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High magnification versus optical magnification in hypospadias surgery: a randomized controlled trial

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Abstract

Background Hypospadias is the most common congenital abnormality of the urethra affecting live male births. The incidence is rising with the increasing pollution. During the last 50 years, developments in surgical instrumentation and optical systems allowed surgeons to increasingly undertake microsurgical procedures. Optical magnification is essential in pediatric surgery. Magnifying loupes are the most frequently used, although they often cause neck pain to the surgeon. Recent advances led to the development of a compact video microscope (VITOM; Karl Storz Endoscopy GmbH, Tuttlingen, Germany) that displays high-definition magnified images on a flat screen.

Objective Evaluate VITOM as a potential substitute for loupes in complex open pediatric procedures and explore VITOM as an effective intraoperative teaching modality for open surgery.

Methods Fifty-two patients enrolled in our study were divided into two groups: Group A (26): high magnification was used either (VITOM Karl Storz Endoscopy GmbH, Tuttlingen, Germany) or (Surgical microscope, Carl Zeiss Microscopy GmbH), along with microsurgical instruments. Vicryl 8-0 suture was used for urethroplasty. Group B (26): patients were operated upon by conventional instruments (fine tip but not microsurgical instruments), sutures, and magnification (3.5x). Vicryl 6-0 suture was used for urethroplasty, with loupes-assisted magnification.

Results More complications were found in group B. Using VITOM was accompanied by less neck pain, enhanced visualization, and an enhanced teaching environment.

Conclusion Operating with high magnification tools minimizes post-operative complications in hypospadias surgery. They enhanced identification of the penile anatomy and topography which facilitated reconstruction techniques as well as enhanced the comfort of the surgeon.

Level of evidence I.

Keywords Hypospadias, High magnification, Magnifying loupe, VITOM

Background

Hypospadias is the most common congenital abnormality of the urethra affecting 1:300 live male births worldwide. The incidence is on the rise with increasing environmental pollution as the suspected cause [1].

By meatal location, hypospadias is classified as anterior (glanular and subcoronal), mid-penile (distal penile, midshaft, and proximal penile), and posterior

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(penoscrotal, scrotal, and perineal) accounting for 50%, 30%, and 20%, respectively [2].

The choice of the procedure is based on the characteristics of the urethral plate irrespective of the meatal location. The hypospadias repairs can be classified into single-stage procedures and two-stage urethral plate substitution procedures (Bracka's repair). The single-stage procedures are (a) urethral plate tubularization (glanular approximation and Snodgrass repair) and (b) urethral plate augmentation (e.g., onlay flap and Snodgrass repair) [3]. When the urethral plate does not need transection then it can be tabularized either by Zaonz's GAP (glanular approximation procedure when the plate is wide and deep or by Snodgrass's TIP in cases of narrow, shallow urethral plates [3].

During the last 50 years, developments in surgical techniques, surgical instrumentation, and optical systems have allowed surgeons to increasingly undertake microsurgical procedures. Magnification allows a more accurate perception of operative anatomy and positioning instrumentation, which can improve outcomes and facilitate procedures that would be impossible to undertake without assisted vision. Intraoperative magnification may also reduce surgeons' fatigue as a result of improved ergonomics [4].

Optical magnification is an essential tool in the practice of pediatric surgery. Magnifying loupes are the most frequently used instrument, although their use often comes at the expense of neck pain experienced by the operating surgeon. Recent advances have led to the development of a compact video microscope (VITOM; Karl Storz Endoscopy GmbH, Tuttlingen, Germany) that displays high-definition magnified images on a flat screen. This study was designed to evaluate VITOM as a potential substitute for loupes in complex open pediatric procedures and to explore VITOM as an effective intraoperative teaching modality for open surgery [5]. Drawbacks of traditional magnifying loupes include poor neck posture and frequent head movement to refocus the view, in addition to the inability to share the magnified visual field with surgical residents and assistants [5].

The VITOM exoscope provides images of superb quality, 2–16 times magnification zoom, and good illumination that are displayed on large-format HD flat screens providing better view for the surgeon, assistants, and other operating room personnel [5].

Two types of optical systems are used by surgeons to produce magnification. Loupes can provide up to 6 times magnification while operating microscopes are required for higher magnifications routinely up to 40 times or greater. Loupes are easier to use, less expensive, and more portable than operating microscopes, but

in procedures undertaking work on structures under 1 to 2 mm in diameter, an operating microscope may be required [6].

The VITOM imaging system lends itself well to neonatal and pediatric surgical cases by providing clear visualization of the operation to all operating room personnel, many of whom would typically not be able to see the small operative field because of limitations of space, lack of magnifying loupes, or both [5].

As in other surgical areas, magnifying loupes are essential and beneficial devices in the practice of pediatric surgery and urology, as they enable surgeons to identify and define critical anatomic structures accurately in younger patients. Loupes with $\times 2.5$ – $\times 4.5$ magnification are the most frequently used types, although an operating microscope may be needed in some circumstances, such as for hypospadias repair [7]. This study aims to evaluate VITOM as a potential substitute for loupes in complex open pediatric procedures and explore VITOM as an effective intraoperative teaching modality for open surgery (Fig. 1).

Patients and methods

Primary outcome

To provide a comprehensive comparison regarding the use of high magnification in hypospadias vs. optical magnification.

Secondary outcome parameters

- 1- To introduce the new high magnification technique in the armamentarium of hypospadias surgery.
- 2- To build a prospective randomized controlled study to evaluate the outcome of high magnification in hypospadias surgery.

Study participants

Fifty-two patients enrolled in our study were divided into two groups:

Group A (26)

High magnification was used (VITOM Karl Storz Endoscopy GmbH, Tuttlingen, Germany or Surgical microscope, Carl Zeiss Microscopy GmbH), along with microsurgical instruments. Vicryl 8-0 suture was used for the urethroplasty.

Group B (26)

Patients were operated upon by conventional instruments (fine tip but not microsurgical instruments), sutures, and magnification ($\times 3.5$). Vicryl 6-0 suture was used for the urethroplasty, with loupes assisted magnification||.

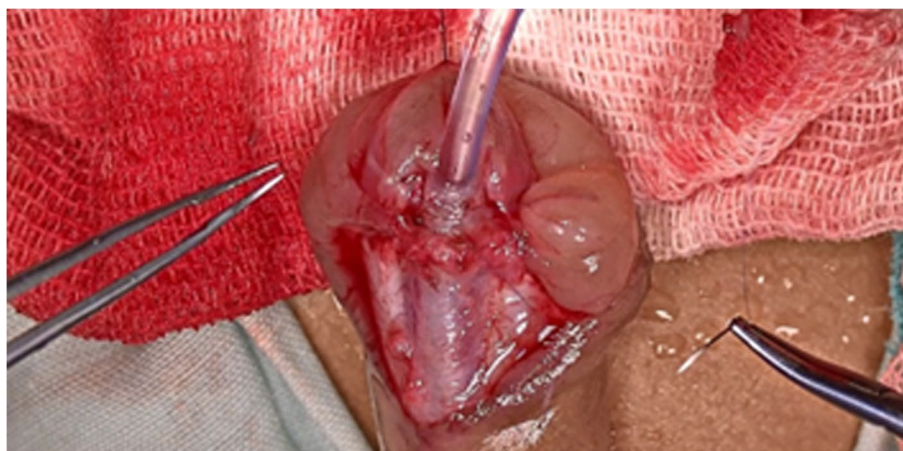


Fig. 1 Picture taken from the VITOM exoscope

Inclusion criteria:

1. Patients with distal hypospadias (down to mid-penile shaft)
2. Patients with mild to moderate chordee (up to 30°).
3. Patient's age is between 6 months and 2 years.

Exclusion criteria:

1. Cases previously operated upon (recurrent, circumcised, or crippled).
2. Cases with proximal hypospadias (proximal penile, peno-scrotal, or scrotal).
3. Patients with severe chordee (more than 30°), if more than 30° by erection test patient is excluded from the study.
4. Associated anomalies or syndromes.

Sample size

The proposed sample size for our study is 52 hypospadias cases divided into two groups.

The justification for the sample size:

Tests-means: difference between two independent means (two groups).

Analysis: a priori: compute required sample size

Input:

Tail(s)=One

Effect size $d=0.7$

α err prob= 0.05

Power ($1-\beta$ err prob)= 0.8

Allocation ratio $N2/N1=1$

Output:

Non-centrality parameter $\delta=2.5238859$

Critical $t=1.6759050$

Df=50

Sample size group 1=26

Sample size group 2=26

Study location

This study was conducted in the pediatric surgery department at Abou El-Reesh Specialized Pediatric Hospital, Kasr Alainy, Faculty of Medicine, Cairo University.

Study timing

From 1st of July 2020 to 1st of July 2021.

Operative details

All patients were positioned in the frog-leg supine position at the foot of the table. After induction with anesthesia but prior to draping, the surgeon's position and adjusting the focus of the microscope/VITOM is done, and then swing it away from the field. All patients were subjected to general anesthesia augmented with a caudal block (with infiltration with 1:100,000 xylocaine and adrenaline solution) for extended post-operative pain relief. We obtained written informed consent to take medical photography as a routine in our practice. The penis is photographed in antero-posterior and lateral views after the drapes application. We used 2 swabs to retract the foreskin, remove the smegma, and povidone-iodine is applied. A vicryl 6-0 suture is passed on the dorsal surface of the glans in a vertical manner for retraction. In some cases, a tourniquet was applied from the start of the operation, in the second case tourniquet was applied just before the urethroplasty, and in other cases, no tourniquet was used at all. Using the tourniquet and its timing was attributed to the surgeon's preference. The tourniquet time is monitored precisely and not used for more than 25 minutes.

According to the surgeon's preference, the high magnification (VITOM or Microscope) could be used throughout the whole procedure, or it may be confined to the urethroplasty.

Surgical microscope

The microscope used is a double foot switch one for the focus and the other for controlling the zoom, with a second head for the assistant. Working distance of 200–415 mm, large visual field with widefield eyepieces ($\times 12.5$ or $\times 10$). The initial parts of the operation including diagramming of the repair, degloving, release of the chordee, and mobilization of tissues are done without high magnification in most of the patients and the high magnification ($\times 6$ –24 magnification) either VITOM or Microscope is used mainly during urethroplasty.

Video telescopic operating microscope (VITOM, Exoscope)

VITOM, (Karl Storz Endoscopy GmbH, Tutlingen, Germany) was used and it served to accurately identify and define delicate anatomic structures by providing images of superb quality, ($\times 8$ –30) magnification zoom, and good illumination. During the procedures, surgeons could view the high-definition (HD) VITOM images displayed on a 26-in. flat screen at a comfortable viewing distance and angle. The use of 3D glasses allowed better visualization of the anatomical and operative details and helped the non-scrubbed colleagues to better visualize the operation and to precisely observe the operative steps.

At the end of each operation, the surgeon and the assistant were asked about the image quality, comfort with the VITOM set-up, neck strain, and fatigue during the operation.

Also, the attending non-scrubbed colleagues were asked about the image quality and the potential teaching value of the VITOM magnification.

Post-operative care

Follow-up visits are scheduled at approximately 2 weeks thereafter. The dressing was removed after the first two postoperative days and the catheter was removed at 7th to 10th days postoperatively.

Complications were classified as early complications, e.g., urethrocutaneous fistula, postoperative bleeding, edema, dehiscence, infection, and retention, and late complications, e.g., meatal stenosis, urethral stricture, and recurrence.

Results

Among group A, the operations of choice were TIP repair which was performed in 23 patients, MAGPI operative repair in 2 patients, and 1 patient tubularization without

dorsal incision performed. While in group B, all patients did classic TIP repair with minimal glans dissection.

The mean duration under high magnification is 15 min out of 70 min total operative time. During these 15 min, the high magnification was used to perform the precise steps of the anastomosis.

In group A, wound infection was found in 6 patients (23.1%), on the other hand in group B, 17 patients (65.4%) experienced wound infection. Comparing both groups, we found the difference in infection incidence to be statistically significant (P value = 0.002).

In our study, the postoperative fistula was diagnosed in 3 patients (11.5%) in group A, 1 fistula was treated conservatively while the other 2 were treated operatively, this is compared to 7 diagnosed fistulas (26.9%) in group B, 2 of them were treated conservatively and the other 5 needed operative intervention.

None of the patients in group A were identified with meatal stenosis postoperatively compared to 6 patients (23.1%) in group B. This difference was found to be statistically significant (P value = 0.023).

Post-operatively, edema was found in 5 patients in group A (19.2%). While in group B edema was found in 7 patients (26.9%),

None of the study patients were diagnosed with post-operative bleeding or retention.

Recurrent hypospadias was identified in 3 patients (11.5%) in group A, coinciding with the occurrence of dehiscence in the same 3 patients. However, recurrence occurred in 4 patients in group B (15.4%). Details of the results are summarized in Table 1.

By asking the operating surgeons, the use of a surgical microscope was associated with neck strain and led to fatigue in the neck muscles, more studies need to be conducted to evaluate the adverse effects of prolonged use of the surgical microscope.

We thought that neck strain and fatigue were reduced compared with wearing magnifying loupes, because the level of the screen improved ergonomic positioning of the head and neck while viewing the procedure, but the neck strain was more in Microscope than VITOM.

VITOM set-up with an articulated stand was easy to learn. We found it took approximately 10 minutes to set up initially, but this decreased to 5 min after several uses.

VITOM images on an HD flat screen greatly enhanced our visualization of the operations performed. Furthermore, we found that this better visualization significantly aided the attending colleagues' better understanding of the procedures and as well as the fine penile surgical anatomy.

The 3D glasses allowed for more precise identification of anatomical structures and they can be used by all the attendees. VITOM allowed high-definition recording of

Table 1 The study results

Variable	Group A (high magnification) (n = 26) N(%)	Group B (optical magnification) (n = 26) N(%)	P value
Early complications			
Infection	6 (23.1%)	17 (65.4%)	0.002
Fistula	3 (11.5 %)	7 (26.9%)	0.159
Fistula closure	One fistula healed conservatively after 10 days. 2 fistulae needed operative intervention.	Two fistulae healed conservatively after 10 days. 5 fistulae needed operative intervention.	
Meatal stenosis	Nil	6 (21.3% (0.023
Dehiscence	3 (11.5%)	4 (15.2%)	1
Edema	5 (19.2%)	7 (26.9%)	0.510
Bleeding	Nil	Nil	
Retention	Nil	Nil	
Late complications			
Recurrence	3 (11.5%)	4 (15.4%)	1
Dilatation	1 (3.8%)	NIL	1
Stricture	Nil	1 (3.8%)	1
Dysuria	6 (23.1%)	12 (46.2%)	0.865

the procedure enhancing the teaching environment for non-attending residents and video publications.

Discussion

Optical magnification has recently been adopted as a standard aid in hypospadias surgical repair to obtain a more precise perception of the anatomical details and fine handling of the tissues. The evolution in the medical optical field led to huge advancements in magnification systems.

Going through the literature, we found a scarcity of established studies addressing the effect of high magnification tools on the functional outcome of hypospadias surgeries. These tools include surgical microscopes, varioscopes, and VITOM exoscopes.

Maher et al. studied the functional outcome of using high magnification in 102 patients who were operated on by a senior hypospadias surgeon. they used The surgical microscope (Carl Zeiss Microscopy GmbH) to aid in visualizing the anatomical landmarks as well as carrying out the procedure under $\times 3.5$ –6 magnification [8].

Also, in another study performed with a new head-mounted miniaturized microscope (Varioscope[®]M5, Life Optics Co., Chicago, IL, USA) ($\times 3.6$ to 7.2) in the surgical correction of hypospadias by Chiummariello et al., the complication rate of the surgical procedure was reported to have decreased from 8.9 to 2.3% [9].

In a study where 14 patients with hypospadias were operated on with the help of a video telescopic operating

microscope, Frykman et al. reported that no complications were determined. They used a VITOM exoscope, with an Image 1 H3-Z HD camera and table-mounted articulated stand During the procedures, surgeons viewed the HD VITOM images displayed on a 26-in. flat screen [5].

Stephen R. Shapiro and his colleagues compared the outcome of hypospadias repair using (3.5x) optical magnification (53 cases) with the results after using the Zeiss reconstruction microscope (59 cases), and they reached a conclusion that although the success of hypospadias repair is not totally dependent on the use of the microscope, it is predicted that it will be used more often in the repair of hypospadias in the future because of its advantages [10].

By asking the operating surgeon and the assistant, VITOM images on an HD flat screen greatly enhanced the visualization of the different structures making the performed operation easier. Furthermore, we found that this better visualization significantly aided the attending colleagues' better understanding of the procedures as well as the fine penile surgical anatomy. The 3D glasses offered sharp images on the HD flat screen.

Wacksman et al reported that the use of the mouth-controlled microscope (Zeiss OPMI 6CH) allows the surgeon to use small sutures with great accuracy. The major advantage of this microscope is that the surgeon can easily relocate or switch fields by simply depressing the mouthpiece which conveniently sits below the eyepieces. This mount can be in any direction so that even at high powers the focus can be adjusted by the surgeon through the mouthpiece [11].

VITOM made it possible to record the procedures in high definition allowing the surgeon to revise the technique post-operatively and making it easier to use the recorded videos in publications and video seminars. Wesson et al. found that the microscope is a very useful teaching aid for residents. Unscrubbed junior colleagues observing will also be able to chronologically follow the surgical steps, to better understand this type of surgery, which does have a steep learning curve. It is also of note that other healthcare staff members in the theatre are aware of the surgery's nature while being performed and able to identify at any given time which phase the surgery reached [12].

One weakness of the present study is that the operations performed were not performed by the same surgeon, more patients need to be operated by a single surgeon increasing the sample size of included patients and increasing the accuracy of the results.

Conclusion

Using high magnification led to a more precise image of the gland topography and detailed anatomy.

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Not applicable.

Authors' contributions

Dr. Khaled Salah was the main operator of the cases, and he also contributed to the manuscript writing. Prof. Sherif Kaddah and Prof. Gamal El Tagy contributed to the study design and the manuscript writing. Dr. Moemen Mohamed Farouk wrote the manuscript and the study design and was the assistant of Dr. Khaled Salah in operation cases. All authors read and approved the final manuscript.

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Availability of data and materials

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Declarations**Ethics approval and consent to participate**

The study was approved by the ethical committee at Kasr Elainy School of Medicine, Cairo University.
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Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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