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DESIGN FEATURES OF PENILE COMPRESSION CLAMPS INFLUENCE THE BIOMECHANICAL STATUS OF PENILE SOFT TISSUES

Hypothesis / aims of study

Post prostatectomy urinary incontinence may be managed variously with absorbent pads, urinary sheaths, body-worn urinals and penile compression clamps (PCCs). Used correctly, PCCs may reduce the impact of incontinence and be useful for managing incontinence during activities. If compression is sufficient to prevent leakage, pain is a commonly reported issue and case reports attest to the potential risks of PCCs. Over a dozen untested, unregulated devices are readily available on the internet but, to date, there are no published evaluations of their biomechanical properties. To support the design of an effective, comfortable and low risk PCC, we wished to objectively and quantitatively evaluate the safety and efficacy of different commercially available PCCs using a combined computational and experimental approach. In this abstract, we report on the computational results.

Study design, materials and methods

A set of computational three-dimensional (3D) models of the human penis was developed, to which were attached five generic PCC types. Finite element (FE) computational simulations were subsequently used to evaluate the states of internal tissue strains and stresses during applied compression on the penis. Modeling was further used to identify specific design characteristics (e.g. geometry, interface material stiffness) of the PCCs, which could provide safer (i.e. lower) exposures to sustained mechanical loading of the soft tissues of the penis during use of the clamps, and minimize the risk of developing penile pressure ulcers. ScanIP® module [1] was used to segment and mesh a geometrical anatomical penile model including skin, fat, tunica albuginea (TA), corpus cavernosum and corpus spongiosum (CS). 3D orthotropic material properties were assigned to skin and TA, while all other tissues were considered to be linearly elastic [2]. In the Preview module [3], uniform circumferential pressure was initially applied to simulate a soft cuff-type clamp. 12 model variants were developed, representing different generic clamp designs and interface materials (flat, angled, cuff and knurl clamp types) (see Figure 1). Opposing vertical displacements were assigned to top and bottom surfaces of each clamp to compress mid-shaft. We examined effective and maximal shear strain and stress distributions during 50% urethral occlusion.

Results

The model yielded effective strain and stress distributions in an axial cut through the penis. Stresses in skin, fat and TA regularly exceeded 10 kPa (75mmHg) with corresponding maximum effective strains of between 14-18% (Figure 2 shows skin stress). Maximal deformations were found in the CS around the urethra. To achieve a urethral closure comparable to that of the other types, cuff-type and knurl-type PCCs imposed enhanced risks to tissue health by producing elevated tissue stresses around the entire perimeter of the penis (cuff) or stress concentrations near the urethra (knurl). The contoured PCC design produced the lowest values of these mechanical parameters.

Interpretation of results

To date, there are no reported biomechanical criteria for design of PCCs, in terms of quantitative parameters for evaluating the safety-versus-efficacy of existing or future PCC designs. The present study enabled the identification of design characteristics, which will provide the safest mechanical conditions in the penis, and thus minimize the risk of tissue damage while still managing incontinence. Such data should help to design a safer clamp.

Concluding message

We believe this is the first study to systematically model the biomechanical properties of different PCCs. PCCs can be useful devices for men to manage incontinence and may improve quality of life when reconstructive surgery is not advisable or desired. However they may cause discomfort and injure soft tissue which is particularly vulnerable to irreversible damage if loaded for prolonged periods. Using finite element modeling we tested key aspects of current clamps and identified favourable and unfavourable design features. Furthermore the model can be modified using laboratory based in vivo patient data. Combining modelling data with clinical and experimental data should enable the design of a safe, effective and acceptable penile compression clamp for incontinence management.

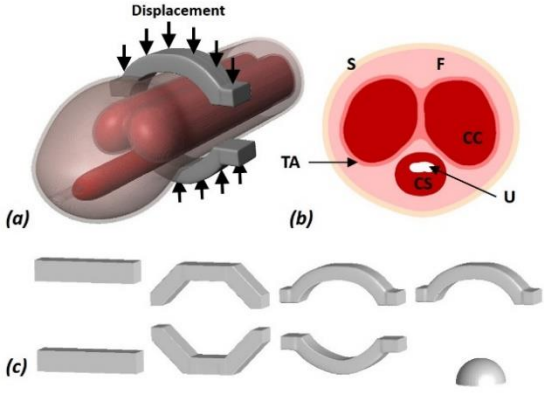

Figure 1: Computational finite element modeling of the penis and penile compression clamps: (a) A three-dimensional (3D) model of the penis, with one example of a contoured compression clamp and corresponding loading configuration. (b) An axial cut through the penis, showing the skin (**S**), fat (**F**), tunica albuginea (**TA**), corpus cavernosum (**CC**), corpus spongiosum (**CS**) and urethra (**U**). (c) The flat, angled, contoured and contoured with knurl clamps, which were modeled in this work (left to right).

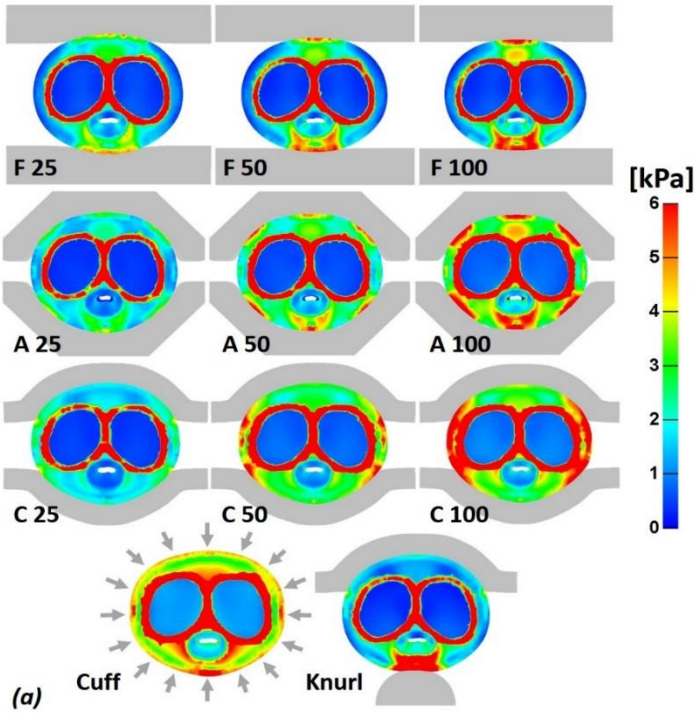

Figure 2: Distributions of effective tissue stresses in an axial cut through the penis, while using different penile clamps, at 50% closure of the urethra, and with the scale focused on skin stresses. **F 25**, **F 50** and **F 100** are flat clamps with stiffnesses of 25, 50 and 100 kPa; **A 25**, **A 50** and **A 100** are angled clamps with stiffnesses of 25, 50 and 100 kPa; **C 25**, **C 50** and **C 100** are contoured clamps with stiffnesses of 25, 50 and 100 kPa; **Cuff** is a cuff-type clamp and **Knurl** is a contoured clamp (50 kPa) with knurl (100 kPa).

References

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3. FEBio: Finite Element for Biomechanics (2012) Theory manual ver. 1.5.

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