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Title: Magnetic Resonance Imaging to estimate Tissue deformations during penile clamp application: A case series.

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Abstract

Background: Penile clamps provide a means of preventing urinary incontinence in males following radical prostatectomy. In order for the devices to function, significant mechanical loads need to be applied to the penile tissues to close the urethra. However, such loads have the potential to cause damage to the vulnerable skin and underlying soft tissues. Accordingly, the study aimed to estimate the magnitudes of tissue deformations resulting from penile clamp application in three individual cases.

Methods: Three individuals were recruited who currently use penile clamps to manage urinary incontinence following radical prostatectomy. Magnetic resonance images (MRI) of the penis were taken to produce a series of high contrast coronal and sagittal images both before and during the application of two commercially available clamps, modified for MRI compatibility. Tissue thickness measurements were estimated with the clamps in-situ and normalised to the unloaded baseline state.

Results: The estimated magnitude of tissue deformations resulting from clamp application ranged between 68-84%. There were minimal differences in these deformations between the clamp designs, both of which appeared effective in closing the urethra. Local stress concentrations were observed in the tissues, which were deformed around the shape of the clamp.

Conclusions: MRI enabled quantification of local tissue deformation during penile clamp application. The results revealed that clamps created large tissue deformations in all three cases, regardless of design. This information could inform the development of new clamp designs and materials to minimise the potential for tissue damage.

Level of Evidence: 4

Key Words: Penile Clamp; Magnetic Resonance Imaging; Radical Prostatectomy; Urinary Incontinence

1. Background

Following radical prostatectomy (RP) men can often suffer from urinary incontinence (UI), with a reported persistent incidence ranging from 1% to 40% [1-3]. In recent years surgical techniques have helped to reduce this value [4], although the overall prevalence continues to rise due to an increase in the total number of prostatectomies performed worldwide. Incontinence has a direct impact on the individual and can restrict participation in many social and sporting activities [5, 6].

Penile clamps (clamp) represent a conservative option for managing UI in individuals post-prostatectomy. These mechanical devices have been shown to cause a significant reduction in Incontinence Impact Questionnaire scores [7]. They represent a discreet and secure alternative to other products e.g. pads and they can prove popular for those wishing to pursue vigorous activities, in this predominantly active population [8]. However, clamps can also cause pain [9] and, when used for prolonged periods, can potentially cause tissue damage. There are few published reports of damage or injury, although a recent case study described a urethral diverticulum in a patient [10]. To minimise the risk of tissue damage, it is recommended to remove the clamp at regular intervals [11].

To date, the optimum design of clamp has yet to be established. A study evaluating the efficacy of different clamp designs revealed that none of the current devices when applied at a comfortable pressure completely eliminated urine loss. In addition, they appeared to reduce distal blood flow velocity in the penis, potentially leading to the risk of ischemic damage [11]. Recently, the authors have used a computer modelling approach to evaluate the relative effects of clamp designs on local stresses and strains in the internal structures. The study revealed that features of clamp design, notably shape and method of application, had a significant effect on the mechanical state of the internal tissue structures [12].

The limited evidence to date suggests that during clamp application, tissues are deformed compromising local blood supply and potentially putting vulnerable tissues at risk of damage. However, the magnitudes of tissue deformation in critical tissue structures have not been determined. Accordingly, the present study aimed to establish the extent of tissue deformation during penile clamp application in a case series of patients who have undergone RP.

1. Methods

Case series study evaluating two different penile clamp designs on a small cohort of men with long-term incontinence following RP.

* 1. Participants.

Three males were recruited to the study, aged between 69-78 years, who had undergone a RP and had UI. Participants had previously used penile clamps (>1 year). They attended a single study day where they were imaged with two clamp designs. Participants provided informed consent and the study was approved by a local ethics committee (Faculty of Health Sciences reference:23407).

* 1. Test methods

Images were acquired using a 3T MRI scanner (MAGNETOM Skyra, Seimens). Participants were instructed to lie in a supine position, where sagittal images of the penis were taken. First, participants were imaged with no clamp to establish unloaded tissue morphology (Figure 1a). They were then imaged in an equivalent position with both the Dribblestop (Dribblestop® , USA) and Wiesner (Wiesner Healthcare Innovation, USA) clamps, each modified with graphite to replace the metal pivot for MRI compatibility (Figure 1b and 1c). The order in which the two clamps were applied was randomised. The participants were instructed to tighten the clamps to a level at which, from their experience, they would expect minimal UI.

A reported protocol was adapted for the MRI scanningof the penis [13]. Briefly, MR imaging was performed with the penis in a caudal orientation. The scanning protocol focused on a small field of view, with the T1-weighted images obtained in the sagittal and coronal planes and the T2-weighted images obtained in all three planes. On the T1-weighted images, the three corpora were visualized with intermediate signal intensity and poor contrast between tissue planes. On T2- weighted images, the images were both of high signal intensity and well differentiated from the adherent low-signal-intensity tunica albuginea (Figure 1). The tunica albuginea and Buck’s fascia were indistinguishable from each another on both T1- and T2-weighted images because of their similarly low signal intensity. The MRI system parameters were as follows: Flip Angle: 160, FOV: 160cm x 160cm, slices: 60-90, matrix: 320x320, voxel size: 0.8mm x0.8mm x 0.8mm, acquisition time: 3-4 min. The in-plane resolution of the images was 0.4 x 0.4 mm.

* 1. Data Analysis

Cross-sectional measurements of the penis were estimated using the high resolution sagittal images (Figure 1). Measures were recorded between the corpus cavernosum (CC) and the corpus spongeosum (CS), representing the cross-section of the penis. Tissue thickness measurements were made in triplicate by two independent researchers (LPC and PW), using a similar methodology adopted in a previous MRI investigation [14]. The mean of three measurements was used from each image, and since no differences were detected between raters, the first set of measurements were retained for analysis. Descriptive statistics were presented for each participant and no formal statistical inferential tests were performed.



*Figure 1. Sagittal plane images (T2) of the penis of participant 1 with (a) no clamp, and following application of the (b) Weisner clamp and (c) Dribblestop clamp.*

1. Results

The MRI protocol was able to achieve high contrast images of the penis, both in the absence and presence of the applied clamps. The measurement protocol was able to define relative tissue deformations, or strains, in all three participants for each clamp design.

The results in Table 1 revealed that in the unstrained state, the thickness of penile tissues varied considerably between the three participants (11.56-30.02mm). When the clamps were applied the strains were significant to the penile tissues, ranging between 68-84%, with the highest values corresponding to the participant with the greatest unstrained thickness of the tissues (P3). There were minimal differences in the estimated strains for the two penile clamp designs. Importantly, the manner in which the tissues were deformed reflected the specific design features of the clamp. For example, as shown in Figure 1C, the square edges of the Dribblestop clamp design created local stress concentrations in the tissues, deforming both structures i.e. CC and CS, to the shape of the device.

*Table 1. Thickness measures and percentage tissue deformations as estimated from the MRI analysis of three participants using two different clamps*

|  |  |  |  |
| --- | --- | --- | --- |
|  | Unstrainedthickness (mm) | Wiesner  | Dribblestop |
|  |  | Strainedthickness (mm) | Strain(%) | Strainedthickness (mm) | Strain(%) |
| Participant 1 | 24.06 | 5.30 | 78 | 5.19 | 78 |
| Participant 2 | 11.56 | 3.49 | 70 | 3.66 | 68 |
| Participant 3 | 30.02 | 5.08 | 83 | 4.94 | 84 |

1. Discussion

Penile clamps provide an effective non-invasive method for controlling urinary incontinence in men post-prostatectomy. However, their application causes tissue strains, which could potentially lead to damage. The extent to which tissues are strained during clamp application has not previously been evaluated. The present study reports a case series to investigate the local tissue strains during clamp application on three post- prostatectomy participants. The results revealed that for two commercially available designs applied to tolerable levels by the participants, high levels of tissue strain were observed in each case (n=3). The implications of these tissue strains are unclear. However, they demonstrate the potential for tissue injury, if the clamp is applied incorrectly or left in-situ for prolonged periods.

This study revealed that MRI scanning provided high contrast images of penile tissues. Indeed, MRI has been used previously to examine tissue deformations during periods of mechanical loading with both able-bodied and at risk sub-groups in clinical settings [15]. These have investigated loaded interfaces associated with the residuum of amputees [16], lying postures on a spine board [17], prophylactic dressings [14] and the plantar surface of the foot [18]. Each of these studies revealed high corresponding levels of tissue strain, which appears to be dependent on factors such as the characteristics of the support surface/device, the underlying anatomy and the manner in which the applied loads are transferred to the various layers of the soft tissues. Indeed, in the present study the magnitudes of tissue strain appear to be somewhat related to unstrained thickness of the tissues.

 The magnitude of soft tissue strains (68-84%) represents a significant risk for the local tissue health. Aetiological research, using animal models, has revealed that direct deformation damage can occur in skeletal muscle when they are subjected to 50 to 60% strain [19]. Indeed cell damage can occur over a short time period, with changes in cell physiology observed after just 10 minutes [20]. In the present study, all three participants revealed strains of up to 80% in the CC and CS tissues of the penis, demonstrating that the use of clamps could result in direct deformation damage. The strains could also occlude local blood vessels causing ischemia, as evidenced with a reduced blood flow during clamp application [11], with the potential to cause pressure ulcers if sustained for prolonged periods.

The findings from this study, involving a small sample size and only two devices are limited in terms of generalisation. The measurements of tissue strains were restricted to the CC and CS structures due to the resolution of the images and the contrast achieved through the T2 weighted images. During the imaging, participants were instructed to apply the clamps to a moderate tension, whereby incontinence was managed. The lack of control regarding the application of external loading could have influenced the findings. However, this reflected the real-life scenario in which patients apply their own device tension. It is of note that despite the application loads not being measured, both devices produced similar deformations for each of the participant.

Based on the marked deformations of penile tissues revealed during this study we would strongly advise caution when using penile clamps for prolonged periods. Current research evidence indicates that application of a clamp for one hour with an equal clamp-free time before reapplication is likely to be safe. Longer periods are often recommended by manufacturers but have yet to be tested.

 The two clamp designs appeared to create severe stresses within local tissues and this may be due to the lack of conformity within the design and stiff materials of the clamps. There is an important balance between the main function, which is to ensure sufficient urethral closure for effective incontinence control, and that of minimising the risk of tissue damage. This can be achieved with more appropriate designs featuring optimum geometries for load application and modulus-matched materials. Evidence-based clinical guidelines would certainly improve safety for individuals using these devices and avoid injury. This is particularly pertinent for individuals who may have lost sensation following prostate surgery.

1. Conclusion

This case series imaging study has successfully revealed how penile clamps can create high strains within vulnerable penile tissues. The strains in the tissue, which if sustained, have the potential to result in tissue damage. Further research is required to optimise penile clamp design and provide safe guidance for individuals with respect to their routine application.

List of abbreviations

 Radical prostatectomy (RP), urinary incontinence (UI), magnetic resonance imaging (MRI), corpus cavernosum (CC), corpus spongeosum (CS).

**Declarations**

*Ethics approval and consent to participate*

Participants provided written informed consent and the study was approved by a local ethics committee (Faculty of Health Sciences, University of Southampton. Reference:23407).

*Consent for publication*

Not applicable.

*Availability of data and material*

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

*Competing interests*

The authors declare that they have no competing interests.

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*Authors' contributions*

LJ, RR, DM, MM, DLB, MF, JB designed the study and was involved in data collection. LPC, AG and PW performed the image analysis. CE designed the imaging protocol. All authors contributed to the writing of the manuscript.

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