

Use of dCELL (Decellularized Human Dermis) in Repair of Urethrocutaneous Fistulas or Glans Dehiscence

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Background: In hypospadias repairs, there is some evidence to suggest that a “water-proofing” layer can be helpful in reducing the risk of urethrocutaneous fistula formation. The most likely role of this layer is to prevent the creation of overlapping suture lines. Many hypospadias surgeons use a dartos fascia interposition flap for this purpose. However, raising a dartos fascia flap adds time to the procedure, can result in devascularization of the overlying skin, and can create unsightly torsion of the penis, which may be hard to correct. To avoid these problems, the senior author has started to use dCELL (decellularized human dermis) as an alternative to dartos fascia to separate the suture lines.

Methods: Between March and July 2018, a pilot study was performed in 8 patients undergoing closure of a urethrocutaneous fistula or glans dehiscence combined with dCELL. Data on infections, wound breakdown, length of stay and catheterization, surgical time, and hospital stay were collected.

Results: All patients had a successful reconstruction. One patient developed a urinary tract infection, possibly related to prolonged catheterization following his repair.

Conclusion: Our results suggest that dCELL may be useful in the repair of urethrocutaneous fistulas and glans dehiscence after hypospadias surgery. (*Plast Reconstr Surg Glob Open* 2020;8:e3152; doi: [10.1097/GOX.0000000000003152](https://doi.org/10.1097/GOX.0000000000003152); Published online 29 October 2020.)

INTRODUCTION

Amongst hypospadias surgeons, there is some consensus that a “water-proofing” layer may be helpful to reduce the risk of fistula formation.^{1,2} Equally, there is some evidence that a waterproofing layer is completely unnecessary.³ Surgeons who believe in the need for a water-proofing layer will often use a dartos fascia interposition flap.⁴ Dartos fascia is readily available during a primary repair and there have been many variants described, including single-layer, double-layer, dorsal-longitudinal, and scrotal flaps raised from this tissue layer.⁵ Regardless of the configuration, most hypospadias surgeons agree that the dartos layer does not actually create a “waterproof” closure. Instead, what the fascia flap does is to avoid the creation of overlapping suture lines, which (if one or the other were to breakdown) might lead to fistula formation (Fig. 1).⁶

Therefore, use of a dartos flap follows the principle of a “belt and braces” approach to hypospadias surgery.⁷

Surgically, raising a small dartos fascia flap is simple and creates few problems (if any). However, when the suture line of the neourethra is long, a larger dartos fascia flap may be needed and more extensive dissection is required to mobilize this amount of tissue. Clinically, this can result in de-vascularization of the overlying skin (Fig. 2).⁸ One of the main justifications for using the dartos tissue is that it is a vascularized layer with a blood supply, which is entirely separate from the skin. Clinically, there have certainly been many studies of the effectiveness of islanded preputial flaps raised on a dartos fascia pedicle.^{9–11} However, to the best of our knowledge, there has been only one human study, which specifically investigated the blood supply to the dartos fascia and the penile skin.¹² This latex injection study was carried out in a limited number (12 specimens) of normal, adult (aged 50–70 years) cadavers. Therefore, the applicability of these findings to a cohort of abnormal, pediatric cases is unclear. Nevertheless, the injections studies suggested that the dartos has an axial blood supply derived from a pair of arteries running in parallel, within the dorsal dartos layer. Failure to include one or other of these vessels in a dartos fascia flap raises the possibility that the

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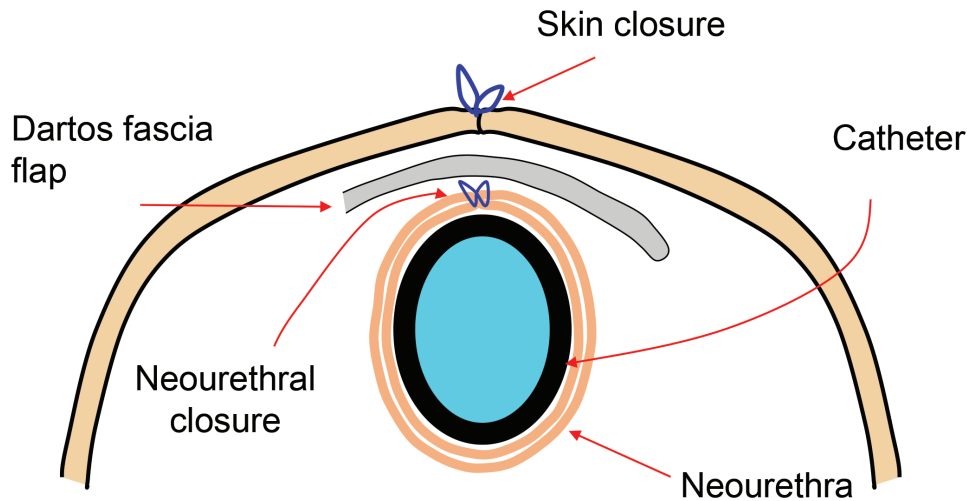


Fig. 1. Illustration of a cross-section through the penis, showing the position of the dartos interposition fascia flap.

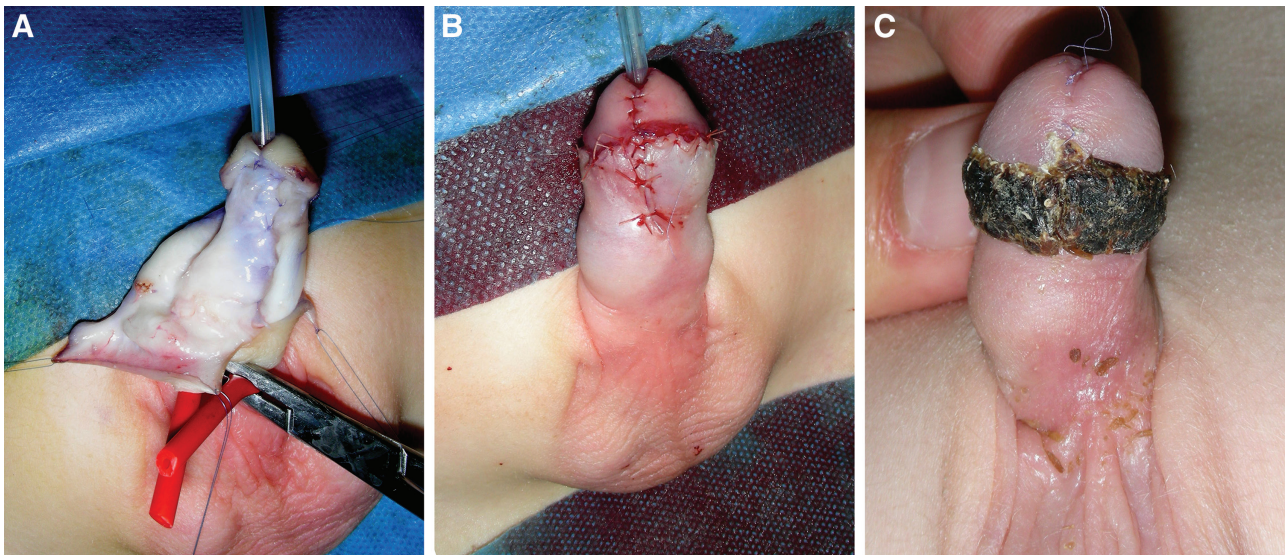


Fig. 2. Complication attributable to raising of a dartos fascia interposition flap. A, Long dartos flap was raised from the right side, requiring more extensive dissection from the overlying skin. B, Appearance immediately after closure. C, Necrosis of ventral skin caused by devascularization following the extensive dissection; appearance at 1-month postoperative.

flap is being raised in a random pattern. This is particularly likely to occur for a small fascia flap, which may then act as a non-vascularized layer of collagen. The study also showed that the overlying shaft skin is supplied by multiple small perforators arising from these axial vessels. This suggests that separating the dartos layer completely from the overlying skin means that the skin survives as a random pattern flap—which may explain the skin necrosis, sometimes observed, after procedures involving extensive mobilization of the dartos layer.

Moreover, taking a dartos fascia flap from only one side can result in torsion of the penile shaft that is very difficult to correct, once healing is complete (Fig. 3).¹³ To avoid this problem, others have suggested taking the dartos flap from both sides of the penis and double-breasting the flaps.¹⁴ However, this has the potential to make an

already complex and lengthy procedure even longer and may further compromise the blood supply to the overlying skin.^{15,16} Although torsion can be avoided by transferring a dorsal dartos flap ventrally, using a button-hole technique,¹⁷ it is impossible to reconstruct the prepuce once this has been done.

The situation can be even more difficult in patients undergoing salvage repairs.¹⁸ These patients may have undergone multiple procedures to try and close a ventral urethrocutaneous fistula or to revise a stricture. Often, the dartos layer is heavily scarred and it is then impossible to raise a dartos flap in the normal manner.¹⁹ The alternative is to use local skin flaps to avoid overlapping suture lines.²⁰ However, this results in more visible scarring on the penile shaft. Moreover, the blood supply for such flaps is entirely random pattern with all its attendant risks.



Fig. 3. Six months postoperative image showing torsion of the penis after inset of dartos flap.

Although additional dartos tissue is available from the scrotum, there are the added risks of a more extensive dissection and the potential for recreation of the original chordee, as the scrotal tissue drags the penis ventrally.²¹ The alternative is to use a tunica vaginalis flap.²² to cover any fistula repair. This flap has been shown to be associated with lower rates of fistula recurrence, penile rotation, or skin necrosis but is then associated with a small risk of testicular atrophy.²²

To avoid the problems related to harvest of dartos fascia, the senior author has started to use dCELL as the interposition layer for both primary and salvage cases of hypospadias. dCELL is a cadaveric, decellularized, human, dermal skin allograft produced from split thickness skin grafts (which include the epidermis and upper part of the dermis). All epidermal and cellular components from the dermis are removed in a patented, sequential, decellularization process—before use. It has a shelf life of 2 years and can be stored easily at room temperature. Importantly, it is readily available and relatively inexpensive.

The theoretical benefits of using dCELL are significant. The dissection required to raise a dartos flap is avoided completely, reducing the risk of both skin necrosis and hematoma. The risk of creating torsion in the final repair is eliminated. The overall surgical time is reduced. The

senior author has also speculated that using the dCELL adds mechanical strength to the neourethra repair. This may be particularly helpful in adolescents where the risk of wound dehiscence due to post-operative erections is increased. In salvage cases, where the dartos layer may be absent or heavily scarred, it gives the hypospadias surgeon the means for reliably separating the skin closure from the neourethra repair. Histological studies have shown that, following human transplantation of decellularized dermal matrices, new fibroblasts, vascular elements, and collagen are present, while the transplanted elastic fibers are retained.²³

In this article, we present a pilot study of a mixed cohort of patients who have undergone hypospadias repairs reinforced with dCELL. We describe our surgical technique and consider how the dCELL may have been helpful in this diverse group of patients.

MATERIALS AND METHODS

Between March and July 2018, a consecutive series of 8 patients underwent a hypospadias repair procedure in which dCELL was used either to strengthen the repair or to separate tissue planes. The case notes of the patients were analyzed to extract their demographic and clinical data. The patients were aged between 2 and 21 years.

dCELL was used as an alternative to a dartos fascia interposition flap for one primary repair. Three patients had previously undergone a 2-stage primary repair of their hypospadias before developing their complication. Five patients had previously undergone a 1-stage primary repair of their hypospadias before developing a complication. Surgery was performed to close a ventral fistula in 5 cases. In 2 cases, surgery was performed to revise a dehiscence of the glans repair.

In all cases of fistula closure, the skin was closed directly over the dCELL without the need to use a local skin flap (eg, unilobed transposition or Mathieu-type). The size of ventral fistula varied from <2 mm up to 10 mm in diameter.

After surgery, the ventral wound was dressed in a standard manner using the Jelonet (paraffin-impregnated gauze) plus gauze wrapped circumferentially around the penis and held in place with the Micropore tape (Merlin Medical, UK). In all cases, a silicone catheter was used to drain the bladder after repair. With the catheter in place, the penis was placed into the anatomical position and was then taped flat against the abdomen using a micropore tape, together with the catheter. The catheter was then looped to the right and drained into a bile-bag, which was taped to the right thigh using the micropore tape.

Data on the number of infections, length of stay, length of catheterization, surgical time and hospital stay were collected.

Surgical Technique

The dCELL is supplied in small, medium, or large sizes, as either thin (0.2–0.5 mm) or thick (>1.2 mm) variants. For all the cases in this series, we used small (3 × 3 cm) and thin (0.2–0.5 mm) dCELL (Fig. 4). Any dCELL that was found to be closer to 0.5 mm thick was easily

thinned using Steven's tenotomy scissors to make it more pliable, thereby allowing it to conform more closely to the contours of the repair. A piece of the dCELL large enough to cover the neourethra (Figs. 5–7) was trimmed from each sheet and sutured into place using a single continuous, peripheral suture of 6/0 or 7/0 Polysorb (Covidien, Medtronic). Once the dCELL was secured, the glans part of the repair was closed over the dCELL and the tourniquet was released to begin the process of achieving hemostasis before final skin closure. At the end of the procedure, the dCELL was palpable as a small raised area underneath the skin closure.

RESULTS

Our data show that all the patients who underwent surgery combined with dCELL had a successful repair of their underlying condition (Table 1). One patient required re-admission for a urinary tract infection at 2 weeks postoperatively. However, it was not clear whether the infection was the result of the dCELL or (more likely) due to the need for prolonged catheterization after the repair. All patients were followed up for a period of 15 months or longer. None of the cases developed recurrent fistulae and all reported normal urination, with no evidence for stricture formation.

Post-operatively, there was no obvious, visible or palpable evidence of the dCELL on examination of the ventral side of the penis for any of the patients in this series. Therefore, the assumption was made that the material had become fully incorporated into the tissues.

DISCUSSION

Use of a “waterproofing” dartos fascia flap has become part of the normal standard of practice for many hypospadias surgeons.⁴ How the flap works to reduce the frequency of fistula formation is unclear and there are many hypospadias surgeons who do not use it. However, the main purpose of this pilot study was not to provide

a definitive answer as to whether or not to use a dartos fascia flap but to raise awareness of an alternative to it. Importantly, in this series, dCELL appears to have been helpful in achieving a successful outcome, in diverse situations, where standard surgical techniques failed—with no obvious increase in morbidity.

The senior author also makes no claims to originality in using dCELL to augment his repairs of difficult urethrocutaneous fistulae or in salvage repairs of hypospadias cases. In 2012, Springer et al. described the use of Pelvicol (Tissue Sciences Lab Ltd, Medtronic, USA), a porcine acellular collagen matrix, as a reinforcing patch placed over their urethral repairs. Their case series included 10 cases of urethral fistula and 2 urethroplasties.²⁴ The photographs from their article are similar to the ones we present in terms of the position of the Pelvicol over the urethral repairs. The main differences are the more pliable and thinner nature of the dCELL compared with Pelvicol. This might make it easier to handle the dCELL or achieve ventral skin closure compared with the bulkier Pelvicol. Similarly, Casal-Beloy et al. used Integra to reinforce their repairs of recurrent urethrocutaneous fistulae following hypospadias surgery.²⁵ They reported a successful repair in 10 of their 12 patients and concluded that Interga was safe and effective as a covering layer in fistula repair. These studies suggest that other dermal substitutes could fulfill a purpose similar to that of dCELL. Further, they suggest that it is not the composition of the material itself, which is important but the fact that there is some form of physical separation between the skin and the urethral repair. As a minimum, together with our own data, the results from these studies suggest that the use of acellular collagen matrices is safe in the context of hypospadias repairs. However, whether dermal matrices actually contribute positively to the repairs in the way that we have speculated will require further study.

Dermal matrices have been used as an adjunct for reconstruction in other sites such as cleft palates. Clark et

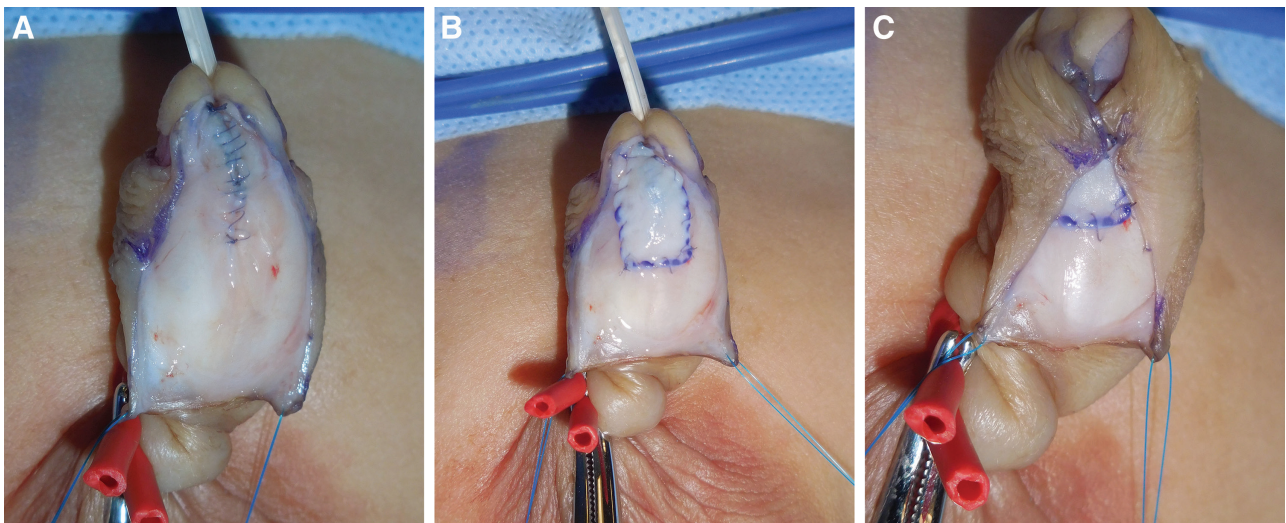


Fig. 4. Use of dCELL as an alternative to a dartos fascia interposition flap. A, Neourethra repair is complete. B, Single layer of thin dCELL is sutured directly over the repair. C, Glansplasty and skin closure over the dCELL.

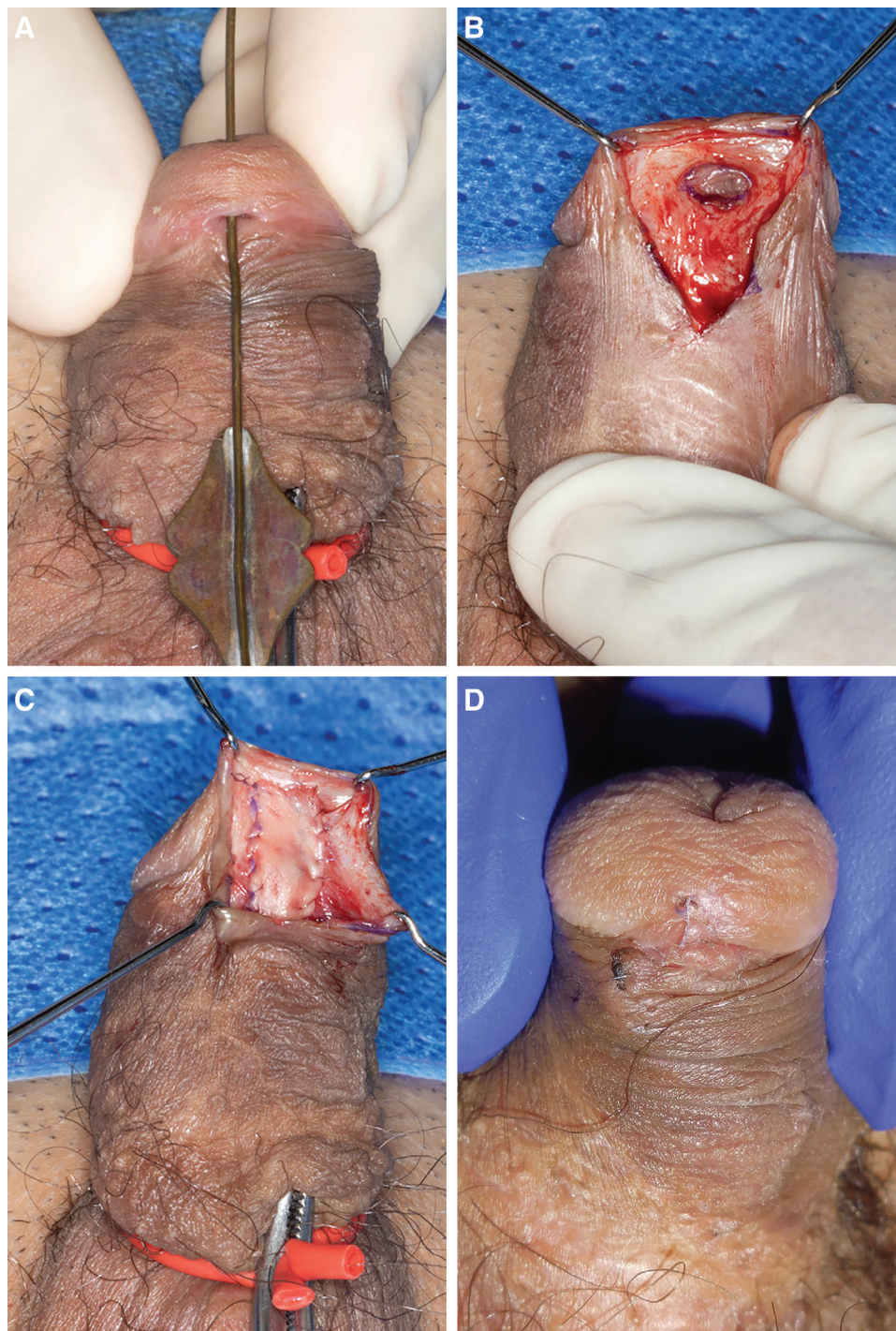


Fig. 5. Use of dCELL for the repair of a urethrocutaneous fistula. A, Peno-scrotal hypospadias repaired with a two-stage technique involving release of chordee and resurfacing of the ventral surface of the penis with Byars flaps. The patient presented with a ventral fistula at age 13. There followed two failed attempts to repair the fistula using conventional techniques, including direct closure, local skin transposition flaps, and dartos interposition. At the third attempt (B–C), dCELL was used for the interposition layer, instead of dartos fascia. The fistula was closed directly and a piece of dCELL was trimmed to fit over the repair. D, Appearance at 1-month postoperative, with no recurrence of the fistula.

al. used decellularized dermal grafts (AlloDerm; LifeCell Corporation, NJ, USA) to reinforce their palatal repairs in a small series of 7 patients.²⁶ After repair, there were 2 cases of oral mucosa breakdown with exposure of the

dermal graft but no cases of complete breakdown. The exposed areas of dermal graft went onto re-epithelialize successfully.²⁶ A similar study by Helling et al. placed AlloDerm at the junction of the hard and soft palates

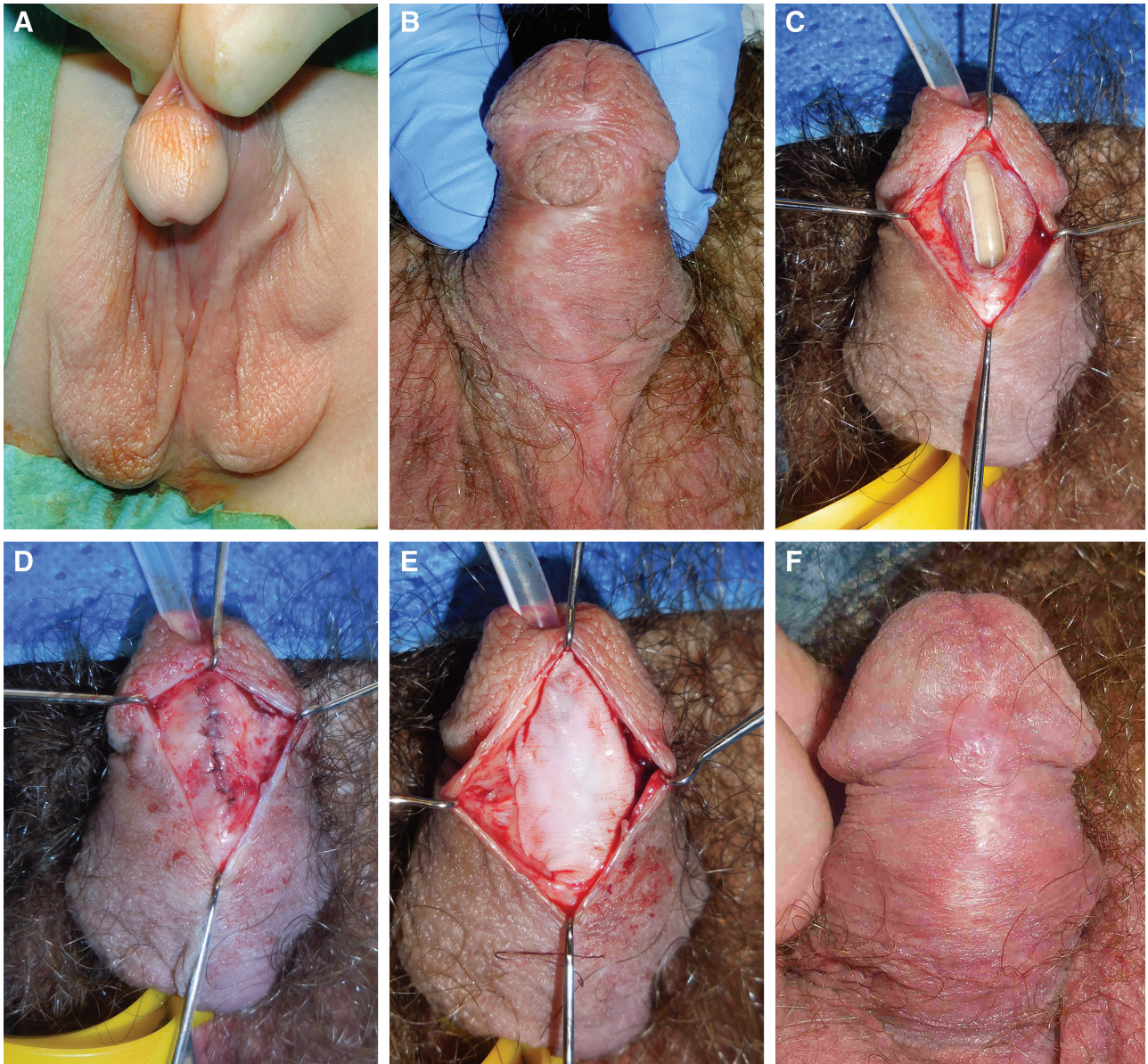


Fig. 6. Use of dCELL in two-stage repair of penoscrotal hypospadias with severe chordee. A, Two-stage repair of a peno-scrotal hypospadias with severe chordee at age 9. Release of ventral chordee using a full-thickness, preputial graft. Second stage of repair delayed by 10 years for personal reasons. B, Ventral fistula formed after the 2nd stage. One attempt at direct closure of the ventral fistula with local transposition skin flap and dartos interposition failed. C, Therefore, dCELL was used for the second attempt. D–E, The fistula was closed directly and a piece of dCELL was trimmed to fit over the repair. F, Appearance at 12 months postoperative, with no recurrence of the fistula.

in Furlow cleft palate repairs. They were able to show a reduced incidence of fistulation (3.2%) compared with conventional methods of repair, where the incidence of this complication may range from 10% to 25%.²⁷ The results of these studies are in keeping with our findings of low complication rates following the use of decellularized dermal matrix in hypospadias repairs.

We do not have histological evidence to prove that the material became incorporated into the surrounding tissues. Examination of the patients at their final follow-up showed no palpable or visible evidence for any residue of the dCELL as either a bulge or thickening over and above that expected from the surgery. This is certainly in

keeping with Singer et al., who observed that the Pelivcol also appeared to become incorporated into the adjacent ventral tissues.²⁴ Incorporation of the dermal matrices has also been observed when used in the context of palatal repairs.²⁶ So, there is every reason to believe that the same will have happened to the dCELL. Moreover, although it is our belief that the dCELL contributed to the mechanical strength of the repairs (especially in Case 1 and 2), we did not have any way of measuring this contribution. Despite the absence of this data, we believe that any measures that are able to reduce the risk of urethrocutaneous fistula formation or wound breakdown after hypospadias repair are important because of the financial and

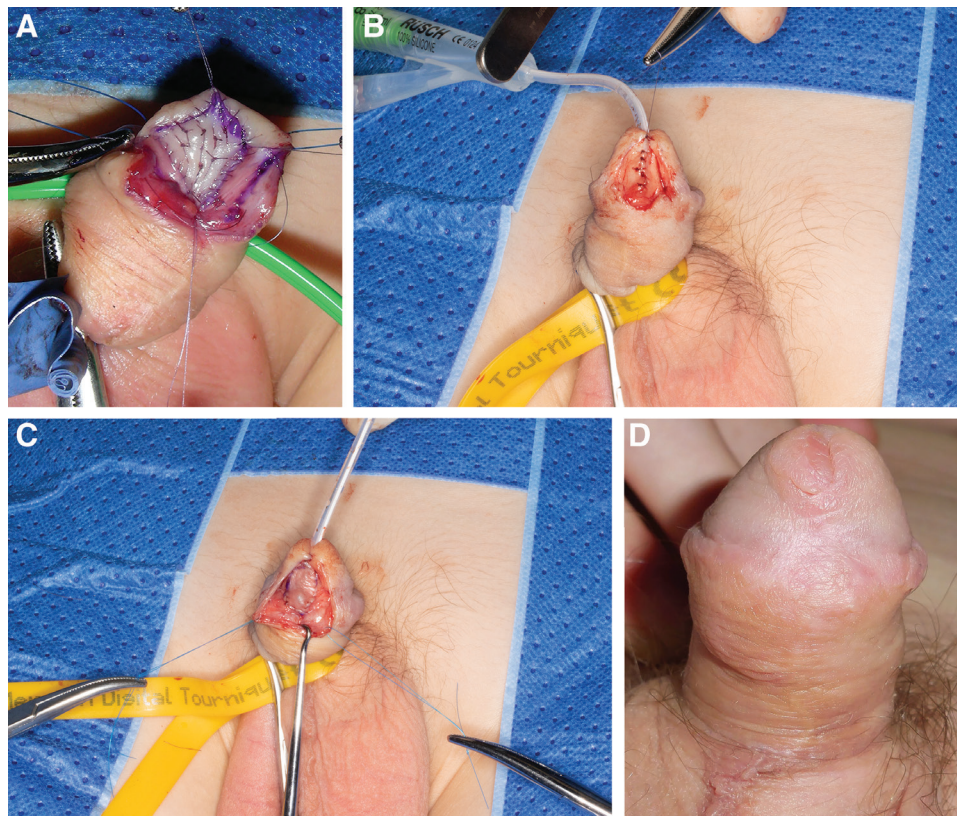


Fig. 7. Meatal stenosis after previous Snodgrass repair in a different unit. A, Buccal mucosa graft inlaid into dorsal wall of urethra for meatoplasty. Glans part of repair dehisced at 2 weeks postoperative. B–C, Repair of dehiscent glans with dCELL placed over the neourethra repair. D, Appearance at 2 months postoperative, with widened meatus.

psychological costs of these complications. We estimated that each readmission for surgery to our unit costs the NHS approximately £2,786. This compares with the cost of a small sheet of dCELL, which is (currently) £214. If dCELL were truly contributing to the overall success of the procedure, then this extra cost to the primary repair seems justifiable, regardless of the exact mechanism by which it is occurring.

The alternative to using dermal matrices is to harvest autologous dermal grafts. However, this raises the concern of extra donor site morbidity and (especially in children) suitable donor sites may be limited.²⁸ Importantly, in cases of proximal hypospadias, where larger skin grafts are often needed to reconstruct the neourethra, the harvest of additional dermal grafts may result in considerable donor site morbidity.²⁹ The use of decellularized dermal matrices eliminates all concerns about donor site morbidity and has complication rates similar to those of dermal autografts anyway.³⁰

As a minimum, our study suggests that the use of dCELL in hypospadias repairs is safe when used in the repair of urethrocutaneous fistulas and cases of glans dehiscence. However, as with any case series, our study is limited by the small number of patients, the heterogeneity of the indications for surgery, the wide age range of our patients, the lack of a long-term follow-up (maximum 16 months), and

the retrospective nature of the study. To demonstrate conclusively that dCELL has a positive impact on the outcome of primary and secondary hypospadias repairs, we would need to carry out a randomized controlled clinical trial comparing similar patients undergoing repair, with and without dCELL.

In this article, we describe the use of dCELL decellularized human dermis as an adjunct for the repair of urethrocutaneous fistulas and glans dehiscence after hypospadias surgery. We speculate that dCELL contributed positively to the outcome in the 8 cases that we report. It was unclear whether the contribution of dCELL was to separate the suture line of the urethral repairs from the suture line of the skin closure or to increase the mechanical strength of the urethral repair, or both. If the former, then dCELL may prove to be an attractive alternative to the use of a dartos fascia flap by eliminating the donor site morbidity associated with raising this tissue in hypospadias repairs. If the latter, then dCELL may prove to be of particular value in salvage repairs where ventral scarring increases the stiffness of the tissues, reducing their pliability. Further studies are required to confirm the value of dCELL in hypospadias repairs and to determine the behavior of this material *in vivo* in the context of hypospadias surgery.

Table 1. Case Series of Patients Undergoing a Urethral Repair Combined with dCELL

	Operations before Reconstruction with dCELL	Age at Previous Operations (y)	Anatomical Type	Reconstruction with dCELL	Age at Repair with dCELL (y)	Size of Fistula (mm)	Length of Catheterization (d)	Length of Stay (d)	Surgical Time (min)	Infection (Y/N)	Complications
1	1st stage hypospadias repair in another unit 2nd stage hypospadias repair Repair of ventral fistula and excision of pyogenic granuloma	9 20 20	Penoscrotal	Repair of recurrent ventral fistula with dCELL	21	10	4	0	70	N	Nil
2	1st stage hypospadias repair with Byars flaps 2nd stage hypospadias repair Repair ventral fistula Repair recurrent ventral fistula	4 5 5 13	Penoscrotal	Repair of recurrent ventral fistula with dCELL	14	3	0	0	65	N	Nil
3	Snodgraft repair hypospadias and circumcision	2	Penoscrotal	Repair of ventral fistula with dCELL	2	3	0	0	70	N	Nil
4	Thiersh-Duplay repair in another unit Meatoplasty with buccal mucosal graft for meatal stenosis	2 11	Distal penile	Repair of dehisced glansplasty and dCELL	12	-	2	0	85	N	Nil
5	None	-	Subcoronal	Thiersh-Duplay repair with dCELL	2	-	2	2	90	N	Nil
6	1st stage hypospadias repair (including correction of chordee and suprapubic lipectomy) Suprapubic catheter for urinary retention	2	Penoscrotal	Redo dehisced 2nd stage hypospadias repair with dCELL	3	-	7	7	93	Y	UTI 2 weeks post-operatively, treated with oral antibiotics
7	2nd stage hypospadias repair Snodgraft repair hypospadias Repair ventral fistula with local skin flap	2 2 3 4	Coronal	Redo repair of ventral fistula with dCELL	16	2	No catheter	0	80	N	Nil
8	1° Hypospadias repair in another unit Meatoplasty for meatal stenosis Redo meatoplasty for recurrent stenosis Repair of fistula with the dartos flap	6 7 7 8	Midpenile	Redo meatoplasty & repair of recurrent ventral fistula with dCELL	11	3	No catheter	0	97	N	Nil

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All authors meet the 4 criteria formulated by the International Committee of Medical Journal Editors regarding authorship.

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