Original article

Prevention and cure of post vesico-vaginal fistula repair incontinence by insertion of skin graft in the bladder neck area of vagina. Update on hypothesis and interim report

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Abstract: Background: There are 2 million women who suffer from vesicovaginal fistula (VVF), and more than 130 000 new cases develop each year in Africa alone. Though the cure rate for the VVF itself is more than 90%, up to 45% of patients continue to leak heavily after successful VVF closure. *Aim:* To present an interim report of the testing of a hypothesis which states that the major cause of post fistula repair incontinence is tissue necrosis consequent upon obstructed labour which leads to scarring in the bladder neck area of the vagina and invalidation of the closure mechanisms. *Methods:* The hypothesis was tested by application of a skin-on Singapore graft to the bladder neck area of the vagina, both prophylactically and in patients with ongoing incontinence following successful VVF repair surgery. *Results:* The flap has been used in 24 cases with severe day/night ongoing incontinence after fistula closure. Some cases had been operated on 9 times before and deemed incurable. After dissection and releasing of the tethered anterior vagina on average there was a 2cm gap created in the anterior vaginal wall that needed to be covered. With urethralisation, sling and the flap 71% of cases were completely dry and 29% improved, often satisfied with their improvement or dry using a urethral plug. The average standard ICS one hour pad test on these patients was 224ml in one hour before the operation and 29ml afterwards with a range of 0-176ml. The same method of urethralisation and sling without the flap yielded a 26% dry rate on the most severe cases of ongoing incontinence with multiple previously failed procedures. Using the graft as a primary repair (n=41), for Goh type 4, 46% with the flap were completely dry as against 19% without. *Conclusions:* The skin flaps restore the closure mechanisms and continence as hypothesized. We believe the initial results from the graft technique are sufficiently convincing to announce this as a significant advance in fistula surgery. Nevertheless, more data is being assembled to complete a statistically valid comparative analysis of the new methods with the old.

Key words: Vesicovaginal fistula; Post-fistula repair incontinence; Singapore graft; Tethered vagina syndrome.

INTRODUCTION

In 2015 we published a hypothesis[1] which originated from preliminary studies at the Addis Ababa Fistula Hospital (AAFH) where the "Tethered Vagina Syndrome" concepts from the Integral Theory of Female Urinary Incontinence[2] were applied to the problem of post vesicovaginal fistula repair incontinence. Our hypothesis stated that a major cause of post fistula repair incontinence is neither a loose pubourethral ligament nor an overactive bladder. Rather, it is tissue necrosis consequent upon obstructed labour which leads to scarring in the bladder neck area of the vagina. This "tethers" the stronger posterior vectors to the weaker forward vectors, figures 1 & 2, overcoming them, so that the urethra is opened out instead of being closed on effort and, in severe cases, at rest. In the normal continent patient, Figure 1, PCM vector (m.pubococcygeus) stretches the distal vagina forwards against the pubourethral ligament (PUL) to close the distal urethra. The backward/downward vectors, levator plate (LP) and conjoint longitudinal muscle of the anus (LMA), stretch and rotate the proximal urethra backwards and downwards around PUL to close the bladder neck. Adequate elasticity in the bladder neck area of vagina, "zone of critical elasticity" (ZCE) (Figure 1) is required for this to occur. With significant scarring at ZCE, the vector forces (backward arrows, Figure 2) are directly transmitted via the scar to overcome the weaker forward PCM vectors. In consequence, the posterior urethral wall is forcibly pulled open, resulting in a sudden rush of urine typically on straining or getting up off a chair. With coughing, there may be little or no urine loss, as there may be just sufficient elasticity for the rapid opposite motion of the fast twitch fibres. This explains why post VVF incontinence patients often leak when downward pressure is exerted with a speculum in the vagina. This action removes any remaining elasticity in ZCE. In women, such as many of those from AAFH who wet constantly, the tethering effect may be sufficiently severe as to keep the urethra in a constantly 'open' position even at rest, so leakage is continuous.

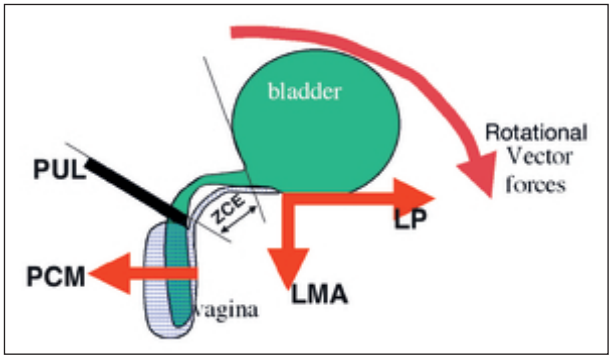

Figure 1. – Normal urethral closure in the female during coughing or straining. PCM = m.pubococcygeus; LP= levator plate; LMA= conjoint longitudinal muscle of the anus; PUL=pubourethral ligament. ZCE (zone of critical elasticity) allows separate action of forward and backward vectors.

Management and surgical methodology according to the hypothesis

In the Hypothesis[1] we stated, "*It is our belief that the focus of treatment for post-fistula incontinence should, above all, be on prevention: ensuring that there is adequate elasticity in the bladder neck area of the vagina during the primary fistula repair. In this endeavor, only a single principle should be observed: if, after dissection, there is a natural gap between the two walls of vagina, the tissues should not be forcibly closed. Rather, a skin graft should be ap-*

plied to cover the gap. Ideally, the graft should come with its own blood supply. A skin-on graft, e.g. Singapore graft (Figure 3)*, needs to be applied to the bladder neck area of the vagina (ZCE), as this is the only way to restore the elasticity required in this area for independent function of the opposite vector forces*."

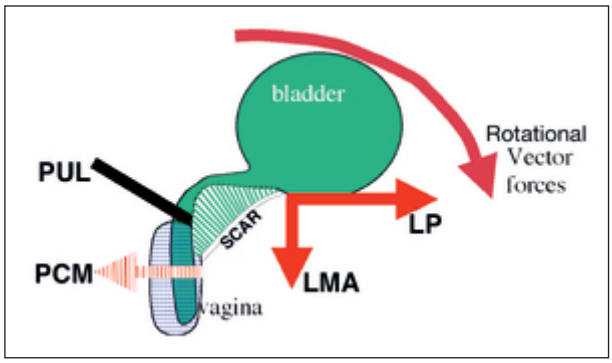

Figure 2. – Mechanism of scar induced incontinence. During effort, LP/LMA vectors overcome the weaker PCM vector (weakness indicated by broken lines) to open out the urethra as per micturition.

Interim Report

Positive results from initial testing of the hypothesis were reported as a postscript[1].

The aim of this report is to present further data. The surgical principles as set out in the hypothesis were followed by the first author (AB), who performed all the surgery. Because application of the graft also loosens the PUL, the middle part of the urethra was surgically reinforced at the same time as application of the graft.

The first author (AB) now has a series of 41 patients where the Singapore flap was used at the time of primary fistula repair. The worse type of fistula with regards to being completely continent after repair is the Goh type 4, meaning nearly all the urethra has been destroyed in the long labour. With the basic principles of maintaining the urethral length and sling with no flap, the more severe type 4 (more scarring, larger, repeat and or circumferential defects), only 19% were completely dry. With the basic principles plus the Singapore flap 46% were completely dry.

For Goh Type 3 fistula, without the flap 46% were dry, with the flap 87% are completely dry.

The flap has been used in 24 cases with severe ongoing incontinence after fistula closure. Some cases had been operated on 9 times before and deemed incurable. After dissection and releasing of the tethered anterior vagina on average there was a 2cm gap created in the anterior vaginal wall that needed to be covered. With urethralisation, sling and the flap, 71% of cases were completely dry and 29% improved, often satisfied with their improvement or dry using a urethral plug. The average standard ICS one hour pad test on these patients was 224ml in one hour before the operation and 29ml afterwards with a range of 0-176ml.

The same method of urethralisation and sling without the flap yielded a 26% dry rate on the most severe cases of ongoing incontinence with multiple previously failed procedures.

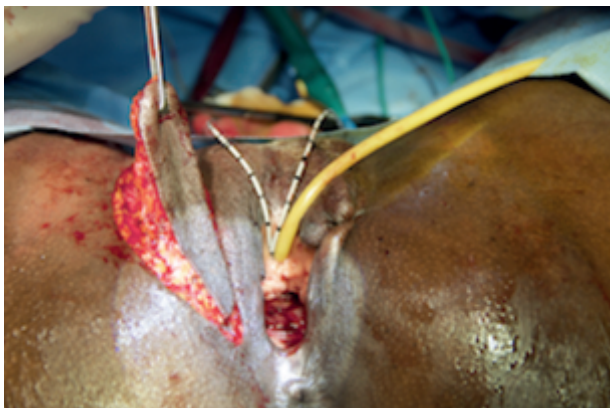

Figure 3. – Augmentation of ZCE with a skin-on Singapore Graft restores independent movement of the vector forces. The Singapore Graft is taken lateral to the labium majus. Ureteric (white) and urethral (yellow) catheters are seen in situ.

DISCUSSION

It was found that insertion of a skin graft either prophylactically in primary procedures or therapeutically in successful VVF repairs which continue to leak, gave far higher cure rates than previous practice. These results seem to support the hypothesis that adequate elasticity is required in the bladder neck area of the vagina to facilitate the 3 directional forces which were demonstrated to activate the proximal and distal urethral closure mechanisms, figs 1&2[2]. The key surgical principle followed for placement of the graft was that if, after dissection of the scar tissue, the two edges of the vagina did not naturally approximate, without tension, a graft was required.

This study provides the ultimate test for the Integral Theory[2], as it tests key predictions of the Theory as to what is required for normal urethral closure: 3 directional vector forces; competent ligaments against which the 3 vector forces contract; sufficient elasticity in the mid-part of the anterior vaginal wall 'ZCE' to allow the *separate function* of the 3 directional forces.

CONCLUSIONS

The skin flaps restore the closure mechanisms and continence as hypothesized. We believe the initial results from the graft technique are sufficiently convincing to announce this as a significant advance in fistula surgery. Nevertheless, more data is being assembled to complete a statistically valid comparative analysis of the new methods with the old.

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Commentary

The risks of reproduction are borne exclusively by females, who face the hazards of childbirth that arise from the "human obstetrical dilemma:" a narrow "hourglass" pelvis whose size and shape are constrained by the requirements of upright bipedal locomotion together with big babies who develop big brains as a result of our species' progressive encephalization[1]. These conflicting evolutionary forces mean that humans are predisposed to obstructed labor. When that obstruction is not relieved by timely intervention (assisted delivery, often by cesarean section), the consequences can be catastrophic. Large areas of soft tissue which line the boney pelvis may be injured or destroyed by pressure necrosis from the prolonged impaction of the fetal head, and the fistulas that result are often breathtaking in size and complexity. As a result, rarely are the tissues around an obstetric fistula completely healthy. Although the neighboring tissues are still living, often they have been severely injured, losing both vitality and elasticity. Sometimes the fistula is so deeply embedded in dense scar tissue that extensive dissection is needed even to locate the opening prior to any consideration of repair.

The "continence gap" that persists in patients whose fistulas have been closed successfully but who remain incontinent (transurethrally) after surgery has been a persistent puzzle[2]. For a long time this post-fistula incontinence was thought to be stress incontinence from severe urethral damage (so-called "Type III" stress incontinence), but urodynamic studies have demonstrated multiple intermingled pathophysiological processes in these patients[3]. Whatever it is, it is clearly not "simple" stress incontinence, but exactly how to describe it, how it originates, and (most importantly) how it should be treated, have all been elusive.

In this issue, Browning, Williams and Petros advance an idea – supported by intriguing preliminary clinical data – to suggest that one of the main culprits in the "continence gap" is tethering of the vagina occasioned by the scarring produced by the pressure effects of obstructed labor. Those familiar with the barely-mobile anterior vagina that may be found in many fistula patients will understand the underlying logic of their argument. The same phenomenon of vaginal tethering may explain the profound stress incontinence that develops in some women with post-hysterectomy vaginal vault prolapse, who, although continent before surgery, may develop debilitating stress incontinence after undergoing sacral-colpopexy. The pathphysiology that produces urine leakage in these cases presumably is also "tethering" of the anterior vaginal wall through excessive suspensory tension which alters the dynamics of the urethral closing mechanism in a similar way as that proposed here. In this case the incontinence is not "unmasked" by reduction of the prolapse; rather, it is created by altering the normal physiologic mechanisms of urethral closure. Further clinical research to verify this hypothesis is greatly to be desired.

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