Setting Up a Penile Transplant Program: A Multidisciplinary Journey

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Outline

- Present penile allotransplantation as an emerging paradigm for penile restoration

- Review basic elements in implementing a penile transplant program

- Identify specific areas of study to be considered in advancing penile allotransplantation
Penile Transplantation in the News

The New York Times

Penis Transplants Being Planned to Help Wounded Troops
By DENISE GRADY  DEC. 6, 2015

CNN

First U.S. penis transplants could help wounded troops
By Nadia Kounang, CNN
Updated 8:18 AM ET, Thu December 10, 2015

Medical News & Perspectives
US Hospitals Prepare for Penis Transplants
Bridget M. Kuehn, MSJ
Military Genitourinary Trauma

- >34,000 injuries and deaths from IED in Iraq (Operation Iraqi Freedom) and Afghanistan (Operation Enduring Freedom) between 2005 - 2011
- >1300 soldiers since 2005 have suffered genital injuries
- Average age of those injured was 24yo
- American Forces Institute of Regenerative Medicine (AFIRM) was started to address tissue loss
Conditions of Severe Penile Defects/Loss

- Congenial birth defects (aphillia, micropenis, classic bladder exstrophy/epispadias complex, cloacal exstrophy)
- Ambiguous genitalia
- History of penile trauma resulting in penile destruction
- Prior penectomy required for malignancy
- Female-to-male gender reassignment

Bladder Exstrophy

Disorder of Sexual Development (DSD)
Sequelae of Severe Penile Loss

- Inability to engage in sexual intercourse
- Inability to urinate while standing
- Abnormal body appearance
- Loss of intimacy/personal relationships
- Feelings of humiliation and emasculation
- Diminished quality-of-life
“Before they went off to fight in Afghanistan, the guys of the 3rd Battalion talked about their deepest fear. Not dying. Not losing a leg or an arm. It was having their genitals blown off…Some guys said they would rather be dead.”

“I remember lying on my side, dust everywhere, and I looked down and saw my arms were split open…my first coherent words to my Marines were, 'Hey! check my nuts!’”

*Huffington Post. Beyond the Battlefield: Afghanistan’s Wounded Struggle with Genital Injuries*
Why Not Autogenous Reconstruction?
Radial Forearm Free Flap Phalloplasty

Schematic for Neophallus Reconstruction

- Skin marked for harvest and skin flap isolated
- Flap to form phallus
- Flap to form urethra

- Urethral portion tubed over catheter and phallic part tubed around urethral tube
- Neourethra
- Flap to form phallus

- Blood vessels anastomosed to femoral artery and saphenous vein
- Cutaneous nerves connected to dorsal nerve and to ilioinguinal nerve

- Urethra tubed forward from perineum and emerges from tip of neophallus

Burnett AL Nat Rev Urol 2016
Complications of Autogenous Reconstruction

- Urethral stricture/urethral erosion rates: 10-20%
- Acute vascular compromise and graft loss: 3%
- Chronic wound issues: 10%
- IPP erosion/dysfunction: 20-40%
- 85% report satisfactory cosmetic appearance

2010 EU Garaffa et al., 2013 JUrol Massanyi et al., 2014 InterJImpot Segal et al.
2013 JSM Callens et al.

Traditional reconstructive options do not fully address all of the ideal goals of the phalloplastic reconstruction, including acceptable appearance, a competent urethra, tactile and erogenous sensation, and sufficient rigidity and durability to allow for sexual penetration.
Arguments Against Penile Transplantation

1. Not a lifesaving organ.

2. Lifelong immunosuppression – increased risk of infections and malignancy.

3. Ethics and psychological factors surrounding donating and receiving a genital organ

4. Technically challenging and unclear if it will meet the patient’s needs.
• 44yo man who suffered an ‘unfortunate traumatic accident’. 8mo. Later he received a penile transplant from a 22yo donor.

• On POD14, ‘because of a severe psychological problem of the recipient and his wife, the transplanted penis regretfully had to be cut off’.
The First Successful Human Penile Transplant
South Africa December 11th 2014

- 21yo man who had a failed ritual circumcision
- News report in the South African Medical Journal documents this event
- A forearm neophallus for the donor served to overcome reluctance of donor families to bury loved ones without a penis.
- Transplanted portion reportedly becomes tumescent.

First penis transplant patient's girlfriend is pregnant, doctor says

By Michael Pearson and Debra Goldschmidt, CNN
Updated 8:46 AM ET, Fri June 12, 2015
Penile Transplant Program Implementation

- De novo protocols
  - IRB approval process
  - Ethical reviews

- Patient selection
  - Severe traumatic penile defects initially

- Screening process
  - Intensive psychosocial evaluation
  - Plan for long-term psychosocial support
Penile Transplant Program Implementation

- Donor matching
  - HLA matching
  - Screening for pathogens
  - Physical appearance match

- Immunosuppression
  - “Conventional” triple-drug regimen
  - Short-course depletion induction, augmented by donor bone marrow cell infusion followed by low-dose maintenance monotherapy (tacrolimus)

- Organ procurement
  - Adherence to standard United Network for Organ Sharing (UNOS) cadaveric transplant donation practices
  - Consent performed by trained organ procurement organization recovery coordinators
Penile Transplant Program Implementation

Multidisciplinary team
- Urologists
- Plastic surgeons
- Psychiatrists/bioethicists
- Intensivists
- Immunosuppression specialists
- Operating room nurses and staff

Procedural considerations
- Cadaver sessions/technical planning
- Clinical evaluations
- “Dry” and “wet” runs
Future Directions

- **Basic science**
  - Develop and study pre-clinical models
  - Evaluate novel immunosuppression regimens (e.g., donor-specific tolerance) and effects on graft viability and function

- **Patient selection**
  - Who are the ideal candidates?

- **Program development**
  - How will programs be accessed?
  - How will expenses be covered?
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