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Early Outcomes of Spongiosum-guided Topographic Anatomical Reassembly Compared with Tubularized Incised Plate Repair for Distal Hypospadias: A Single-Center Pilot Randomized Trial

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Introduction

Hypospadias has been suggested to occur in one in every 250 male births [1]. However, accurately estimating the prevalence of such a congenital anomaly has not been successful; with studies varying widely in its incidence [1]. Different surgical techniques have been adopted through the years with ongoing modifications and refinements [1, 2]. Although plenty of techniques have been suggested, the results were satisfactory to both surgeons and the family.

Tubularized Incised plate (TIP) was presented in the late 20th century, and ever since has become one of the most adopted techniques in the repair of the distal penile hypospadias (DPH) [3-6]. According to several publications TIP in the hands of an expert can offer optimal functional and cosmetic outcomes [7, 8]. However, the technique carries its own complications to varying extent including; meatal stenosis, fistula formation, glanular dehiscence, cosmetic complications, in addition to the impairment of glanular vascularity [6, 9]. These complications were significantly reported in patients with narrower glanular width [10-12]. In a study of more than 2000 patients, a total complication rate of 10.8% was reported. Urethrocutaneous fistula was the most prevalent complication at 5.7%, followed by meatal stenosis at 4.7% and dehiscence at 1.3% [11]. However a metanalysis done in 2014, complications rate was estimated at 21.8% [13]. Despite generally good distal TIP repair results, complications; especially urethrocutaneous fistula (UC fistula) and meatal stenosis) persist and are higher with unfavorable urethral plates. (UP).

As part of the ongoing development of hypospadias surgical repair techniques, a modern surgeon presented a new technique that describes less dissection of the penile tissues and avoids excessive glanular incisions. The technique follows the anatomy ‘topography’ of the penis as illustrated in the surgeon’s published papers, hence the suggested name Spongiosum-guided Topographic Anatomical Reassembly (STAR) [14].

STAR, has been introduced in 2021 [14] Few studies have been published so far, mainly focusing on the technical aspects of the newly presented technique and its outcome [4]. The proposed technique in STAR is based upon an embryological theory that the entire male urethra, is developed by dorsal growth of the urethral plate into the genital tubercle with a ventral fusion of the urethral folds in a proximal to distal sequence (a closing zipper); progressing to the glans

tip. Hence based upon this theory, an interrupted mesenchymal spongiosal folding and thus ventral fusion is the key cause of distal hypospadias. Depending on this theory, the STAR technique was proposed relying mainly on spongioplasty [14, 15]

This prospective pilot RCT aimed to evaluate the feasibility and preliminary safety of STAR adoption by a non-originator team, comparing early complication rates with TIP to inform the design of a future adequately powered confirmatory trial. We aimed to achieve this by comparing short term complication-free rates between STAR and the well-established TIP at 3 months (primary endpoint) and 12 months (secondary endpoint) in a prospective RCT in a high-volume single pediatric urology center [16, 17]. We state that these short term (12 months) outcomes may not reflect those encountered in adolescent and adults' life.

Methods

This is a prospective randomized control study with a relatively short-term follow-up (12 months). Institutional Research Ethics Committee approval (0108103) was granted prospectively in December 2023, and all pre-specified endpoints, inclusion criteria, and the block randomization sequence were locked prior to the first enrollment in January 2024. While public registry on ClinicalTrials.gov (NCT07832760) occurred retrospectively in September 2026 due to administrative delay, the authors attest that no deviations from the original ethics-approved methodology or primary outcome measures occurred at any point. The study was conducted in a high-volume pediatric urology center in a tertiary referral hospital. Patients with fresh distal penile hypospadias presenting to our pediatric urology department in the period between January 2024 till August 2025 were included in the study. Pilot STAR surgeries were conducted prior to this study, where they were conducted in the presence and/or guidance of the index originator surgeon.

The surgical team had established experience with TIP and had completed structured training in STAR before trial enrollment. The study compared outcomes after the two procedures at this center; it was not designed to measure a learning curve or to determine whether surgeon experience caused any observed difference.

The inclusion criteria included patients with uncircumcised fresh distal penile hypospadias younger than the age of 16 years old. Patients who were circumcised, had a previous hypospadias surgery, patients diagnosed preoperatively of proximal hypospadias, and patients with a notable penile curvature of 30 degrees or more were excluded.

Patients were randomly allocated in a 1:1 ratio to either Group A (STAR) or Group B (TIP). The computer-generated allocation sequence was created by an independent statistician utilizing permuted block randomization with a block size of ten to ensure balanced group sizes. Allocation concealment was strictly maintained using sequentially numbered, opaque, sealed envelopes (SNOSE) prepared by an independent administrator. The allocation sequence was concealed from the surgical team, and envelopes were only opened in the operating room immediately prior to the procedure. The operating surgeons were not masked to treatment allocation. Outcome assessments were performed by an examiner who was not involved in surgery and was masked to allocation. Both verbal and written informed consent was obtained from the parents or legal guardians prior to any intervention.

Statistical analyses were performed using SPSS version 28.0 (IBM Corp., Armonk, NY). Continuous variables are presented as median (IQR) or mean ± SD, as appropriate. Age and urethral-plate width, summarized as median (IQR), were compared using the Mann–Whitney U test. Variables summarized as mean ± SD were compared using the independent-samples *t*-test. Categorical variables were compared using Pearson's chi-square test with asymptotic p-values when expected cell counts exceeded 5, and Fisher's exact test otherwise. Monte Carlo estimation of Fisher's exact p-values was applied for tables with sparse cells, using 10,000 permutations. All tests were two-sided, and $p < 0.05$ was considered statistically significant.

An a priori sample-size calculation was performed using G*Power version 3.1.9.7 (Heinrich Heine University Düsseldorf, Germany). Assuming complication-free rates of 92% in the TIP group and 82% in the STAR group (Cohen's $h \approx 0.303$), a two-sided significance level of 0.05 and 80% power, the required sample size was 196 participants per group. A total of 104 participants were randomized, and 101 were included in the primary analysis. Recruitment ended in August 2025 at the close of the prespecified recruitment period; enrollment was lower than anticipated. The study therefore did not reach the planned sample size and was not adequately powered to establish superiority, non-inferiority, or equivalence. We interpret the between-group findings as preliminary and report confidence intervals to show their uncertainty. Secondary and subgroup analyses were exploratory.

A total of six follow-up visits postoperatively at 5-7 days, 2 weeks, 1 month, 3 months, 6 months and 12 months were registered. In addition, a HOSE score (Hypospadias Objective Scoring Evaluation) [20, 21] assessments were performed by an independent examiner (pediatric urology attending not involved in the surgical procedures) who was blinded to group

allocation. HOSE is a validated, examiner-scored instrument that objectively assesses surgical outcome across (meatal position and shape, urinary stream, straightness of erection), assessed at the 3 months and 12 months visit in addition to assessment done after the secondary repair in those who required a revision surgery. HOSE scoring is formulated with a minimal score of 5 points and a maximum score of 16 (corresponding to the lowest and the highest possible scores in each entity respectively). A score of more than or equal to 14 points in this scoring system has been considered a universal benchmark for an acceptable surgical outcome [22].

Urethral plate width was selected as the stratifying covariate because it is the validated anatomical determinant of outcome in TIP repair [10];enabling a like-for-like comparison across arms.

The primary outcome was the proportion of participants who were free of any post-operative complications following distal hypospadias surgery at 3 months after the primary operation. Complications listed as (Fistula, Meatal stenosis, and Glanular dehiscence). Fistula was defined as abnormal unintended opening that forms between the neourethra and the skin. Meatal stenosis was defined as having an abnormal narrowing of the newly constructed urethral meatus. Glanular dehiscence was defined as partial or complete separation of the surgically approximated glans wings.

The secondary outcome at 12 months was defined as current unresolved complication status at the 12-month assessment.

The 3-month primary endpoint was selected to capture early-onset complications while minimizing attrition in this exploratory comparison; 12-month follow-up served as a secondary endpoint to assess delayed complications and revision burden.

To characterize morbidity burden beyond the binary complication-free endpoint, complications were additionally summarized by Clavien-Dindo severity grade [20] for each arm. This stratification distinguishes low-grade, self-resolving events from high-grade complications requiring surgical revision, which the binary endpoint treats as equivalent.

Patients were classified at each assessment point according to current complication status, not cumulative history. At 12 months, patients who had experienced a complication but achieved successful revision were classified as 'complication-free'; patients with unresolved complications or pending revision were classified as 'complicated.' The modified intention-to-treat (mITT) population, comprising all randomized patients who completed at least two

postoperative assessments, was pre-specified in the ethics-approved study protocol prior to patient enrollment. This study is a single-blinded randomized trial. Surgeons were necessarily aware of allocation due to the nature of intervention however the outcome assessment was blinded. Analysis followed the pre-specified mITT approach defined above.

STAR was deemed feasible for local adoption if the observed complication-free rate at 3 months was ≥80%, or within 10 percentage points of the originator's published benchmark (90%).

Surgical technique:

Both STAR and TIP repairs were performed by a consistent two pediatric urology attendings, who both had equivalent fellowship training and independent experience with TIP. (H.S) developed the STAR technique and provided structured approach to the trial surgeons. (H.S) was not involved in patient recruitment or treatment. Before trial enrollment, the team completed structured STAR proctorship and an independent pilot phase before study commencement and performed at least 30 STAR procedures. Outcomes from the pretrial STAR procedures were not prospectively recorded. Therefore, the present study evaluates outcomes in this center after the stated training. This team-based approach eliminated between - surgeon variability as a potential confounder. Intraoperative decision-making, suture materials, and postoperative care protocols were standardized across both arms.

Steps in group A (STAR group):

1. All surgeries were done under general anesthesia and caudal block
2. Patient was placed in a frog like position at the edge of the operating table
3. Intraoperative assessment of the glanular width and urethral plate (UP) width was done in millimeter (mm) using a metal ruler with (mm) markings.
4. A traction suture is placed in the glans just dorsal to the anticipated dorsal end point of the neomeatus
5. 2 mini mosquitoes were used to mark the junction point between the inner and outer preputial layers.
6. Identification of the spongiosal pillars starting at the proximal bifurcation point up to the natural ventral meatal marks at the level of the glans, just below the side protrusions.

7. Exposure of the whole length corpus spongiosum using a tenotomy scissors
8. The ventral hypoplastic urothelial sheet is excised along its whole length
9. 2 stay sutures are applied at the point where the natural ventral endpoint of the urethral meatus was supposed to be located. (at the conjoining point of the converging and diverging parts of the glanular wings)
10. Micro dissection of the covering epithelium of the glans wings is done in the subepithelial plane to a depth of approximately (5 mm), preserving the underlying vascularized bed and avoiding entry into the deep glanular tissue.
11. A silicone catheter is inserted.
12. A single approximating 6-0 (Vicryl) suture is applied at the coronal sulcus, approximating both limbs at the spongio-glanular interface without circumferential narrowing of the neo-meatal lumen (calibrate to admit a 10 Fr sound).
13. Spongioplasty is done in a single interrupted layer using absorbable Vicryl 6-0, with sutures placed to oppose the pillars without visible tissue balancing (a proxy for excessive tension)
14. Using 3 interrupted 6 – 0 polyglactin (Vicryl) sutures, the glanular wings are zipped together in a subcuticular fashion.
15. Excision of the preputial skin is done, and skin closure was completed with 6 – 0 Vicryl sutures.
16. An 8 Fr Silicone catheter was placed intraoperatively and maintained for 7 days. The wound was dressed in paraffin gauze and a compressive bandage, removed at 48 hours with daily cleaning thereafter.

Before trial enrollment, the surgical team completed structured training in STAR and had performed at least 30 STAR procedures. Individual pilot phase complication data were not prospectively recorded and thus readiness criterion compliance is based on surgeon attestation rather than independently auditable documentation. The trial was not designed to measure a learning curve or to compare outcomes by case sequence.

Intraoperative protocol adherence was supported by a standard operative checklist completed for each case, supplemented by intraoperative photographic documentation and

video recording of the procedure. These records allowed the STAR surgery protocol to be verified against the intended technique.

Blinded review of the operative videos identified no systematic difference in technique execution between complicated and uncomplicated cases, indicating that complications were not attributable to gross protocol deviations, while acknowledging that video review cannot exclude subtle execution variability below the threshold of visual detection.

Surgical technique and steps in group B (TIP group):

The repair was performed following the technique of Tubularized Incised Plate described by Snodgrass, et al [5]. Urethral plate tubularization and glans closure employed 6-0 polyglactin (Vicryl) sutures, matching STAR specifications. An 8-Fr silicone catheter was placed for 7 days postoperatively. Dressing protocol was identical to the STAR arm (paraffin gauze, compressive bandage removed at 48 hours, daily wound care thereafter).

Results

An initial cohort of 120 patients was assessed for eligibility. Sixteen patients were excluded (five did not meet inclusion criteria, four declined participating in the study, one withdrew consent, and six did not present for surgery). The remaining 104 patients were randomized to Group A (STAR) or Group B (TIP). Postoperatively, three patients (one in STAR, two in TIP) were lost to follow-up before completing two assessments and were excluded from the final analysis, yielding a modified intention-to-treat cohort of 101 patients (Fig. 1). Group A (STAR) had 51 patients (median 1.8, IQR: 0.7 – 6.0) years while group B (TIP) had 50 patients (median 2.0, IQR: 0.8 – 5.6) years.

Meatal site was predominantly sub-coronal in both group A & B 27/51 (52.9 %), 29/50 (58.0 %) respectively (Table 1). Two measurements were obtained intra-operative; Glanular width (GW) and urethral plate (UP) width. In group A, the (UP) width median (9, IQR: 8-10) mm. In group B, the (UP) width median (8mm, IQR: 7-11). No statistical significance was found between both groups regarding the (UP) width (P value = 0.73) (using the Mann–Whitney U test). (Table 1)

The site of the spongiosal bifurcation following penile degloving was documented. In Group A, 54.9% of patients had mid-penile bifurcation, while 50% in Group B had mid-penile bifurcation. (Table 1)

The operative time; defined as the time from skin incision till skin closure, was recorded in both groups. Group B (TIP) had a longer operative time; mean of 79 minutes (SD ± 5.4 minutes) compared to group A (STAR); mean of 57 minutes (SD ± 6.18 minutes). This was statistically significant (P value < 0.001) using the t-test. (Table 1)

The results of the repair in both groups were categorized into successful or complicated repair. Successful repair is defined as an uneventful, uncomplicated and sequalae free repair. While complicated repair is defined as surgery with post-operative complications including fistulae formation, glanular dehiscence, meatal stenosis or any other undesirable sequalae.

Surgical Outcome:

Group A (STAR) included 51 patients, nine patients (17.6%) had post-operative complications. A urethrocutaneous (UC) fistula component was present in five patients (9.8%); in four this was the sole complication, and in one (2.0%) it co-occurred with meatal stenosis (classified as combined presentation). One patient only presented with meatal stenosis (2.0%). Fistulae were mostly seen at the site of the first approximating suture taken at the white line. In four of the five patients, the fistula was located sub-coronally; the remaining patient developed a fistula in the glans head. The remaining three patients had glanular dehiscence representing (5.9 %).

Group (B) included 50 patients, only five patients (10 %) had post operative complications. Four patients presented with fistulae along the suture line (8.0 %). One patient presented with meatal stenosis (2.0 %). The difference in complications rate between both groups A and B was not statistically significant (P value 0.266) using the Chi square test. (Table 2)

Sensitivity analysis tested the robustness of the primary outcome under varying assumptions for the three excluded patients. Under worst-case assumptions (all exclusions classified as complications), complication-free rates were 80.8% (STAR) versus 86.5% (TIP), p=0.62. Under best-case assumptions (all exclusions classified as healthy), rates were 82.7 % versus 88.5 %, p=0.65. The non-significant between-group difference was consistent across all scenarios.

Management of the complications differed between both groups. In group (A), all patients with fistulae underwent surgical revision successfully at 5, 6 months. Two had a successful revision while three patients had recurring fistula formation. Regarding the three patients (with glanular dehiscence); one patient underwent redo hypospadias surgery at 10th month post-

operative and had a successful repair. The remaining two patients chose to delay their revision surgery thus they were not managed within the study period. In group B, all five patients (10.0 %) were planned for surgical revision during study period. Four of the patients underwent successful revision at 5 & 6 months postoperative which was successful in three out of four patients. The last patient had his surgery done in the 11-month post operative; however, it was not a successful revision.

At 3 months, cumulative complication incidence was 17.6% (9/51) for STAR versus 10.0% (5/50) for TIP (p=0.266). Following revision surgery in twelve patients in both group (A) and (B) (7 in STAR group and 5 in TIP group) respectively, 12-month point prevalence of unresolved complications was 9.8 % (5/51) for STAR versus 4 % (2/50) for TIP (p= 0.436). Cumulative incidence remained unchanged, as no new complications emerged between 3 and 12 months.

Complication-free rates at three months were 82.4% (42/51) for STAR versus 90.0% (45/50) for TIP, yielding an absolute risk difference of −7.6 percentage points (95% CI, −21.5 to 6.3; $p = 0.266$). The 95% confidence interval includes no difference and is compatible with the STAR complication-free rate being up to 21.5 percentage points lower or 6.3 percentage points higher than the TIP rate.

At 12 months, unresolved complications were present in 5 of 51 participants (9.8%) in the STAR group and 2 of 50 participants (4.0%) in the TIP group (two-sided Fisher exact test, p = 0.436). After revision surgery, 46 of 51 participants (90.2%) in the STAR group and 48 of 50 (96.0%) in the TIP group were complication-free.

At 3 months endpoint, by Clavien-Dindo severity; nine & five patients had complication grade III b in Group (A) & (B) respectively. No Grade I,II, IIIa, IVa/b, or V events occurred in either arm.

When looking into the urethral plate parameter; in narrow urethral plate subgroup (< 8 mm), complication rates were 36.4% for STAR (4/11; 95% CI: 2.3% - 51.8%) versus 37.5% for TIP patients (3/8; 95% CI: 10.9% - 69.2%). (Table 3,4) The wide confidence intervals reflect limited subgroup size, precluding definitive conclusions regarding differential technique performance in anatomically challenging cases. In the wide urethral plate subgroup (≥8mm), STAR demonstrated a 12.5 % complication rate (5/40; 95% CI: 4.2% - 26.8%) compared to 4.8 % for TIP (2/42; 95% CI: 0% - 9.0%).

Complication rates by urethral plate width were 4/11 (36.4%) after STAR and 3/8 (37.5 %) after TIP for plates narrower than 8 mm, and 5/40 (12.5 %) after STAR and 2/42 (4.8 %) after TIP for plates at least 8 mm wide. These subgroup analyses involved small numbers and are reported descriptively. They do not establish that complication rates differ by plate width or that the comparative effect of STAR and TIP varies with plate width.

Regarding HOSE score, Group A (STAR) had a mean score of 13.68 (SD ± 2.36). Group B had a mean score of 14.62 (SD ± 1.14) at the three months assessment, mild improvement was noted at the twelfth month assessment up to (14.22 ± 0.69) and (14.98 ± 0.77) in group A and B respectively. The P-value was found to be 0.71 at 3 months and 0.1 at 12 months, denoting a statistically non-significant difference between the HOSE scores of both groups. The scores showed no significant difference between groups at either timepoint (3 – month p =0.71, 12- month p=0.1) though interpretation is limited by a ceiling effect (maximum score 16).

Median post-revision follow-up was 10.8 months (IQR: 8.6-11.2) for STAR and 11.2 (IQR: 8.9-11.1) months for TIP. This 12-month endpoint therefore represents the point prevalence of complications after any revision surgery, reflecting overall salvageability rather than the efficacy of the primary repair. Primary-repair success is captured separately by the 3-month endpoint, before revision procedures.

STAR achieved a primary (mITT) complication-free rate of 82.4% (42/51), meeting both pre-specified feasibility criteria: it exceeded the ≥80% floor and fell within 10 percentage points of the originator benchmark (90.0% − 82.4% = 7.7 pp). A worst-case sensitivity analysis assuming the one post-randomization dropouts were failures yielded 80.8 %, which still satisfies both criteria.

Discussion

In the pursuit of finding the optimal technique for the repair of hypospadias; many techniques have been described over more than a century; all of which aim to restore the normal anatomy and function of the penis [23, 24]. All of the previously reported techniques based their repair on the embryogenesis theory, suggesting that the glans is formed by a canalization of a solid ectodermal ingrowth, with the glans originating as a distal continuation of the corpora spongiosum [25].

Recent evidence suggests that the glanular part of the urethra is a continuation of the whole length of the urethra, hence originates via a dorsal growth of the urethral plate into the genital tubercle with a ventral fusion in a proximal to distal fashion up to the glans [26, 27].

This newly proposed technique is based on restoring “zip-up” the ventral continuity of the corpus spongiosum in a proximal to distal fashion [15]. No studies were found in the literature that compared between the outcomes of TIP and STAR in a randomized fashion. However, evidence could be compared to descriptive studies discussing the results of both.

Operative logistics were standardized across arms (suture material, catheterization protocol, dressing regimen). However, surgeon experience was inherently asymmetric: TIP repairs reflected established proficiency, whereas STAR cases occurred during the post-training adoption phase.

The participating surgeons had established experience with TIP and had completed STAR training before trial enrollment. Because outcomes from the pretrial STAR procedures were not prospectively recorded and trial outcomes were not analyzed by case sequence, this study cannot determine whether the observed between-group differences were related to a learning curve. Differences may reflect the procedure, surgeon experience, chance, or other factors. The results should therefore be interpreted as preliminary outcomes after STAR training at a single center.

STAR outcomes in our series were numerically lower than those reported in the originator's descriptive studies; direct comparison is limited by differences in study design, surgeon experience, and outcome definitions. In the very few published papers discussing the technique, the reoperation rate was reported to be limited to 7%. During our study period, revision surgery was performed in 7 of 51 participants (13.7%) in the STAR group and 5 of 50 (10.0%) in the TIP group. These descriptive rates should be interpreted cautiously and are not directly comparable with rates from other studies with different populations, follow-up periods, or definitions of revision surgery. Following revision, success rates did not differ significantly between groups; however, the study was insufficiently powered to establish equivalence. The observed complication-free rates favored TIP numerically; however, the 95% confidence interval spans both clinically meaningful inferiority and modest superiority for STAR, precluding directional inference. This result is best characterized as inconclusive rather than evidence of equivalence or inferiority.

Regarding (TIP), Snodgrass et al, have reported a complication rate of =< 7% in their extended case series [28], whereas a meta-analysis performed including 49 studies and about five thousand patients; concluded the prevalence of postoperative fistulae formation at 5.7% and the re-operation rate at only 4.5% [8].

The UP-width subgroup analyses in relation to complication rate involve small numbers and should be considered exploratory. They do not establish that the effect of treatment differs by plate width or explain why complications occurred. A larger study designed to assess this interaction would be needed.

Given the limited statistical power of this pilot cohort, our observation of STAR-specific complications in anatomically favorable wide urethral plates must be interpreted with strict caution. While this pattern invites intriguing biomechanical hypotheses—such as potential devascularization during glanular micro-dissection or perpendicular tension from spongiosal pillar approximation—these remain entirely speculative mechanisms that require rigorous validation in future, adequately powered trials.

Operative variables requiring further study include: (1) optimal glanular wing dissection depth to balance mobilization against devascularization, (2) objective tension thresholds for spongiosal pillar approximation, and (3) suture caliber and spacing at the coronal sulcus. Until these parameters are standardized through larger multicenter experience, these exploratory subgroup data do not support any recommendation for patient selection by urethral plate width.

This study describes outcomes after STAR training by two surgeons at a single center. It does not establish reproducibility across teams or centers. Further studies involving independently trained teams are needed to assess how consistently these outcomes can be achieved. Multicenter trials with independently trained surgical teams are needed to confirm whether these results extend across diverse practice settings.

Our study had several limitations including an inherent experience asymmetry: TIP outcomes represent established surgeon proficiency, whereas STAR outcomes were captured during the post-training adoption phase. This design, while intentional to simulate real-world adoption conditions, constitutes a technique-confounded performance bias that cannot be statistically adjusted. The observed STAR complication rate describes outcomes in this study population and should not be assumed to represent outcomes in other settings or after additional surgical experience. We acknowledge the relatively small sample size enrolled, which may not be enough to fully assess a new technique's outcomes, particularly with the familiarity of the surgeons to the other technique. Thus, future studies with larger number of patients are warranted to overcome these limitations.

HOSE outcomes are reported here as aggregate total scores; component subscales (meatal position and shape, urinary stream, erectile straightness, and fistula) were not analyzed

separately. This limits detection of technique-specific functional differences in the meatal and stream domains where STAR and TIP are mechanistically expected to diverge, and subscale-level comparison is a priority for the confirmatory trial. We also realize that HOSE-based functional equivalence should be interpreted cautiously. The meatal shape and position sub-scores assess morphological features that systematically differ between STAR and TIP, potentially compromising assessor blinding. Additionally, a ceiling effect (median HOSE 16/16 in both arms) reflects the anatomically favorable distal population and limits HOSE's capacity to detect subtle between-technique differences. HOSE equivalence therefore reflects absence of gross functional disparity rather than confirmation of equivalent cosmetic or anatomical outcomes.

Future comparative studies should supplement HOSE with uroflowmetry and validated patient- or parent-reported cosmetic satisfaction instruments to capture functional and aesthetic dimensions that aggregate scoring may obscure.

The exclusion of three patients for incomplete follow-up converted our analysis from strict ITT to modified ITT. The asymmetric distribution could theoretically bias results in favor of STAR if excluded TIP patients experienced complications; however, sensitivity analysis classifying all exclusions as treatment failures did not materially alter the primary outcome.

Conclusion

In this single-center pilot randomized trial, the 3-month complication-free rate was 82.4% after topography-guided repair and 90.0% after tubularized incised plate repair. The study was not powered to establish superiority, non-inferiority, or equivalence, and the observed difference should be interpreted as preliminary. These findings describe outcomes at one center and do not establish why the groups differed. Larger, adequately powered trials are needed to evaluate the comparative outcomes of these techniques.

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Conflict of interest: (H.S) developed the STAR technique and provided structured simulation to the trial surgeons. (H.S) was not involved in patient recruitment.

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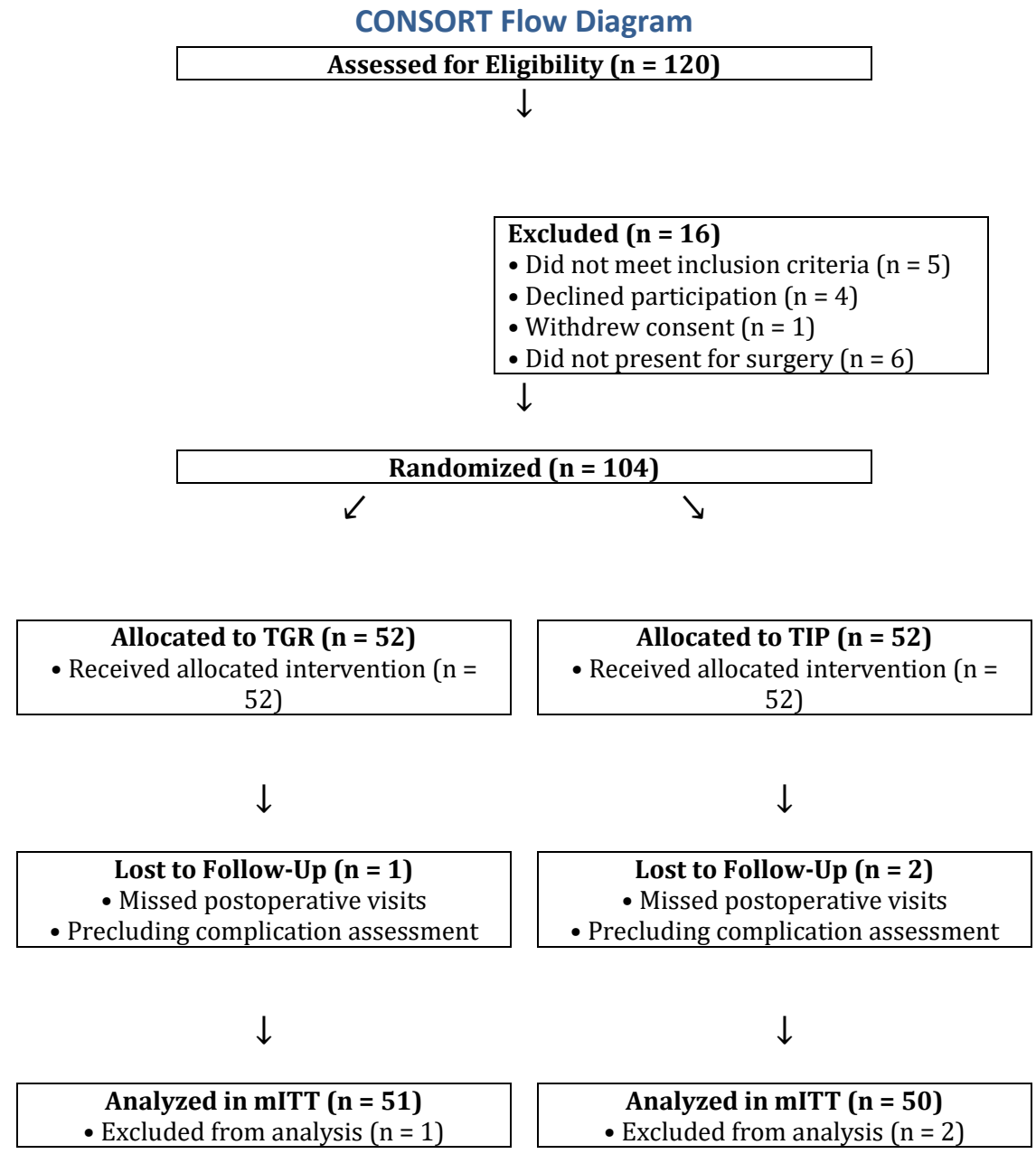


Fig (1) : CONSORT Flow diagram of the study population

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