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Early Clinical Experience with the ALPFA GRAIL System for the Minimally Invasive Treatment of Benign Prostatic Hyperplasia

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INTRODUCTION

The ALPFA GRAIL procedure delivers non-thermal Pulsed Field Ablation (PFA) to ablate prostate tissue. The ablation affects prostate glandular and stromal cells that are lysed by the ablation, with cellular debris therefrom resorbed naturally and locally as part of the post-ablation healing process. The ablation is tissue-selective and ablates prostate tissue while sparing other sensitive collateral structures such as the spermatic ducts or sphincters.

The ablation results in local glandular atrophy and subsequent tissue remodeling that includes collagen deposition, with the remodeled tissue having enhanced tissue elasticity compared to that of dense BPH tissue. Normal urethral function (and urethral expansion during urine flow) is restored due to the enhanced elasticity of remodeled prostate tissue.

Objective

To evaluate the safety and feasibility of the ALPFA GRAIL System in a first-in-human cohort of men with symptomatic BPH.

METHODS / STUDY DESIGN

Methods / Study Design

- Prospective, open-label, single-arm, multi-stage pilot study
- First-in-human evaluation of the ALPFA GRAIL System

Population

- Men ≥ 40 years with symptomatic BPH

Sample Size

- Total subjects treated: 76*

* Optimized-dose cohort (n=39), treated using a standardized technique and dose

Follow-up

- 7 or 14, 30, 90, 180, and 360 days†

† Planned follow-up to 3 years (pending regulatory approval)

Endpoints

Primary Safety Endpoints

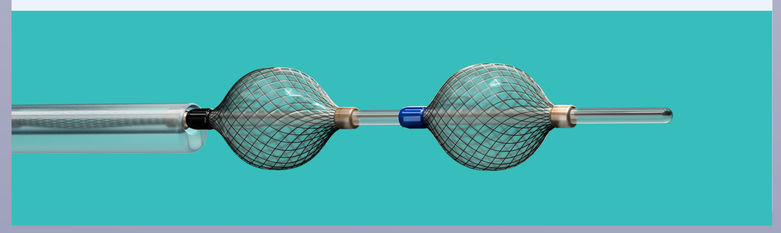
- Composite Safety Endpoint (CSE) defined as the proportion of subjects with one or more device- or procedure-related serious adverse events (SAEs) through 30 days post-procedure.

Primary Effectiveness Endpoints

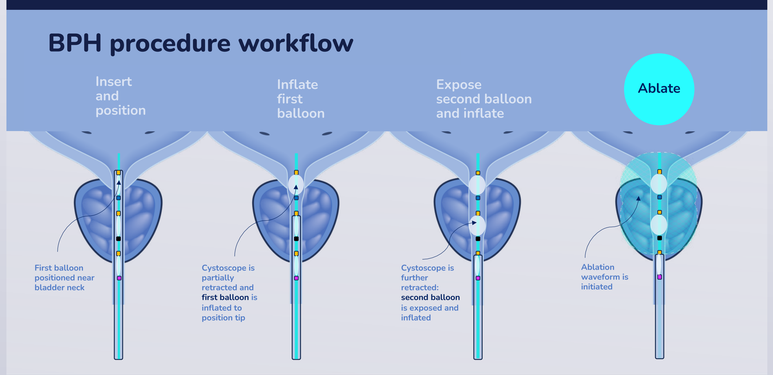
- Change in International Prostate Symptom Score (IPSS):
  - Mean change from baseline
  - Responder rate (>30% improvement)

Additional Endpoints

- Maximum urinary flow rate (Qmax)
- Sexual function (MSHQ-EjD)



PROCEDURE



RESULTS

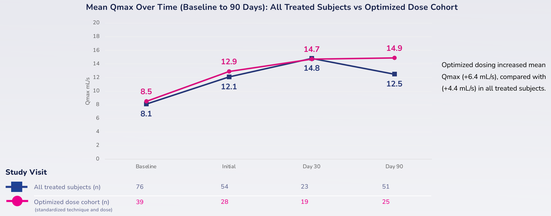
Safety

Serious Adverse Events and Post-Procedural Outcomes (N=76)		
	Subjects (n/N)	Percentage
Serious Adverse Events (SAEs)		
Device- or Procedure-Related SAEs	0/76	0%
Post-Procedural Outcomes		
Retrograde Ejaculation	0/76	0%
Erectile Dysfunction (ED)	0/76	0%
Incontinence	0/76	0%
Hematuria at Discharge	0/76	0%
Post-Procedural Catheterization		
< 7 days (Median 4 days)	10/76	13.2%
> 7 days (Median 19 days)	3/76	3.9%

IPSS

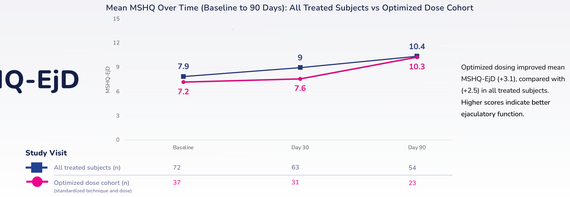
Optimized dosing reduced mean IPSS (−17.6; 83%), compared with (−12.3; 58%) in all treated subjects.

Qmax



Optimized dosing increased mean Qmax (+6.4 mL/s), compared with (+4.4 mL/s) in all treated subjects.

MSHQ-EjD



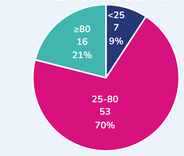
Optimized dosing improved mean MSHQ-EjD (+3.1), compared with (+2.5) in all treated subjects. Higher scores indicate better ejaculatory function.

PATIENT OVERVIEW

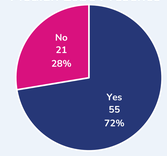
Variable	Value
Sample Size (n)	76
Age (years)	66.3 (49-95)
IPSS	22.1 (13-33)
Prostate volume (g)	57.5 (15-181)

Age, IPSS, and prostate volume are presented as mean (min-max).

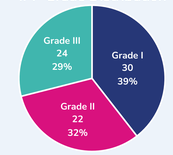
Prostate Volume Distribution



Median Lobe Presence



IPP Grade Distribution



N = 76; Values shown as n (%)

CONCLUSIONS / KEY FINDINGS

- The ALPFA GRAIL system, delivered via flexible cystoscope under local or conscious sedation, was safe and well tolerated in men with BPH.
- No device- or procedure-related serious adverse events were observed.
- Early results demonstrate clinically meaningful improvements in LUTS.
- Urinary flow improved, with increased Qmax.
- Ejaculatory function was preserved, with no reported erectile dysfunction or retrograde ejaculation.
- These findings support PFA-based ALPFA GRAIL as a safe, minimally invasive treatment, warranting evaluation in larger and more anatomically complex cohorts (e.g., median lobe, IPP).

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