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PHYSIOLOGICAL IMPACT AND USER ACCEPTABILITY OF PENILE COMPRESSION DEVICES (PCD)

Hypothesis / aims of study

Penile compression devices (PCDs) or clamps are applied to the shaft of the penis to compress the urethra thereby preventing urinary incontinence (UI) in men. PCDs are significantly more secure and less likely to leak than pads or other devices allowing men to participate in short vigorous activities, such as swimming or dancing (1). However, they can be uncomfortable, can affect penile blood flow (2) and are not currently recommended by the National Institute for Health and Care Excellence (NICE). Of the 16 clamps available on the open market, designs vary widely and further investigation is needed to assess their comparative efficacy, strengths and limitations of each as well as the effect on penile circulation and skin integrity.

The objective of the present study was to evaluate existing clamps for physiological impact and user acceptability.

Study design, materials and methods

12 men with post prostatectomy UI were recruited to review 16 existing clamps; 5 were selected for further investigation in a home-based usability study: Cunningham, Weisner, Dribblestop, Cook & Uriclak (Fig. 1). Measures of superficial circulatory impedance (Doppler flow), applied interface pressure and inflammatory response were made in the clinic/hospital. MRI scanning was used to measure physiological impact of the Dribblestop and Weisner. Informed consent was obtained from all participants.

Results

User Acceptability: No single clamp design proved ideal for all users with varying opinion amongst participants as to their preferences (Fig. 4). The Weisner was acceptable to most and most effective at preventing leakage. It was also the only clamp associated with haematuria (x1 episode) and elicited the highest pain score.

Physiological Impact: Varying interface pressures were noted between clamps for each individual participant to the order of 156.5mmHg and across all participants (mean 137.4mmHg, SD 69.7; range 20-310mmHg). Pressures >300mmHg were recorded with the Cunningham clamp and associated with a substantial decrease in superficial penile blood perfusion distal to the clamp. On clamp removal perfusion levels were restored. Other than the Uriclak, pressures generally decreased with wear time. In practice, this required adjustment of the clamp by the participants to maintain continence.

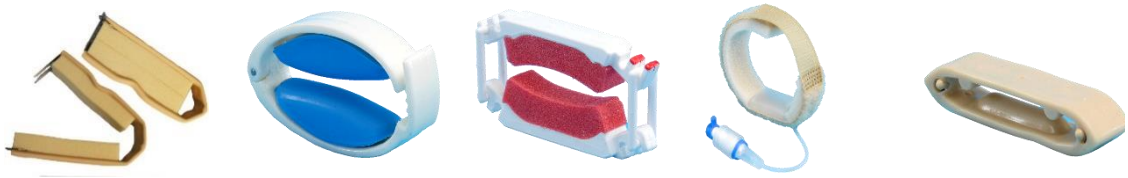
MRI scanning of the penis identified substantial deformation compared to the unloaded morphology (Fig. 2a/b) under clamping pressure from the Dribblestop (Fig. 3a) and Weisner (Fig. 3b). The corpus cavernosum and corpus spongiosum were flattened in cross-sectional images. Tissues external to Buck's fascia, incorporating blood vessels and skin, were displaced laterally to areas outside of the clamp pads. Urine was contained within the urethra proximal to the clamp site.

Interpretation of results

The four effective PCDs affected superficial blood flow and caused pain to an unsuitable user. Most participants however found a device that prevented incontinence with little discomfort for wear times up to 2 hours. Raised perfusion flux upon some clamps' removal, implies prior occlusion to the superficial blood vessels. Based on the current findings, future work will develop a new PCD with acceptable and appropriate features.

Concluding message

PCDs are favoured by some men but modifications in design are necessary before being more widely acceptable. A computational penile model (FEBio), with morphological features and dimensions provided from the MRI images will aid in designing an acceptable PCD.



Cunningham **Weisner** **Dribblestop** **Cook** **Uriclak**

Fig. 1: *Brief testing shortlisted 5 clamps from 16 commercially available devices*

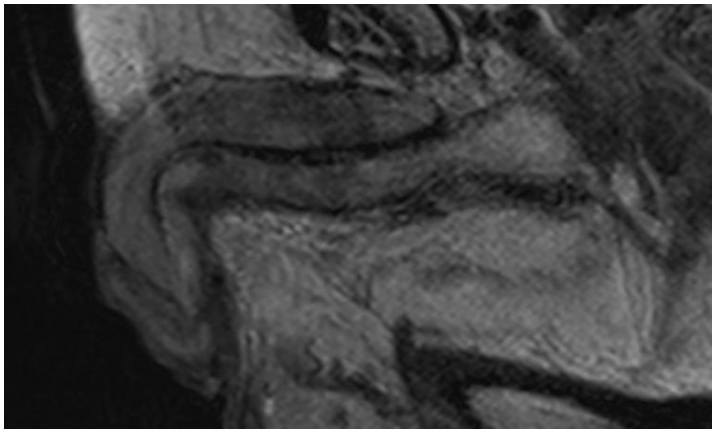


***Fig. 2a**: MRI T2 space image taken on the mid-sagittal plane of the penis without a clamp.*

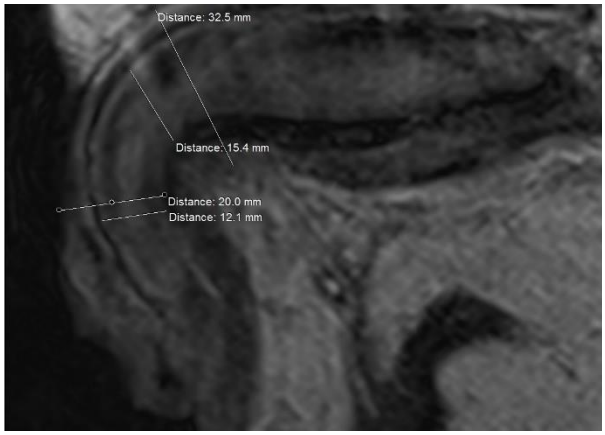


***Fig. 2b**: Image taken 11.2mm distant from Fig. 2a.*

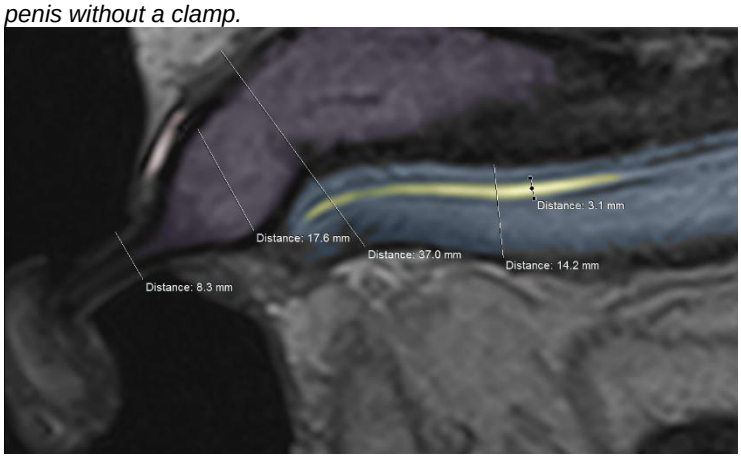


***Fig. 3a**: Dribblestop clamp compressed penis with a square edged profile. Occluded urine (yellow) is present in the urethra. Occluded blood is present in the dorsal vein (red). Corpus cavernosum (purple) and corpus spongiosum (blue).*

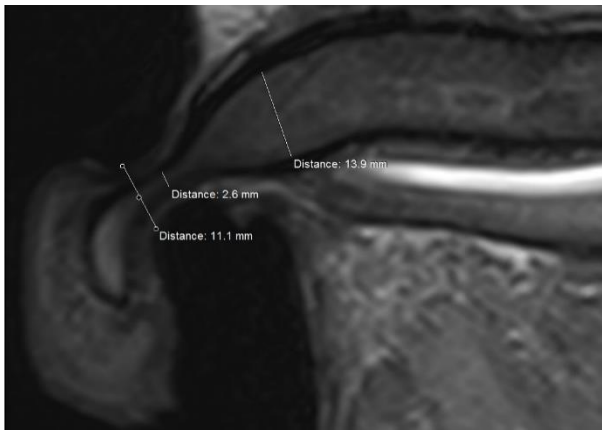


***Fig. 3b**: Weisner clamp compressed penis with a smoother edged profile.*

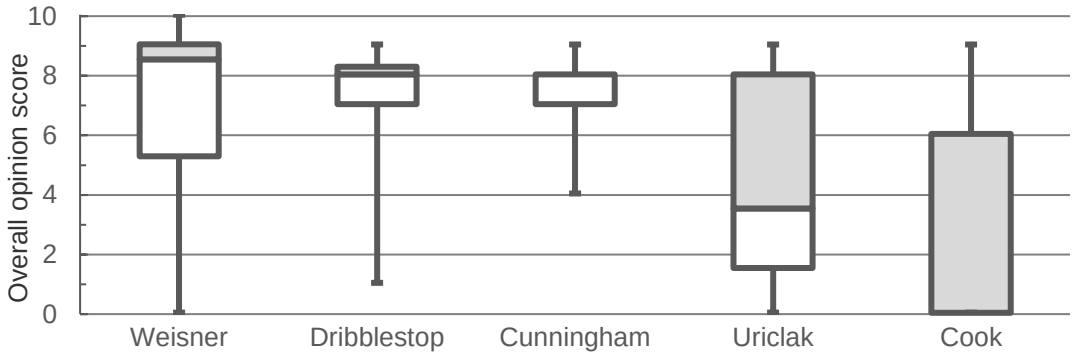


***Fig. 4**: Boxplot distributions of PCD overall opinion scores (n=12)*

References

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Disclosures

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