order assess existing pelvic floor dysfunction that could be exacerbated by surgery. |

**(2) Description and appraisal of Implementation of a Pelvic Floor Physical Therapy Program for Transgender Women Undergoing Gender-Affirming Vaginoplasty by Jiang DD, Gallagher S, Burchill L, Berli J, Dugi D., 2019**

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| **Aim/Objective of the Study/Systematic Review:** |
| The objective of this study was to examine the incidence of pelvic floor dysfunction in transgender women undergoing a gender-affirming vaginoplasty, along with the outcomes that a pelvic floor physical therapy (PT) program could provide for this population. |
| **Study Design**  [e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]  Note: For systematic review, use headings ‘search strategy’, ‘selection criteria’, ‘methods’ etc. For qualitative studies, identify data collection/analyses methods. |
| This is a retrospective case series from one setting, and one surgeon that looks at the 77 vaginoplasty patients referred to pelvic floor PT prior to surgery in the timeframe of May 2016 until February 2018. The patients’ medical records were reviewed for baseline demographics that included age, BMI, and distance from the facility, medical comorbidities, insurance data, attendance of pelvic floor PT and their dilation measurements of the neovagina at 3 and 12 months post-surgery. Both written and verbal consent was provided by the patient before undergoing pelvic floor PT, and the visit note was reviews for content relating to patient-reported bowel, urinary and skeletal pelvic floor muscle dysfunction. Patients were also asked about their history of abuse, but responses were voluntary and they were not expected to elaborate on the topic. The only follow up question was regarding appropriate past or current mental health counselling. No formal patient-reported outcome measures were administered. |
| **Setting**  [e.g., locations such as hospital, community; rural; metropolitan; country] |
| This study took place at the Oregon Health and Science University, with the Department of Urology, Division of Plastic Surgery, Transgender Health Program and Department of Physical Therapy and Rehabilitation. |
| **Participants**  [N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]  Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article. |
| This study examines all patients who underwent a primary gender-affirming vaginoplasty between May 1, 2016 and February 28, 2018 at this single institution. This was a total of 77 patients with a mean age of 41.4, mean BMI of 27.7 and an average of 5.7 years on hormone therapy. Most (41, 53%) lived locally (less than 20 miles from the facility), with 19 living less than 100 miles away and 18 living more than 100 miles away. Hypertension, diabetes and HIV were the most common comorbidities. Of the 77 patients, 72 (94%) attended pelvic floor physical therapy in this timeframe at least once. 55% of the patients had government-supported insurance (Medicaid or Medicare). |
| **Intervention Investigated**  [Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* |
| As this was a retrospective case study, there was no control group. |
| *Experimental* |
| Again, as this is a retrospective case study, there is no true experimental group. With the population that is being studied, every person who was scheduled for a vaginoplasty beginning in May 2016 was also referred to pelvic floor PT prior to surgery and after dilation, which is typically 10 days post-surgery. At the surgical consultation, the purpose of pelvic floor PT is explained to the patient and they are provided with a handout at the visit. The rationale for PT is explained again to them by the physical therapist as well, so the patient feels empowered to make their own decision to pursue physical therapy, but patients who therapists have specifically determined have pelvic floor dysfunction are encouraged to attend PT. The patients who decided to pursue pelvic floor PT reviewed and signed a standard written consent form and verbal consent was needed to proceed to each stage of the exam process, and the patient had the option to terminate the exam at any point.  The exam began with a visual evaluation of the perineal area, looking for the presence of haemorrhoids or skin tags and then observing pelvic floor muscle contractions. This was followed by a manual exam which included palpation of the perineal area and an internal exam of the external anal sphincter, while the patient contracted and relaxed their pelvic floor muscles. The therapist was mindful of gluteal compensations during this component of the process. Exercises taught were varied dependent on the impairments found. If the patient had difficulty relaxing, they were taught breathing exercises that involved slow inhales to expand the lower abdomen and pelvic floor, as well as exercises to stretch their Levator Ani complex. For patients with great strength, they were taught a supported deep squat to promote extensibility. Electromyelogram biofeedback was used as a way to improve patient’s awareness of their pelvic floor contractions and to facilitate complete relaxation. Therapists also educated patients on desensitization techniques to help reduce post-surgical pain and down-regulate the central nervous system, such as deep breathing exercises and guided relaxation. Lastly, the therapist provided information and guidelines regarding exercise prescription and return to normal daily activities following surgery.  At the first follow-up 10-14 days following surgery, patients begin dilation as instructed by their surgical team. They are given a set of dilators increasing in size from 7/8 in diameter to 1.5 in diameter and instructed to perform dilation 3x a day for 30 minutes at a time. They are told to gradually increase the size until they reach their personal goal. At 3 months, they were considered to be successful if they could perform scheduled dilation with no significant pain or difficulty using at least a 1 1/8 in diameter dilator. At a year follow up, they were considered successful if they had met their goal dilator size. |
| **Outcome Measures**  [Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| The main outcome measure considered in this study to track patient progress post-surgery was dilator size, with follow ups at 3 months following the procedure and 12 months following the procedure. Patients were given a set of dilators, P1 at 7/8 of an inch diameter, P2 at 1 inch diameter, 1 at 1 1/8 inch diameter, 2 at 1 ¼ inch diameter, 3 at 1 3/8 inch diameter and 4 at 1 ½ inch diameter. Success of dilation was self-reported by the patient.  Other factors investigated was the in the study was the incidence of pelvic floor dysfunction as determined by a therapist, the incidence of abuse as reported by the patient and the attendance to pelvic floor PT, the specific issues addressed there and the rate of resolution of those issues. |
| **Main Findings**  [Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. Use a table to summarize results if possible.] |
| **Attendance**: Of the 77 patients who had vaginoplasty surgery between May 1, 2016 and February 28, 2018, 72 (94%) of them attended at least one pelvic floor PT visit. Of the 72, 65 (80%) attended preoperative pelvic PT with 52 of those patients only completing a single visit and 13 who had attended multiple sessions. 50 patients attended postoperative pelvic floor PT and of those 22 had a single visit and 28 were seen more than once. 43 of the patients attended at least one pre-op and one post-op pelvic floor PT session.  **Pelvic Floor Muscle Dysfunction:** 42% of the patients seen in the preoperative pelvic floor PT sessions had pelvic floor muscle dysfunction, with 37% that presented with bowel dysfunction. Postoperatively, 36% of the patients had pelvic floor muscle dysfunction, 28% had urinary dysfunction and 22% had bowel dysfunction. Of the 43 patients that attended both post and pre-op therapy, the incidence of pelvic floor muscle dysfunction was significantly lower at the postop than the preop visit, as compared to the 7 patients whose first session was post-surgery (P=.006).  **Resolution of Pelvic Floor Dysfunction:** The rate of resolution of pelvic floor muscle dysfunction by the first postoperative PT visit consisted of 69% of the patients. 73% of the patients with bowel dysfunction resolution by this same visit.  **History of Abuse**: A history of abuse correlated to a higher rate of preoperative pelvic floor muscle dysfunction, with 91% of patients with a reported history of abuse demonstrating dysfunction and only 31% of those with pelvic floor dysfunction with no history of abuse (P<.001).  **Dilation:** At the 3-month follow-up, post-surgery 89% of patients were able to successfully dilate to their goal on a routine schedule while 11% were unable due to pain, anxiety or other health/personal reasons. The availability of information regarding the 12 month follow up was limited, but of the 24 patients that reported this information, 88% had met their goal dilation. |
| **Original Authors’ Conclusions**  [Paraphrase as required. If providing a direct quote, add page number] |
| The authors concluded that pelvic floor PT should be an integral component of transgender gender-affirming surgery programs and is a necessary aspect of a multidisciplinary approach in transgender healthcare, particularly for those pursuing surgical gender-affirmation. |
| **Critical Appraisal** |
| **Validity**  [Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.] |
| **Internal Validity**: Downs & Black, 17/29  This study has fair internal validity according to the Downs & Black scale. There were many limitations as it was a retrospective case study, so blinding and randomization obviously did not happen.  **Weaknesses**: The major weakness of this study is though it had a fairly sizable sample size, all patients came from the same facility and were seen by the same surgeon which limits generalization of the outcomes to a larger population. Additionally, there was a lack of valid and reliable outcome measures used, due to the fact that there are no validated measures for pelvic floor muscle dysfunction appropriate for use within the transgender female population who are undergoing vaginoplasty. However, there was still no patient reported information regarding their impression or satisfaction with pelvic floor PT, which could have provided more insight and data for this study. Lastly, the short follow up time, and reduced data from that follow up also are limiting factors in this study. The healing process post vaginoplasty can take a year or more, so longer follow ups would be important to more accurately track outcomes.  **Strengths:** This study did find a high incidence of pelvic floor muscle dysfunction within the female transgender patients preoperatively, highlighting that this is an ongoing issue that this population faces. Additionally, including pelvic flood physical therapy in the treatment plan for vaginoplasty helped to improve this dysfunction and was generally well accepted by patients. It also examined a psychosocial cause for pelvic floor muscle dysfunction, as it included data about the patients’ reported history of abuse, which is a common finding within the cisgender female population.  **External Validity:** Due to the fact this study focused on a group of patients seen by one surgeon, from one institution, its applicability to a larger population may be questionable. |
| **Interpretation of Results**  [This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.] |
| In this day and age, pretty much any research done on healthcare in the transgender population is valuable, and though this study is far from perfect it provides valuable information regarding issues this population faces as well as the effectiveness of a multidisciplinary approach to care for this population. Preoperative pelvic floor PT visits uncovered a high incidence of pelvic floor dysfunction prior to surgery, that were lowered or resolved over the course of the study, indicating the clinical importance of incorporating pelvic floor physical therapy in this population. Along these lines, this study made the correlation within its sample size that there was a higher incidence of pelvic floor muscle dysfunction in patients with a reported history of abuse. This is a significant takeaway as therapists are healthcare professionals who develop a trusting relationship with their patients and can help ensure that they are seeking the mental and emotional support they need, while addressing the associated physical issues they face. Lastly, the patients that attended both preoperative and postoperative physical therapy demonstrated lower pelvic floor muscle dysfunction or resolution of symptoms all together. Though the sample was very specific in terms that they were all patients of one surgeon, these results indicate that pelvic floor therapy is greatly beneficial for transgender women seeking vaginoplasty and that beginning therapy preoperatively is crucial in order to identify issues prior to surgery and develop a treatment plan to address these impairments. |
| **Applicability of Study Results**  [Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.] |
| While this study is a retrospective case study, it is highly applicable to the clinical question at hand as it focuses on the exact patient population and investigates the use of pelvic floor physical therapy both before and after surgery. This study brings to light the importance of beginning pelvic floor therapy pre-operatively as many patients are not aware of their pelvic floor muscle dysfunction and this can be identified and treated before a more invasive procedure is performed on those muscles. The preoperative use of pelvic floor PT can identify impairments that could hinder recovery postoperatively, and due to the higher prevalence of pelvic floor dysfunction found in the transgender female population this is again relevant to the clinical scenario and question. |

**SYNTHESIS AND CLINICAL IMPLICATIONS**

[Synthesize the results, quality/validity, and applicability of the two studies reviewed for the CAT. Future implications for research should be addressed briefly. Limit: 1 page.]

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| Overall, these two studies are fairly similar in their findings, as both highlighted the importance of preoperative pelvic floor PT, in order to identify and treat pelvic floor dysfunction before vaginoplasty, as the surgery in and of itself generally does not lead to dysfunction. Both studies reported a high incidence of pelvic floor dysfunction upon patients’ initial physical therapy examinations, and both remarked that it was a much higher rate than reported in similar studies in the cisgender female population. This could be due to the hormone therapy transgender women receive, the discrimination that this population faces decreasing the likelihood that they would seek out additional medical care, increased incidence of abuse in this population or other unknown causes.3,5  With this high prevalence of pelvic floor muscle dysfunction, again both studies reported significant improvement or even resolution of these symptoms by the time patients were evaluated postoperatively after pelvic floor PT intervention. This is important to note in regards to the clinical scenario, as if impairments are discovered by a physical therapy exam before vaginoplasty, it is indicated by these studies that it can be likely resolved through therapy before the surgery, particularly if the patient is highly motivated and compliant with a home exercise program.3 Both studies determined that preoperative pelvic floor therapy can considerably improve post-surgical outcomes and pelvic floor therapists should be considered part of the multidisciplinary team of those undergoing gender-affirming vaginoplasty.  Both studies had similar limitations in that the samples made it difficult to generalize to a larger population. Manrique et al.’s study had a small group who underwent pelvic floor therapy and though Jiang et al.’s sample size was nearly double, it was limited in that all patients were from the same surgeon. Additionally, both studies were retrospective and therefore there was no blinding or randomization involved. Another shared weakness was the lack of reliable and valid outcome measures used, though this is mainly due to the fact that appropriate outcome measures for this population do not exactly exist. Manrique et al.’s study was stronger in this sense with the use of the PFDI-20 and PFIQ-7 in order to evaluate pelvic floor dysfunction and its impact on daily life. Though the use was not consistent pre and postoperatively, it did provide significant information about patients’ improvement after pelvic floor therapy.3  Future research is most certainly indicated for the use of pelvic floor physical therapy in the treatment plan of gender-affirming surgeries within the transgender population. Prospective studies with a larger and more diverse sample would be greatly beneficial in seeing the outcomes of therapy in a more general population. Another avenue for related research would be on valid and reliable ways to quantify pelvic floor dysfunction in this population, relevant to both pre and post-operative anatomy. |

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