EADV Congress 2026
Vienna, 30 September - 3 October

P2705

MDC-75: A Novel Solution for the Painless Removal of Superficial Skin Lesions

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INTRODUCTION

Superficial skin lesions management

Benign superficial skin lesions may warrant removal for cosmetic concerns or physical discomfort. Established methods include cryotherapy, electrocautery, shave excision and laser therapy.

Depending on the technique, treatment may involve **pain, local anaesthesia and post-procedure wound care**. Potential complications include **blistering, bleeding, scarring and pigmentary changes.** Cryotherapy and energy-based treatments also **require dedicated supplies or equipment**.

A simple topical treatment with low procedural pain could broaden the options for office-based lesion removal.

Background & objective

Chemical Destruction through cauterization and mummification represents an alternative approach.



MDC-75 is an acid-based topical medical device class IIa.
Designed for the safe and effective treatment of superficial skin lesions in adults.
Its active component, 2-chloropropionic acid, acts via a self-limiting protein denaturation process, leading to irreversible cellular damage and controlled mummification of the treated tissue.

Two studies were conducted to determine the safety and performance of MDC-75 at the removal of certain superficial skin lesions: Seborrheic Keratosis, Isolated Low Grade Actinic Keratosis, Common Warts, Acrochordons and benign non-active naevi.

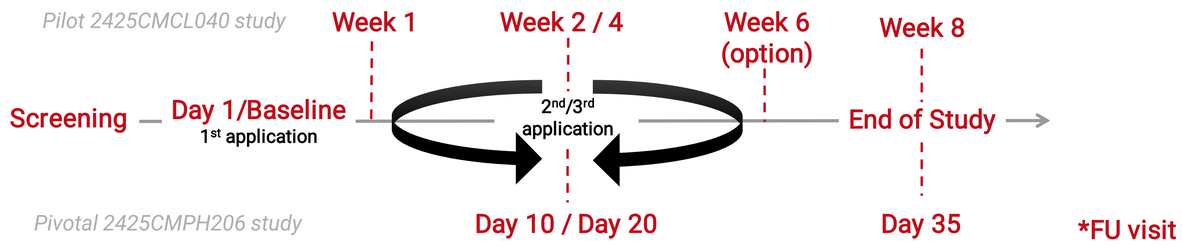
MATERIALS & METHODS

Study design

Two open-label, proof of concept and pivotal before-versus-after design (each subject acting as their own control) studies in adult subjects with clinically diagnosed superficial skin lesions (2425CMCL040 and 2425CMPH206).

Performance evaluation:
- Changes in lesion size/volume,
- Investigator global assessment
- Global assessment of improvement
- Patient satisfaction

Safety evaluation:
- Adverse events
- Local tolerance,
- Immediate pain scores,
- Dyspigmentation



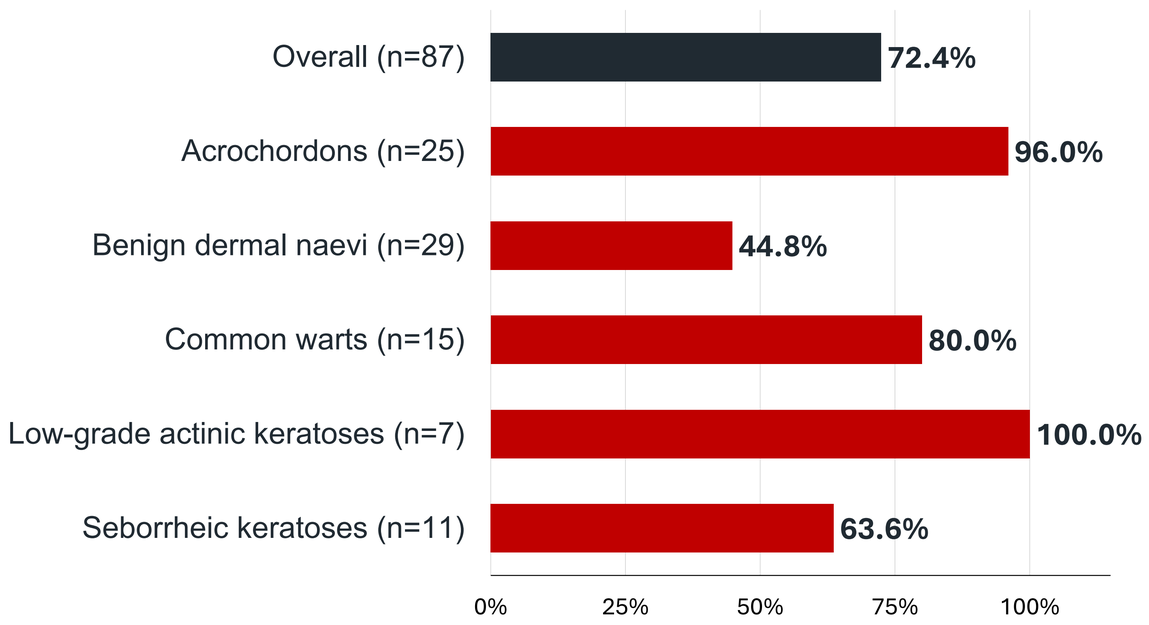
*Follow-ups were limited to most problematic patient PIH outcomes

RESULTS

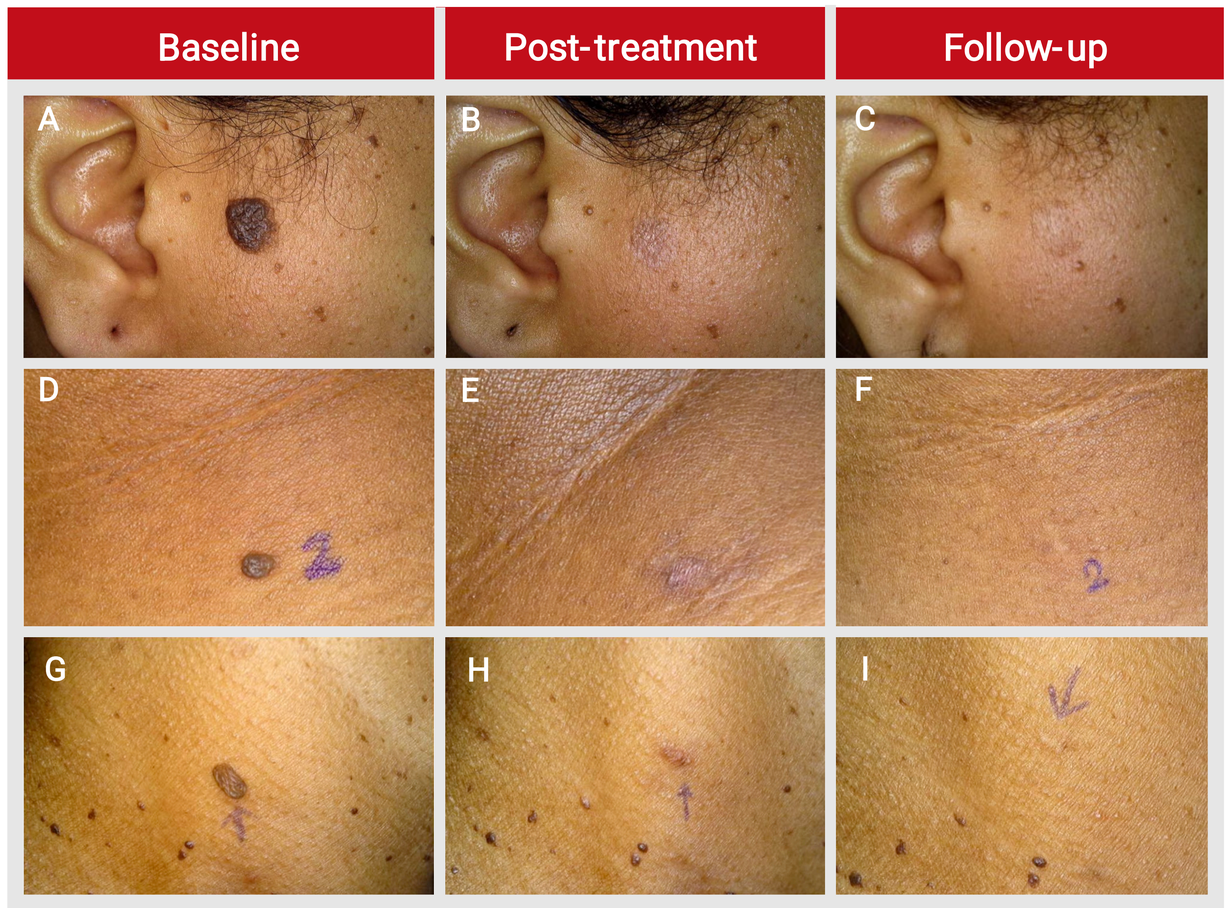
Demography

Parameter	Sub-category	PoC Study	Pivotal Study
Sample Size	N	24	27
Age (years)	Mean (min, max)	48 (20-69)	47 (24-73)
Gender	Female	75%	85.20%
	Male	25%	14.80%
Fitzpatrick skin Phototype	I	0%	0%
	II	14.8%	8%
	III	25.9%	21%
	IV	33.3%	42%
	V	18.5%	29%
	VI	7.4%	0%
Ethnicity	Caucasian	33.3%	17%
	Mixed race	48.1%	50%
	Indian	7.4%	25%
	Asian	3.7%	8%
	African	7.4%	0%

Proportion of lesions reduced by >75% (51 Patients, 87 lesions)

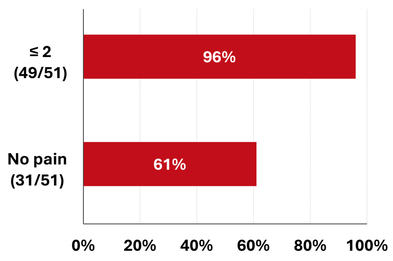


Sources: 2425CMCL040 and 2425CMPH206 clinical trials



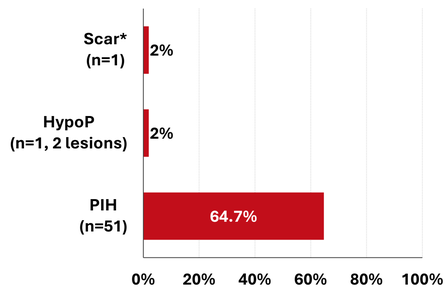
Photographs of subjects. Seborrheic keratosis (A) before, (B) post-treatment and (C) after about 7 months follow-up in woman of 36 years with a skin phototype of IV. Acrochordon (D) before, (E) post-treatment and (F) after about 6 months follow-up in man of 55 years with a skin phototype of V. Acrochordon (G) before, (H) post-treatment and (I) after about 6 months follow-up in woman of 56 years with a skin phototype of V.

Pain score (range 0 – 10)



MDC-75 is a novel medical device that provides an effective and nearly painless option for the treatment of benign superficial skin lesions.

Pigmentation change (%)



*One hypertrophic scar resolved post-study (Week 13), with a residual PIH.

Patients' satisfaction

Satisfaction Score (mean):

8.75/10

Patients' recommending (mean):

9.22/10

The treatment was well tolerated with transient mild inflammation

CONCLUSIONS

- Studies demonstrated robust performance and favorable safety profile in the management of superficial skin lesions.

72.4%
of 87 lesions had >75% reduction

96%
of patients reported minimal pain ≤2/10
61% of subjects scored 0/10

9.22/10
patients recommend

8.75/10
mean patient satisfaction