CLINICAL ARTICLE SUMMARY

Local anaesthesia eluting property of Coloplast Titan penile prosthesis hydrophilic coating: An in-vitro drug elution profile and a randomised double-blind clinical outcome study

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ABSTRACT

Objectives: A two-part study to provide proof-of-concept with in-vitro analysis of drug elution property, and to evaluate the clinical outcome with Titan penile prosthesis hydrophilic coating dipped in local anaesthesia agent.

Material and Method: An in-vitro analysis of local anaesthesia eluting property of hydrophilic coating to determine the amount and duration of local anaesthesia elution and examine if the addition of local anaesthesia agent will dilute anti-microbial property of hydrophilic coating. Following internal ethics approval, a pilot study was conducted with 40 men randomised to receive Titan's penile prosthesis dipped with or without 0.75% Ropivacaine and 0.5% Marcaine. An independent third-party survey with objective measurement of pain score (visual analog scale, VAS), analgesia requirement (opioid dose equivalence) and time to penile prosthesis recycling.

Result: In vitro-release kinetics confirmed passive drug elution above the minimum inhibitory concentration. The minimum local anaesthetic concentration (MLAC) of 0.75% Ropivacaine and 0.5% Marcaine was sustained over the 14 days of in-vitro drug elution test. The hydrophilic coating with combination local anesthesia and antimicrobial drugs showed sustained elution and zone of microbial inhibition at day 1, 3, 7 and 14 ($p<0.05$). In the clinical study, patients with Titan penile prosthesis dipped in local anaesthesia reported lower VAS score ($p<0.05$), less analgesia requirement ($p<0.05$) and shorter time to penile prosthesis recycling ($p=0.08$).

Conclusions: Coloplast Titan hydrophilic coating provides an avenue to provide adjunctive analgesia in penile prosthesis implant patient care based on in-vitro drug elution profile, with clinical outcomes showing lower pain score and analgesia requirement, and shorter time to prosthesis recycling, without compromising the antibacterial property, when the Titan penile prosthesis is dipped in local anaesthesia agent and antimicrobial drugs.

COLOPLAST KEY TAKEAWAYS

- The Titan® HydroVANTAGE™ coating facilitates an option to add a local anesthetic, which can reduce post-op localized pain.
- HydroVANTAGE™ coating with combination local anesthesia and antimicrobial drugs, showed sustained elution and zone of microbial inhibition at 14 days ($p<0.05$).
- Patients with Titan penile prosthesis dipped in local anaesthesia reported lower VAS score ($p<0.05$), less analgesia requirement ($p<0.05$) and shorter time to penile prosthesis recycling ($p=0.08$).
- Promising proof-of-concept analysis of the ability of HydroVANTAGE™ coating to provide adjunctive analgesia allowing a shorter time to prosthesis cycling, without compromising the antibacterial properties.

Indications: The Titan, Titan OTR and Titan Touch Inflatable Penile Prosthesis is indicated for male patients suffering from erectile dysfunction (impotence) who are candidates for implantation of a penile prosthesis.

Contraindications: The Titan, Titan OTR and Titan Touch Inflatable Penile Prosthesis is contraindicated in patients with an active infection present anywhere in the body, especially urinary tract or genital infection; with a documented sensitivity to silicone; with unresolved problems affecting urination, such as an elevated residual urine volume secondary to bladder outlet obstruction or neurogenic bladder; or, unwilling to undergo any further surgery for device revision.

Warnings: Implantation of the device may make latent natural erections, as well as other interventional treatment options, impossible. Men with diabetes or spinal cord injuries, as well as immunocompromised patients, may have an increased risk of infection associated with a prosthesis. Failure to evaluate and promptly treat erosion may result in a substantial worsening of the condition, leading to infection and loss of tissue. Implantation of a penile prosthesis may result in penile shortening, curvature or scarring. Pre-existing abdominal or penile scarring or contracture may make surgical implantation more complicated or impractical.

Precautions: Surgeons implanting penile prostheses should be familiar with the currently available techniques for measuring the patient, determining implant size, and performing the surgery. Removal of an implanted prosthesis without timely reimplantation of a new prosthesis may complicate subsequent reimplantation or may make it impossible.

Potential Complications: Potential complications include scrotal swelling, auto-inflation, discomfort, angulation/curvature, edema, device malfunction, chronic pain, difficulty with ejaculation, transient urinary retention.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company Website at www.coloplast.us.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. See the device manual for detailed information regarding the implant procedure, contraindications, warnings, precautions, and potential complications/adverse events.

For further information, call Coloplast Corp at 1-800-258-3476 and/or consult the company website at www.coloplast.us.

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