



Australian Government
Department of Health and Ageing



Horizon Scanning Technology Prioritising Summary

Intracavernosal plaque excision method for Peyronie's disease

June 2004



**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**



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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by staff from the Australian safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).



NAME OF TECHNOLOGY:

Intracavernosal plaque excision for the treatment of Peyronie's disease.

PURPOSE & TARGET GROUP:

Intracavernosal plaque excision may become an alternative treatment for male patients with Peyronie's disease (curvature of the erect penis due to inflammation and scarring of the tunica albuginea). This procedure is less invasive and may decrease pain, loss of sensation, erectile dysfunction and reduction in penis length associated with other surgical techniques.

STAGE OF DEVELOPMENT (IN AUSTRALIA): Yet to emerge in Australia

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely Diffused
Poland		✓	

IMPACT SUMMARY

Background:

Intracavernosal plaque excision is performed under spinal anaesthesia, a circular clamp is placed at the base of the penis angle and an artificial erection is performed using a saline solution to estimate the angle of deviation. After circumcision and degloving of superficial and deep fascia, the tunica albuginea is exposed. The plaque is located and a longitudinal incision (about 3 cm) is made in the tunica albuginea approximately 5 mm parallel to the edge of the plaque. After separation from the tissue of the corpus cavernosum, the plaque is pressed with a finger from the outside to separate it from the tunica albuginea. Following excision of the plaque, the tunica albuginea is closed, an artificial erection is performed to make an estimation of complete straightening and the penile skin closed.

The skin sutures are removed seven days postoperatively and a broad spectrum antibiotic administered for five days. Patients are advised to refrain from sexual intercourse for six weeks.¹

Clinical need and burden of disease:

Peyronie's disease is an inflammatory condition of the penis. In the early phases of the disease, regions of reversible swollen patches of inflamed tunica albuginea are found. In later stages, these develop into inelastic, permanently disfiguring scars. The plaques most



commonly appear along the mid-top of the penis. Pain, bending of the penis during erection, difficulty with sexual intercourse and emotional distress are common effects of this disease; in addition, the shape of the erection may be affected, resulting in diameter reduction, indentation or loss of length. Both an urology medical group (US) website² and an US Department of Health and Human Services website³ report that this disease is more common in diabetics and men with gout, affecting 1% to 3% of men, mainly in their mid-fifties. Some cases can be mild, requiring little or no treatment; others may require surgical intervention.^{2,3}

Surgical intervention has its own risks and may not completely remove the curvature. Postoperative changes resulting from traditional surgery can include shortening of the penis, temporary interference in skin sensation and loss of erectile rigidity or inability to maintain an erection. With this new procedure, only a single incision is made in the tunica albuginea from which the plaque is removed, further excision or replacement of the tunica albuginea is not required.

Estimated speed, geographic and practitioner use patterns of diffusion in the health system:

Intracavernosal plaque excision for treatment of Peyronie's disease was developed by researchers in Poland. Results for 16 patients who were treated with this new procedure were published in 2004.¹

Existing comparators:

Medical treatments:

Most medical treatments have a 60% success rate in improving curvature of the penis; however the lack of controlled studies makes it difficult to determine which of the treatments are most effective.^{2,3,4}

- Vitamin E has been used in the treatment of Peyronie's disease since 1945
- Potassium P-aminobenzoate (POTABA) is designated by the FDA as 'possibly effective', large doses are required which may cause stomach upsets
- Colchicine acts against the inflammation and inhibits the formation of scar tissue
- Verapamil is usually administered by direct injection into the plaque, it also interferes with the synthesis of scar tissue precursors
- Collagenase is an investigational drug that enzymatically breaks down scar tissue
- Steroids: cortisone may cause death of healthy tissues
- Various modes of energy transfer, including ultrasound, radiation and laser therapy have also been used.

Surgical treatments:

Surgery is only attempted in patients who have had the disease for at least one or two years and who have severe curvature of the penis. The best surgical outcomes are in men with unchanging conditions.^{2,3,4}



- The Nesbit procedure corrects the curvature by removal or pinching the tunica albuginea on the opposite side of the plaque, thus cancelling the bending effect. Length is reduced, but this procedure is less likely to cause erectile dysfunction than tissue grafting and remains the first choice for moderate bends without associated diameter reduction. There are various modifications to the original procedure.
- Tissue grafting involves replacing or expanding the scarred tunica albuginea with grafts of healthy tissue. Though some calcified plaques still require removal, the expansion approach seems less detrimental to erectile function and less likely to cause postoperative impotence. Grafting is mainly used for severe bending and/or diameter constriction.
- Implants of biocompatible cylinders, which are either solid or inflatable. They are surgically implanted into the corpora cavernosum to produce a functional erection. In some cases an implant will be adequate; in others, a combination of the implant with a technique of incisions and grafting will result in straightening. This is generally used for men with Peyronie's disease and erectile failure (impotence).

Estimated cost impact:

The costs associated with intracavernosal plaque excision are not available. The Medicare Benefits Schedule reimbursement fee for the cost of surgery (not intracavernosal plaque excision) for Peyronie's disease (procedure only) ranges from A\$463-617.

Efficacy and safety issues:

Short-term safety and efficacy data exist from one case series.¹

Sixteen males aged from 34 to 65 years (mean 50 years) were treated. Patient selection criteria for the operation were: duration of the disease for at least 12 months, an unchanging state of the disease for at least three months, localised lesions, impaired sexual intercourse, curving during erection and a patient's motivation to regain a straight penis.

The duration of the disease in the selected patients was from 14 months to 3 years (mean 21 months). The sizes of the plaques were from 0.5 cm x 2.0 cm to 1.5 cm x 4.0 cm and were located in the dorsal aspect of the penis. The angle of penile curvature was 30° to 60°. Sexual intercourse was impaired in 13/16 (81%) patients and prevented in 3/16 (19%) patients. The mean quality of life score (QoL) according to a six-point scale was from 3 to 6 (mean 4.8). The International Index of Erectile Function (IIEF-5, validated scale) score can range from 5 to 25 (the higher the score the better the outcome). In this study scores ranged from 11 to 21 points (mean 15.1). Length of follow-up was 12 months.

Safety:

- no intraoperative complications were reported
- postoperatively, 7/16 (44%) patients had transitory swelling of the prepuce lasting a few days.

**Efficacy:**

- after excision of the plaque, complete straightening of the penis was observed in all cases (16/16; 100%) by means of an artificial erection
- follow-up at 3 months revealed normal and painless erections in all patients (16/16; 100%)
- ultrasound measurements revealed no presence of the plaques
- no loss of sexual function during PGE₁* injection test and colour doppler ultrasound
- at six-month follow-up, 14/16 (87%) patients were able to have intercourse, in 2/16 (13%) patients, intercourse was impaired by persistent penile curvature of over 20°
- no reduction in penile length was reported
- mean QoL score was evaluated as -1.1[†]
- at 3 months mean IIEF-5 was 19.2 points (mean scores increased by 4.1)
- no change in results was reported between 6 and 12 month follow-ups.

The study indicates that the potential benefits of this new technique are:

- removal of the plaque from the inside, without excising parts of the tunica albuginea eliminates the need to mobilise the vascular bundle, which can result in disturbances in sensation in the glans penis and increase the risk of impotence
- no requirement for grafting, which can delay healing and cause erectile disturbances
- penis length is not compromised.

Ethical issues:

Not applicable.

Cultural or religious considerations:

Not applicable.

Other issues:

- This new technique may be less invasive than standard surgical techniques for Peyronie's disease.
- The authors suggest that the duration of the operation may be reduced

Conclusion:

Limited evidence exists on the safety and efficacy of this procedure as an alternative treatment for Peyronie's disease. Long-term safety and efficacy data of controlled trials would be required before this procedure could be widely accepted.

* PGE₁ – prostaglandin E₁ intracavernous injection test for erectile function.

[†] This is a 6-point scale, in the text the postoperative QoL score is reported as -1.1, this figure may be the decrease in score rather than the actual score.



HealthPACT decision:

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| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor | <input checked="" type="checkbox"/> Archive |

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SOURCES OF FURTHER INFORMATION:

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SEARCH CRITERIA:

A search of MEDLINE, PubMed and Cochrane Library, Current Controlled Trials metaRegister, UK National Research Register International, Network for Agencies for Health Technology Assessments, relevant online journals and the Internet was conducted in January 2004.

Search terms used were: Peyronie's disease, intracavernosal plaque excision and penile deformity.