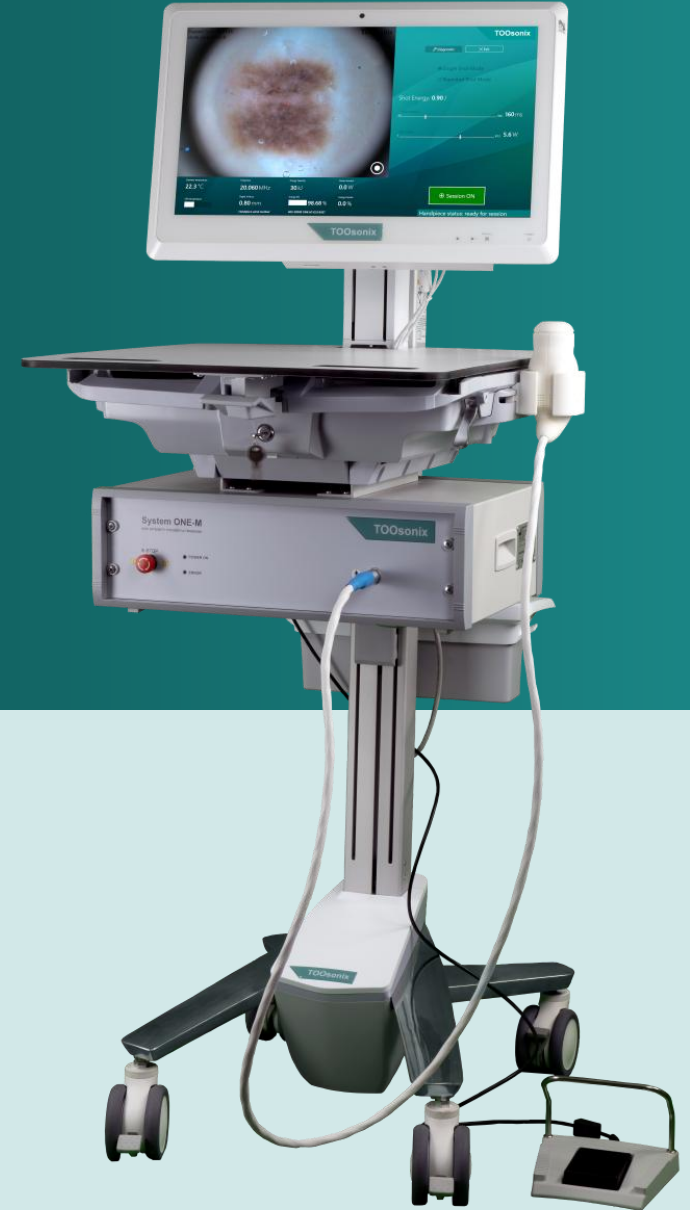
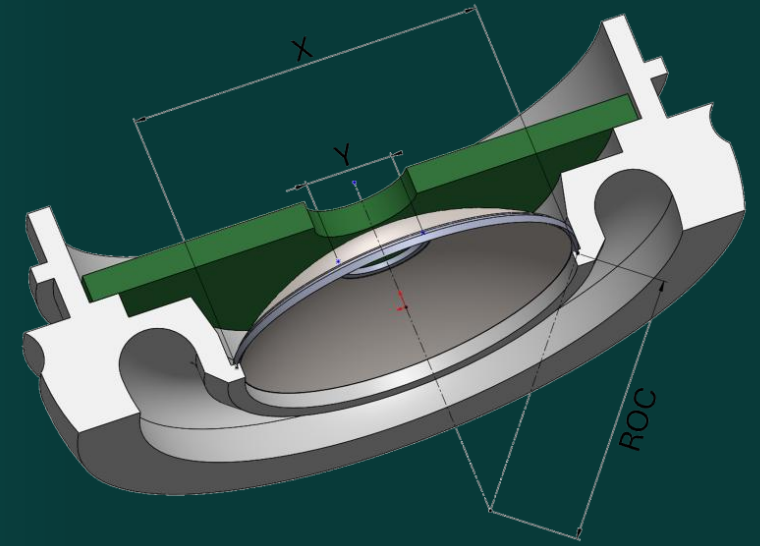


TOOsonix

*Dermatological
Ultrasound Therapy*



HIFU Technology

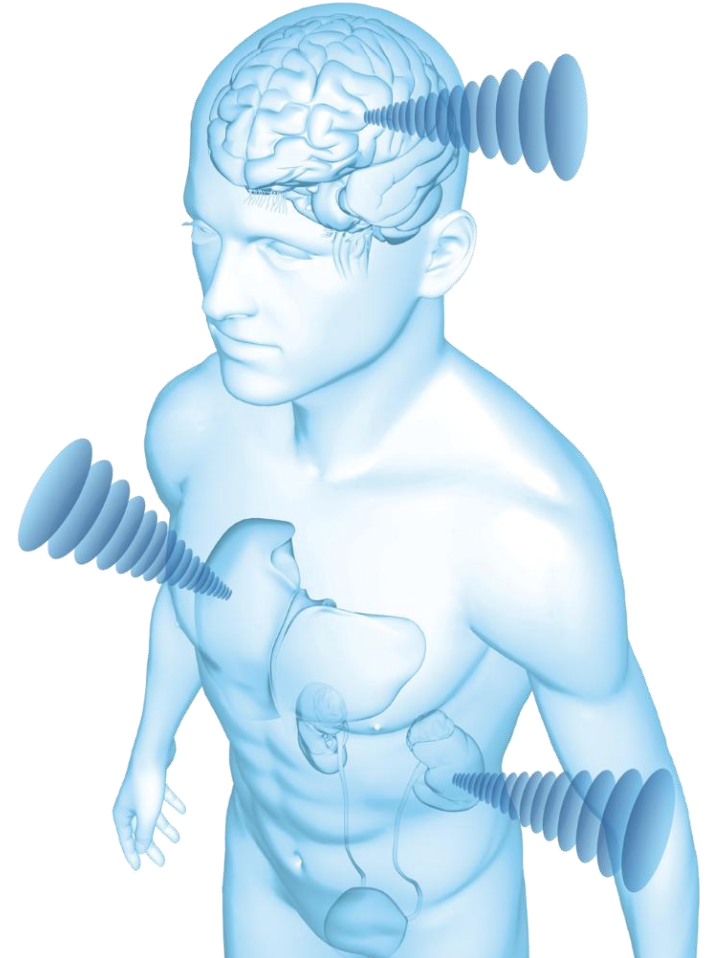


High Intensity Focused Ultrasound

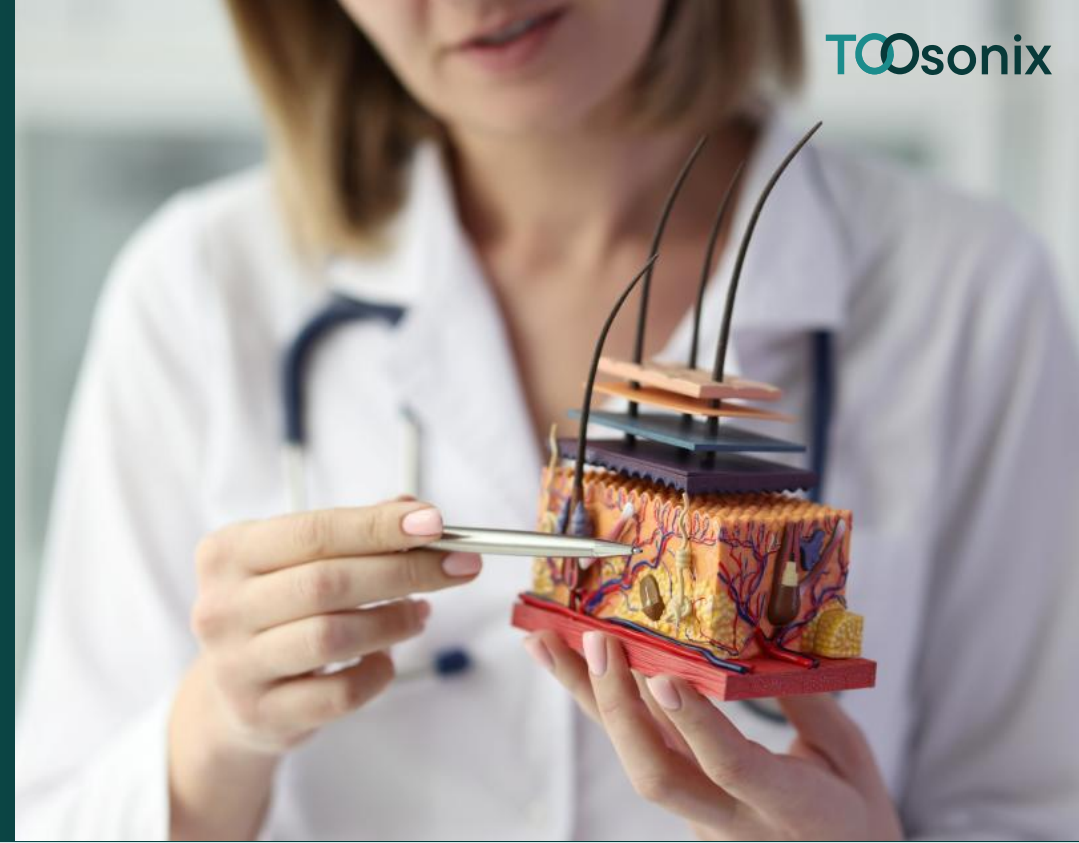
HIFU = High Intensity Focused Ultrasound

- « Ultrasound is focused into a small focal point with very high acoustic energy density
 - Ultrasonic focal zone created inside body without surgical procedures etc.
 - Localized heating induce thermal effects (e.g. cell necrosis)
 - Localized mechanical forces induce tissue disruption (e.g. denaturation)

- « Direct non-invasive procedure
 - No surgery
 - No radiation
 - No pharmaceuticals
 - No need for anesthesia
 - No fumes or smells
 - No need for hospitalization
 - No down-time after treatment

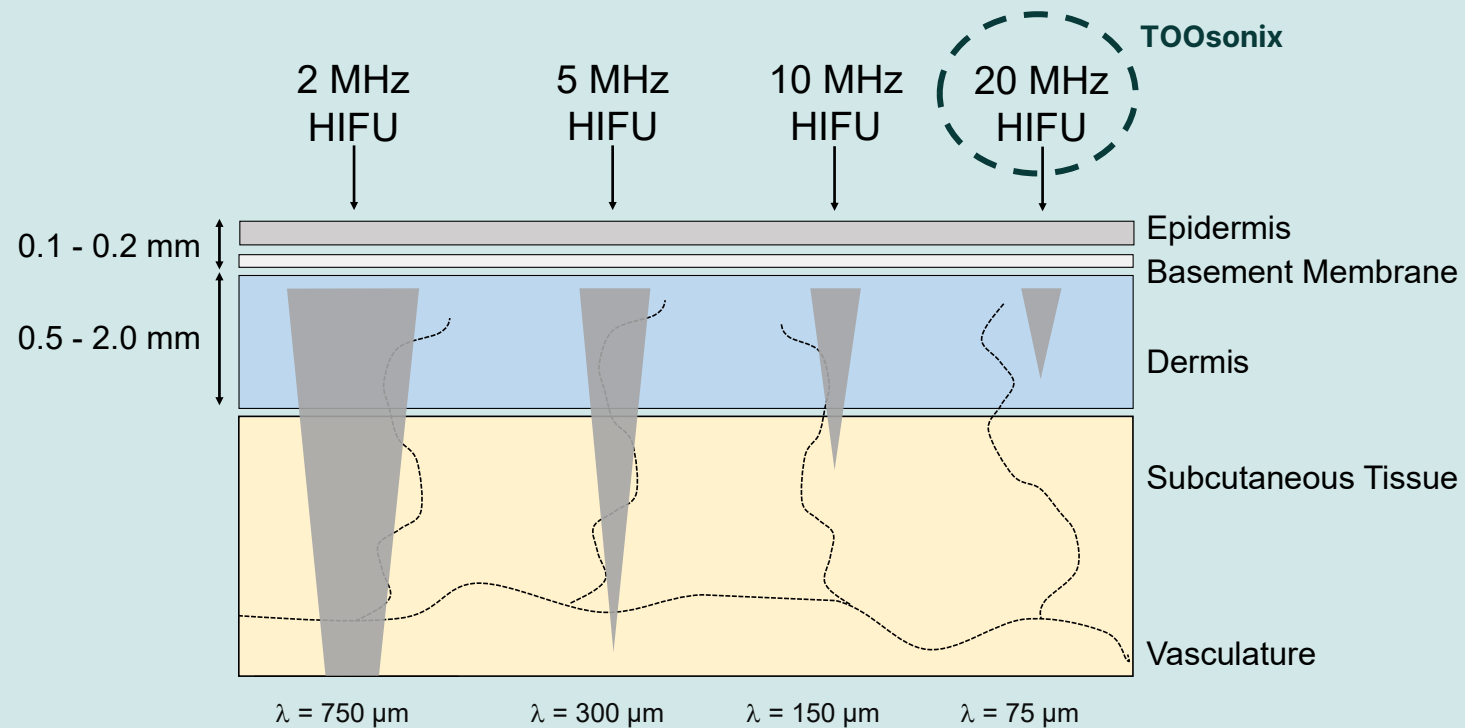


HIFU For Dermatology

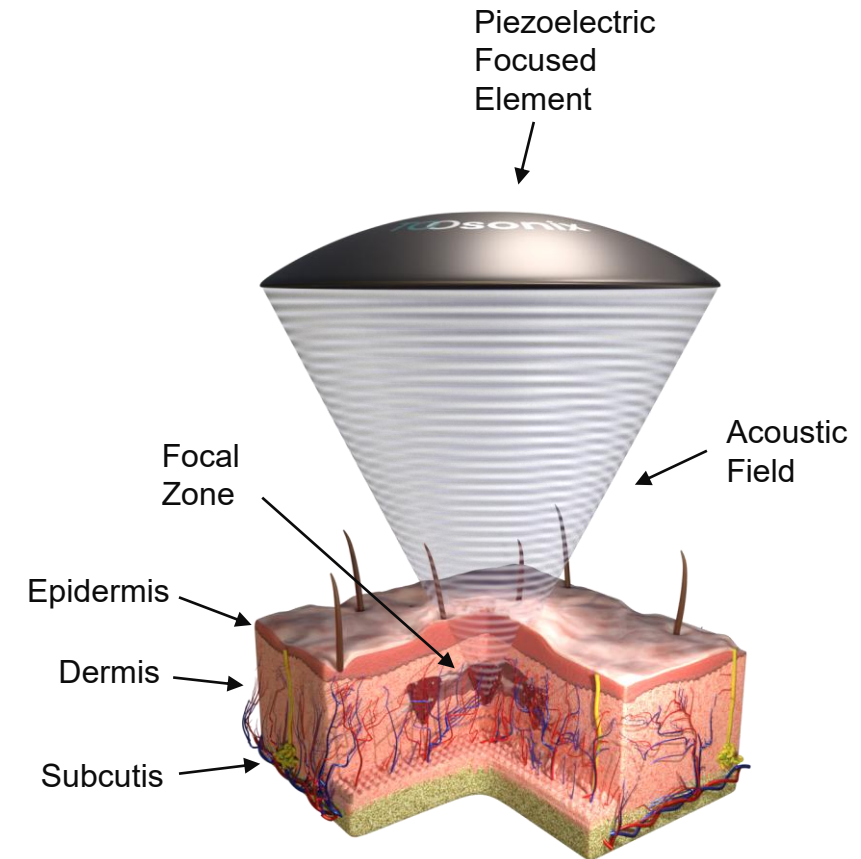


Requirements and characteristics of HIFU applied to the human skin

Fundamental relation between HIFU frequency and size of focal zone



20 MHz is optimum for confined focal zones in the epidermis/dermis

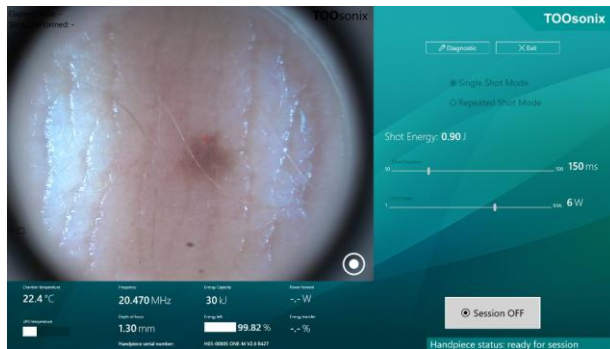


Therapeutic 20 MHz HIFU focal zones can be accurately confined to a specific depth and volume in the skin without damaging tissue above or below

[Link to Video - How it Works](#)

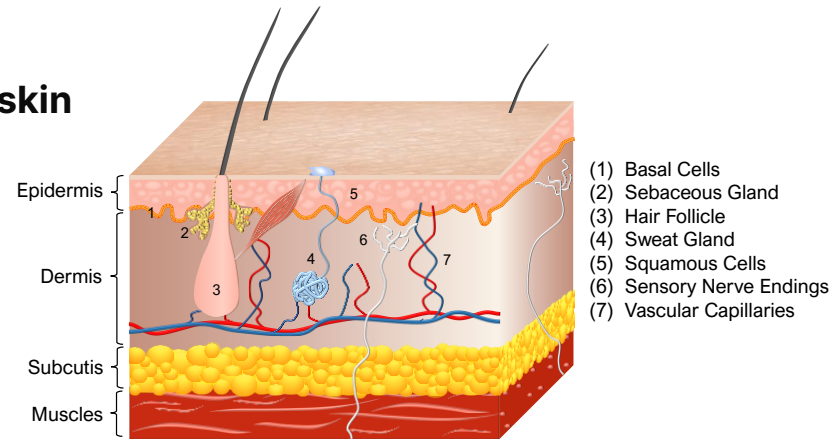
TOOsonix System ONE – HIFU Equipment for Dermatology

- 20 MHz Ultrasound
 - Focus zone tuned to dimensions in human skin
- Four HIFU probes with fixed focus depths
 - Quick selection and switching between fixed processing depths
- Integrated real-time color dermoscope
 - 2 Megapixel camera integrated into the HIFU handpiece for precise guidance
- User-friendly management of processing parameters via TOOsonix software
 - Simple setting of the dosage for a treatment
- Foot pedal activation
 - Maximum control over the treatment and clinical response

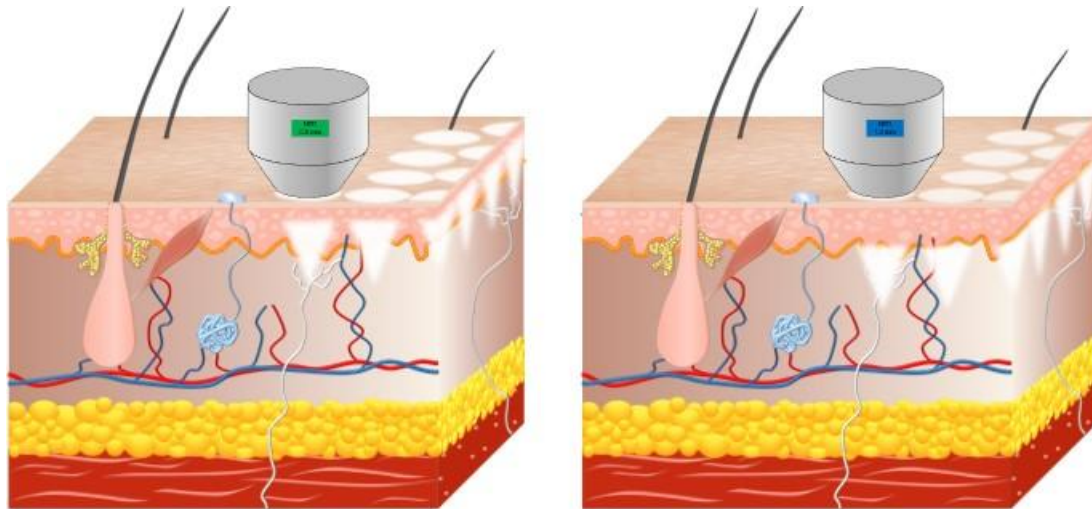


TOOsonix HIFU handpieces – Choice of 4 fixed focal depths

Structure of normal skin



Ablative treatment – Wound crust

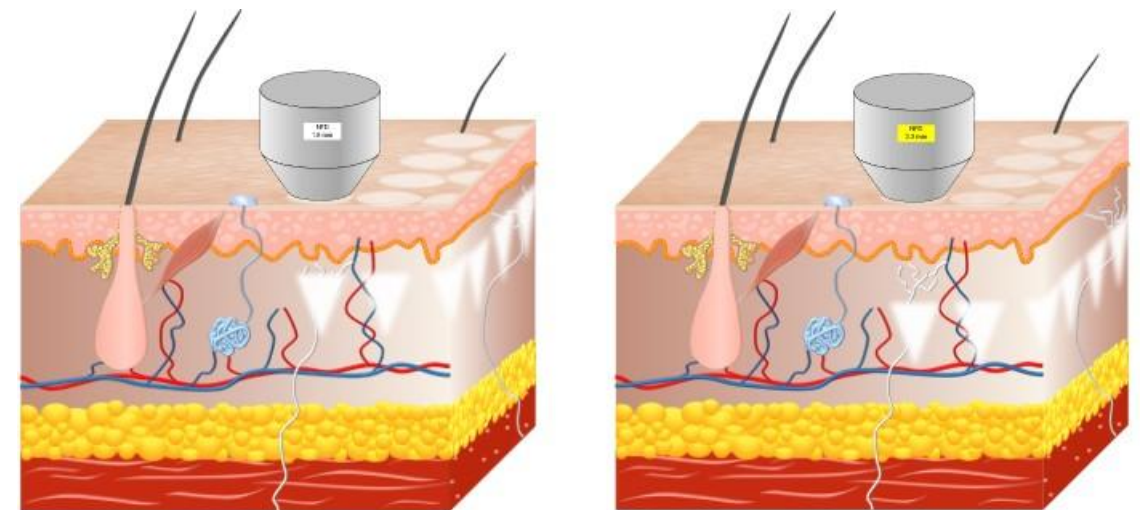


Focal depth 0.8 mm

Focal depth 1.3 mm

[Link to Video – Ablative Modality](#)

Non-ablative treatment – No wound crust

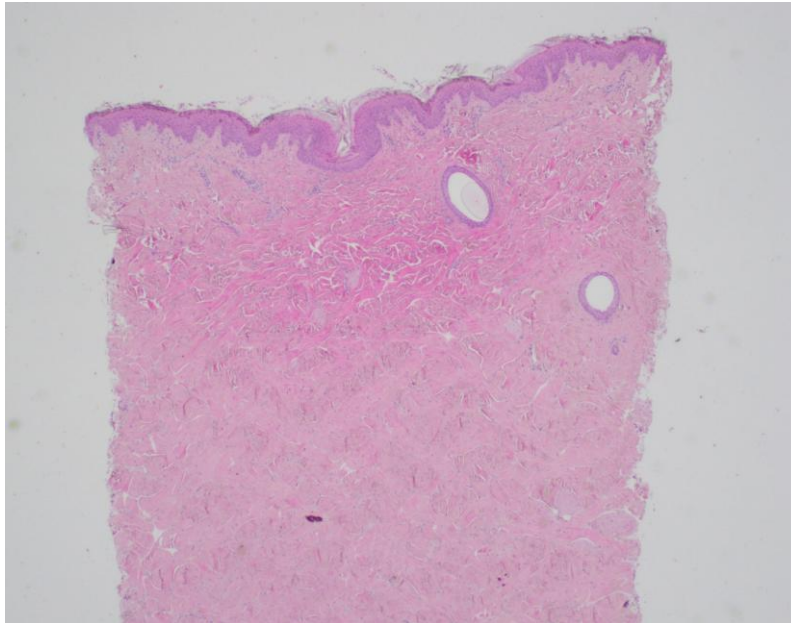


Focal depth 1.8 mm

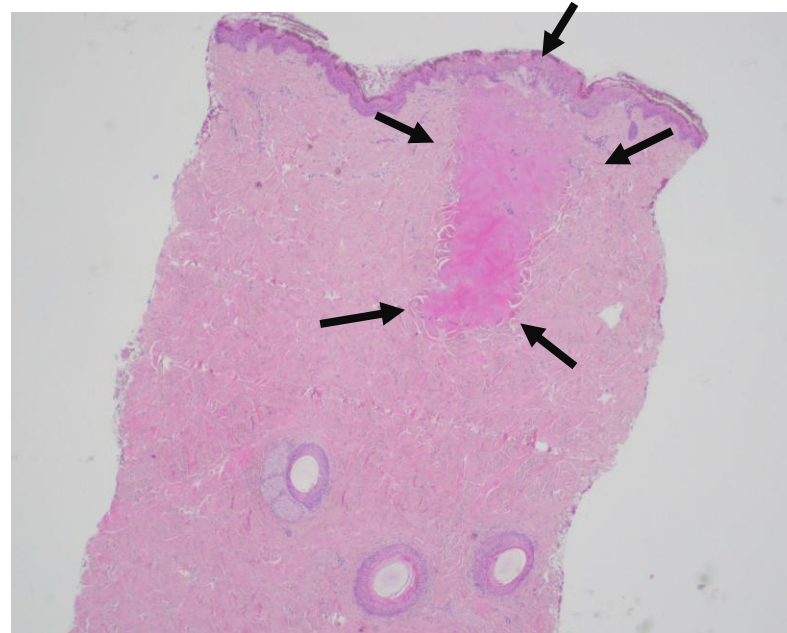
Focal depth 2.3 mm

[Link to Video – Non-ablative Modality](#)

3 mm punch biopsies taken directly after HIFU treatment

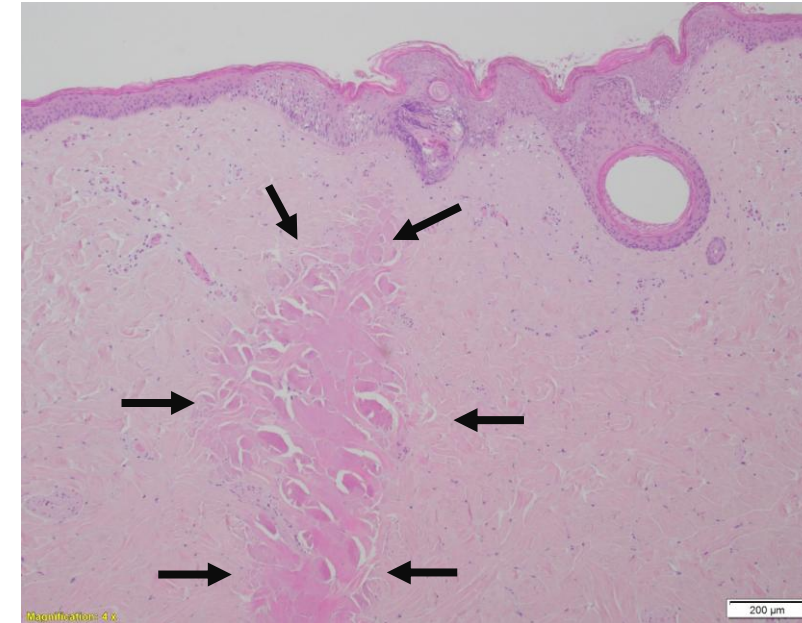


Untreated control biopsy



Shallow transducer
0.6 J / 150 ms / 4 W

Ablative method



Deep transducer
0.6 J / 150 ms / 4 W

Non-ablative method

HIFU creates acute necrosis in epidermis and/or dermis depending on transducer selection

TOOsonix ONE-M Handpieces – Selection guide

Focal Point	Color Code	Nominal Focus Depth	Typical setting	Key features (depending on settings and treatment type)	Treatment Examples
Superficial	Green	0.8 mm	150 ms 0.6 - 0.9 J	Ablative effect Quick healing	Flat Seborrheic Keratosis Flat and superficial Actinic Keratosis Solar Lentigines Small Sebaceous Hyperplasia
Upper dermis	Blue	1.3 mm	150 - 250 ms 0.6 - 1.0 J	Ablative effect Wound crust formation at medium shot coverage	Lightly keratotic Actinic Keratosis Superficial Basal Cell Carcinoma Slightly protruding Seborrheic Keratosis Cherry Angiomas Flat Verruca Slightly protruding Sebaceous Hyperplasia
Middle Dermis	White	1.8 mm [†]	150 - 400 ms 0.7 - 1.1 J	Semi-ablative effect Wound crust formation at dense shot coverage	Nodular Basal Cell Carcinoma Keratotic Actinic Keratosis Slightly protruding Seborrheic Keratosis Protruding Sebaceous Hyperplasia Cutaneous neurofibromas - Sessile, upper dermis Mild Verrucae
Deep Dermis	Yellow	2.3 mm [†]	250 - 400 ms 0.7 - 1.2 J	Non-ablative effect Typically no wound crust	Fine-line wrinkles Cutaneous neurofibromas - Mid-dermis Nodular Basal Cell Carcinoma
Stacked Treatment	Yellow	2.3 mm	150 - 500 ms 0.7 - 1.2 J	1 st "Stacked treatment"	Thicker Verrucae (use 400-500 ms dosing) Nodular Basal Cell Carcinoma (use 150 ms dosing)
	Blue	1.3 mm		2 nd "Stacked treatment"	

Intended purpose

- System ONE-M is intended for treatment of the human epidermis and dermis layers by administering high-intensity focused ultrasound (HIFU) doses to small and confined volumes in the human skin.

Intended users

- System ONE-M is used by qualified and trained healthcare professionals who may preferably have past experience with ultrasound, laser, electrotherapy, photodynamic therapy, or similar clinical practices.

Intended patient population

- The patient population is adults (18 years and above).

System ONE-M is essentially approved for treatment of almost any non-metastasizing skin disease



Intended conditions (Indication for use)

System ONE-M is indicated for medical and aesthetic dermatological therapy including, but not limited to, the following general categories:

Medical indications

- Basal cell carcinoma
- Actinic keratosis
- Vascular hemangiomas and tumors of the skin
- Cutaneous NF1 fibromas (cNF)
- Verruca vulgaris (common warts)
- Condylomata acuminata (genital warts)
- Cystic acne and acne comedones
- Seborrheic keratosis / Seborrheic warts
- Superficial telangiectasia (spider veins)
- Sebaceous hyperplasia
- Other benign epidermal and cutaneous neoplasms of the human skin (e.g. hidrocystoma, Fox Fordyce Disease, Birt-Hogg Dubé syndrome, epidermal inclusion cysts, etc.)

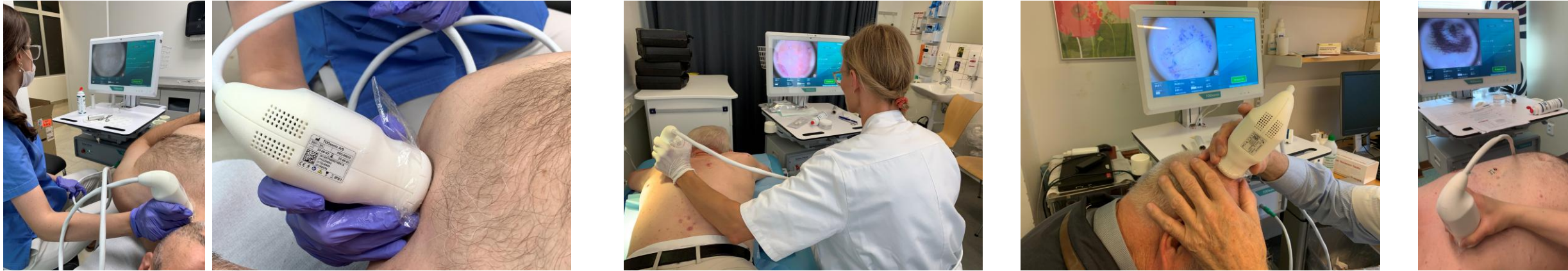
Non-medical (aesthetic) conditions

- Vascular lesions (cherry spots and venous lakes)
- Small acrochordons (skin tags)
- Solar lentigines (liver spots)
- Fine-line wrinkles
- Removal of smaller tattoos and tattoos not responding to laser removal
- Other aesthetic HIFU treatments of the human skin

Clinical Treatment



Treatment using optical guidance in real-time



- ⌘ Treatment area is marked with permanent ink before treatment is started
- ⌘ Operator is positioned to see computer screen during treatment
- ⌘ Handpiece is always kept perpendicular to the skin surface
- ⌘ Good acoustic coupling without bobbles or air-pockets in acoustic path is important

The operator can perform a treatment almost entirely guided by the accurate real-time video-feed on the user interface.
No other dermatological treatment modality offers this level of accuracy.

Preparing for a treatment – Three easy steps

1 Select handpiece with right depth for treatment

- 4 focal depths available
- Guidance and training provided at installation

Focal Point	Color Code	Handpiece Focal distance	Typical setting*	Key features (depending on settings and treatment type)	Treatment Examples
Superficial	Green	0.8 mm	150 ms* 0.6 - 0.9 J**	Ablative effect Quick healing	Flat Seborrheic Keratosis Flat and superficial Actinic Keratosis Solar Lentigines
Upper dermis	Blue	1.3 mm	150 - 250 ms* 0.6 - 1.0 J**	Ablative effect Wound crust formation at medium shot coverage	Lightly keratotic Actinic Keratosis Superficial Basal Cell Carcinoma Slightly protruding Seborrheic Keratosis Cherry Angiomas Flat Verruca Vulgaris 2 nd "Stacked treatment" for deep lesions (see 2.3 mm)
Middle Dermis	White	1.8 mm†	200 - 400 ms* 0.7 - 1.1 J**	Semi-ablative effect Wound crust formation at dense shot coverage	Nodular Basal Cell Carcinoma Keratotic Actinic Keratosis Slightly protruding Seborrheic Keratosis Cutaneous neurofibromas - Sessile, upper dermis Mild Verruca Vulgaris
Deep Dermis	Yellow	2.3 mm†	250 - 500 ms* 0.7 - 1.2 J**	Non-ablative effect Typically no wound crust	Fine-line wrinkles Cutaneous neurofibromas - Mid-dermis Nodular Basal Cell Carcinoma 1 st "Stacked treatment" for deep lesions (see 1.8 mm)

2 Fill handpiece and apply film

- Easy process for water-filling
- Change film between patients to secure hygienic conditions



3 Choose dose duration and energy

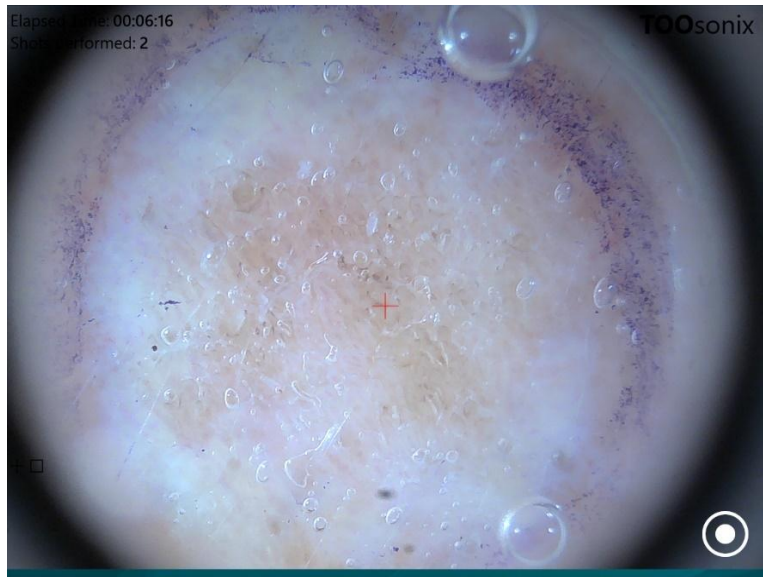
- Adjust two parameters on touchscreen
 - Dose duration
 - Dose power
- System is auto-limited to safe levels only



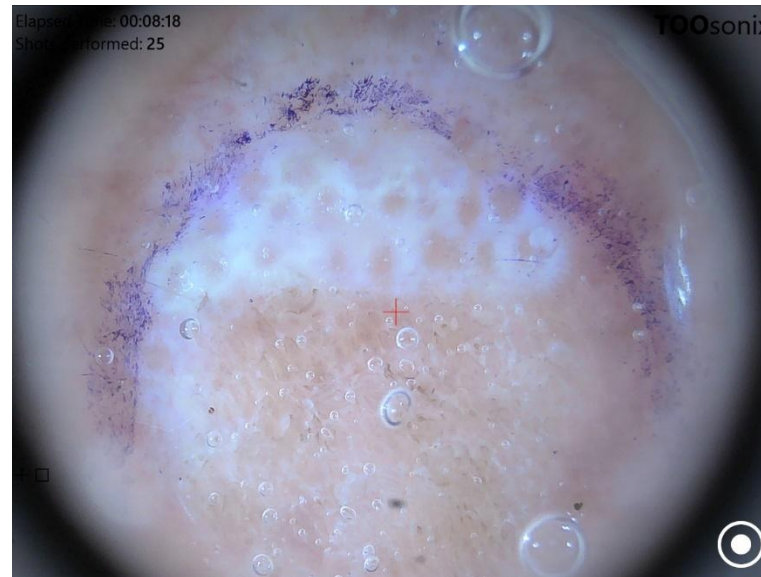
[Link to Video](#)

Real-time image-guided treatment

- View-field is approximately Ø8 mm
- Resolution is below 20 µm
- Cross-hair on screen for accurate targeting
- Footswitch activation of HIFU doses
- Operator gradually “fills out” target area with HIFU doses



Just before treatment



During treatment



Just after treatment

Video Example - Removal of Seborrheic Keratosis

Methodology

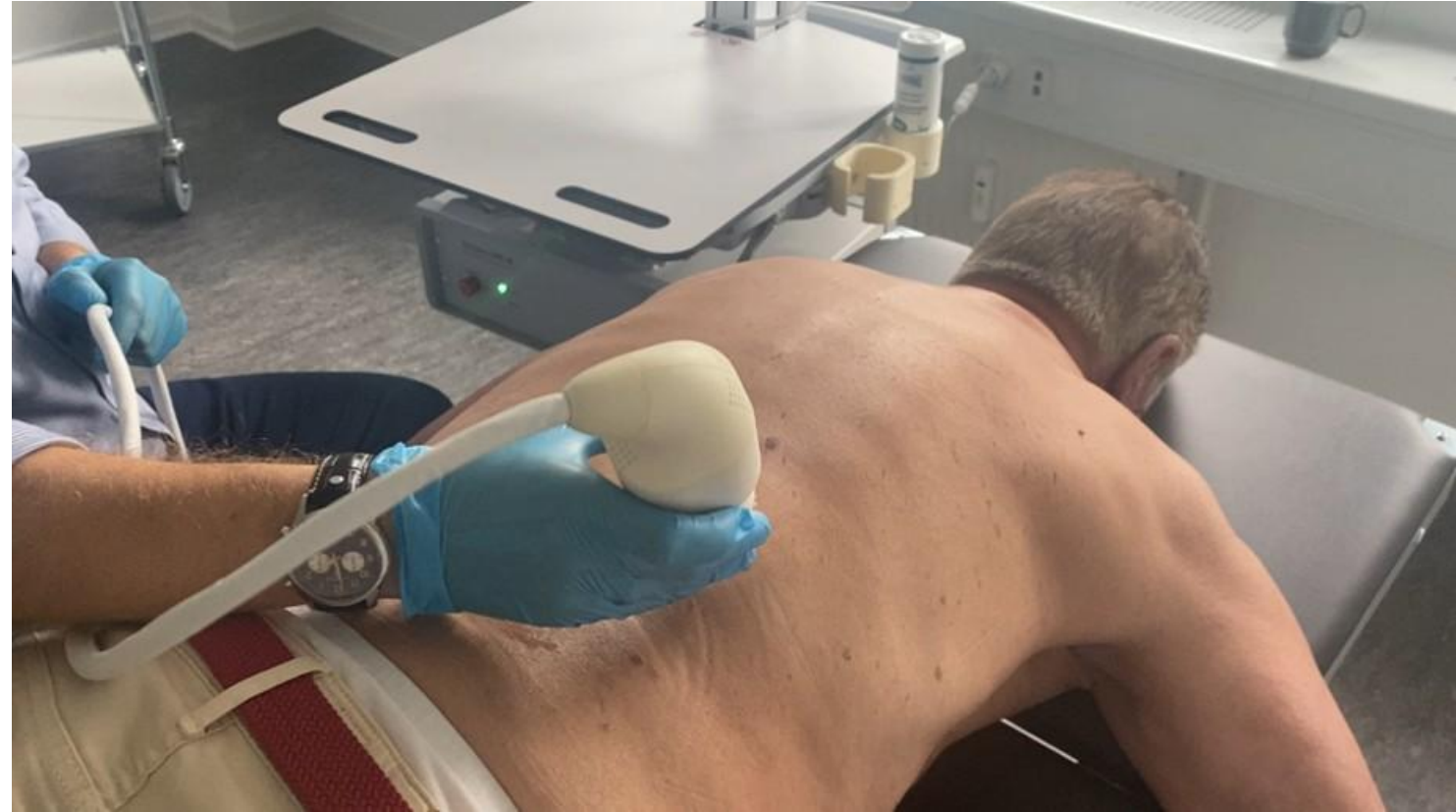
- ⌘ Superficial necrosis
- ⌘ Renewal with normal-pigmented skin

Proposition

- ⌘ Easy process with good aesthetic outcome
- ⌘ Many lesions can be treated in one session
- ⌘ No good clinical alternatives
 - Laser and Cryo are painful + risk of scarring

Typical treatment selections

- ⌘ Handpiece 0.8 or 1.3 mm (upper dermis)
- ⌘ 150 ms, 6W, 0.9 J/dose
- ⌘ 5-50 doses per lesion for full treatment



[Link to Video – Anterior trunk](#)

[Link to Video – Posterior trunk](#)

Other Video Examples from Clinics



Case-presentation: Treatment of BCC on scalp

*Prof. Joergen Serup
Dept. of Dermatology
Bispebjerg University Hospital, Denmark*

[Link](#)



Treatment Video: Treatment of Cherry Angiomas

*Dr. Tomasz Zawada
TOOsonix A/S*

[Link](#)



Treatment Video: 13 mm BCC on back of female patient

*Dr. Jacek Calik
Dept. of Clinical Oncology,
Wroclaw Medical University, Poland*

[Link](#)



Treatment Video: Globular cutaneous Neurofibroma

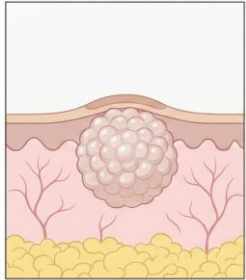
*Prof. Joergen Serup
Dept. of Dermatology
Bispebjerg University Hospital, Denmark*

[Link](#)

Clinical Examples



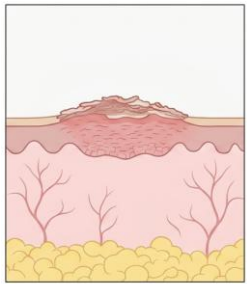
Selected results from clinical partners



Basal cell carcinoma (BCC)

Basal cell carcinoma (BCC)

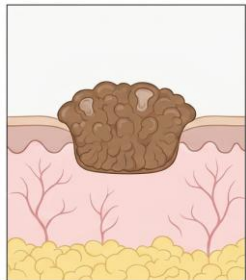
- (((BCC is the most common form of skin cancer worldwide.
- (((Approximately **3.6 million cases** of BCC are diagnosed in USA alone each year



Actinic keratosis (AK)

Actinic Keratosis (AK)

- (((AK is a pre-cancer condition.
- (((Approximately **58 million** people in USA alone have one or more AK



Seborrheic keratosis (SK)

Seborrheic Keratosis (SK)

- (((SK is a benign skin condition with unwanted aesthetic appearance.
- (((Approximately **70-90%** of people above 60 years have one or more SK

BCC - Typical healing phase after superficial treatment



Before Treatment



Just after treatment



Day 4



6 weeks after treatment



2 years after treatment

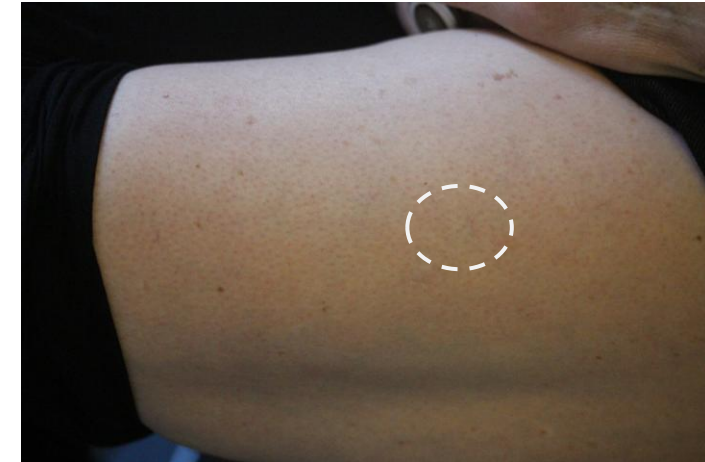
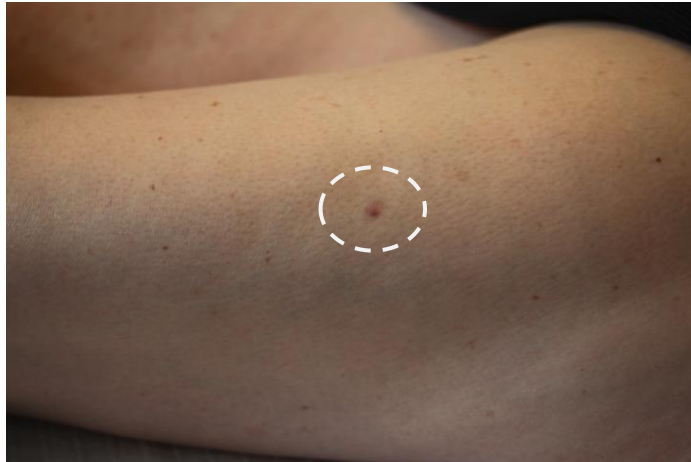
Patient has been surgically treated for BCC (see surgical scarring).
Recurrence in periphery of original area treated by HIFU.

No visual signs of BCC
remains in treated area

Case – De-novo BCC on wrist



Case – De-novo BCC on upper outer thigh on female patient



**Before
Treatment**



**Just after
treatment**



**2 weeks after
treatment**



**3 months after
treatment**



**6 months after
treatment**

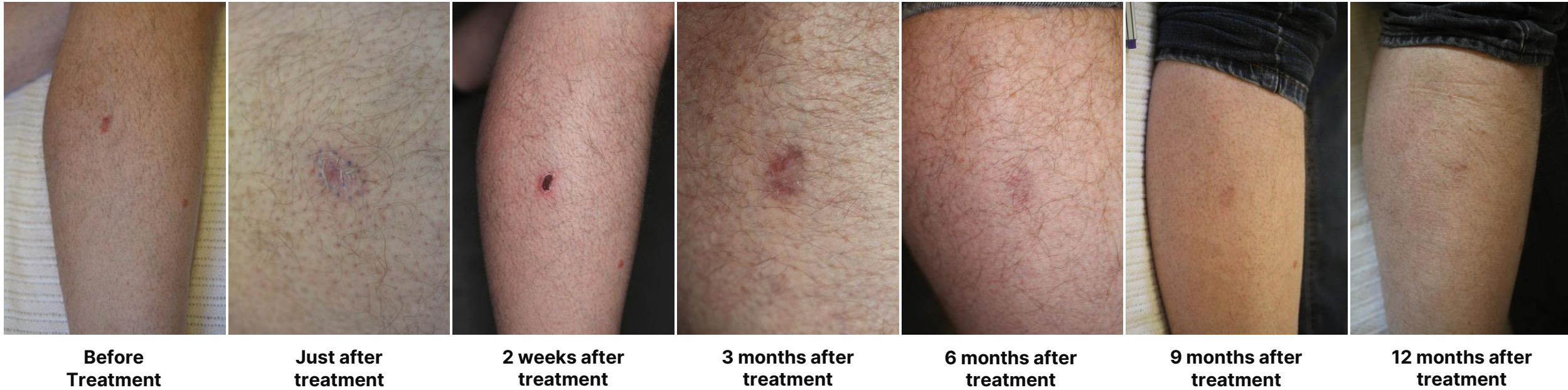


**9 months after
treatment**



**12 months after
treatment**

Case – De-novo BCC on lower leg



Case – Recurrent nodular and superficial BCC in scalp area



Before HIFU treatment.

sBCC and nBCC confirmed by biopsy

Initial two nBCC treated by HIFU.
Larger sBCC- area not treated.



2 weeks post test treatment

Good reduction of nodules was observed.

Full treatment of entire BCC area
(diameter ~20 mm).



12 months post treatment

Full reduction of BCC in treated area.

No recurrence after 12 months confirmed by
histopathology.

No additional hair-loss

AK - Typical healing phase after superficial treatment



Before Treatment



Just after treatment



Day 3



6 months

Patient has been surgically treated for BCC and had several untreated AK lesions pending suitable treatment.

Two areas in face selected for HIFU treatment

No visual signs of AK remains in treated area as per dermoscopy verification.

Cases – Multiple Actinic Keratoses on typical sun-exposed areas



17 AKs before and 12 weeks after treatment



Before and 8 weeks after treatment

Cases – Actinic Keratosis on typical sun-exposed areas



Before and 8 weeks after treatment



Before and 5 weeks after treatment



Before and 26 weeks after treatment



Before and 12 weeks after treatment

Case - Seborrheic keratosis



Before and after single HIFU treatment

[Link to Video](#)



Before and after single HIFU treatment

[Link to Video](#)

Case - Seborrheic keratosis



Before and after single HIFU treatment

[Link to Video](#)



Before and after single HIFU treatment

[Link to Video](#)

Cases – Sebaceous Hyperplasia in face



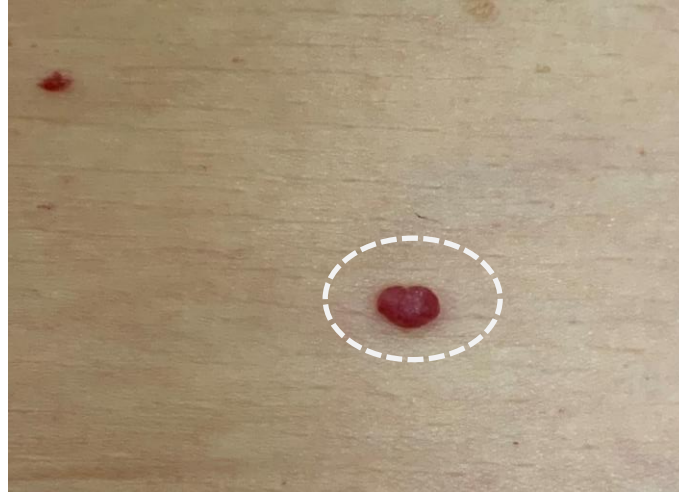
Before and after single HIFU treatment



Before and after single HIFU treatment

[Link to Video](#)

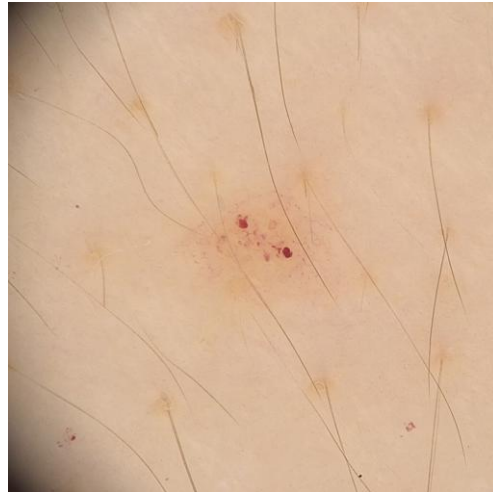
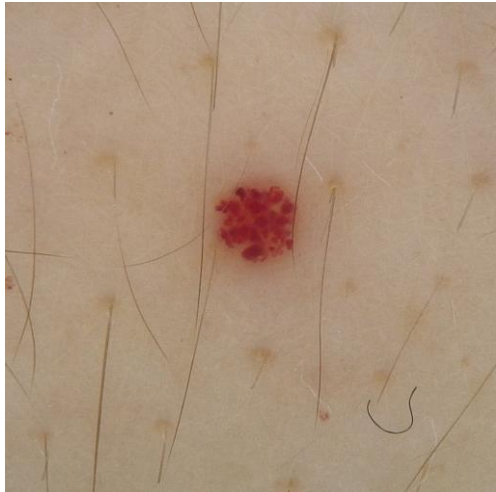
Cases – Cherry Angiomas on trunk and legs



Before treatment



16 months after treatment



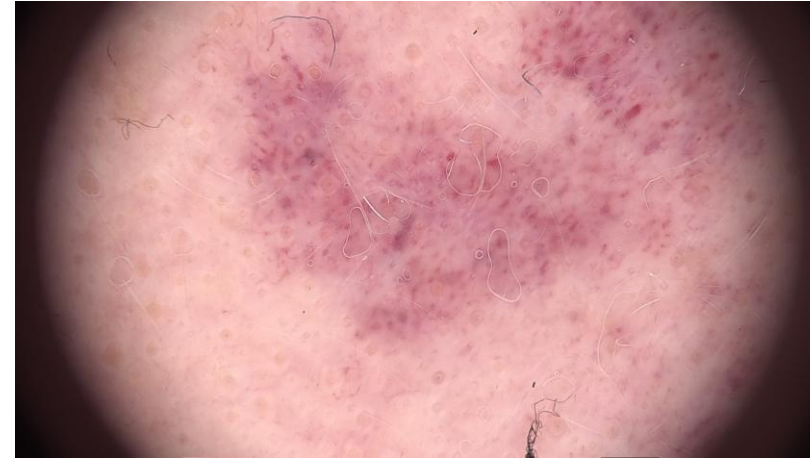
Before and after single HIFU treatment



Before and after single HIFU treatment

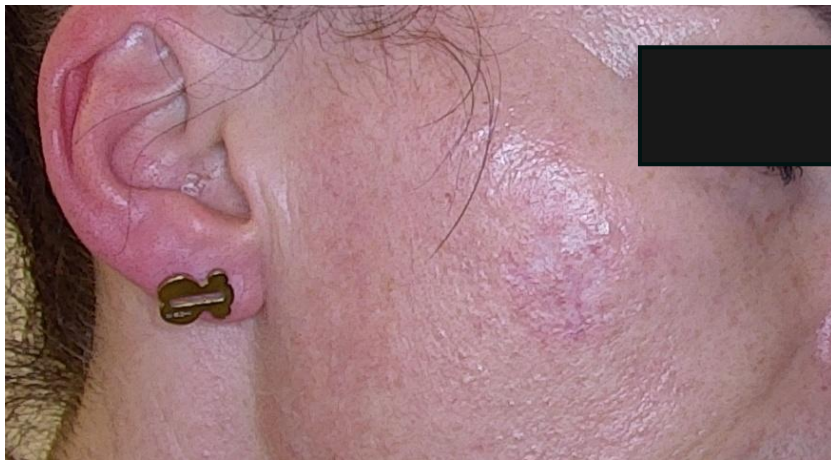
[Link to video](#)

Case – Vascular Malformations / Congenital Hemangioma (two treatments)



FotoFinder
Dermoscope

Before treatment



FotoFinder
Dermoscope

15 weeks after 1st treatment

Case – Recalcitrant Verruca Vulgaris in face



Dermoscope
Before HIFU



Dermoscope
Directly after HIFU



Dermoscope
8 weeks after HIFU



Before treatment

Wart treated several times with cryo and topicals without effect



8 weeks after treatment

No HPV cells in treated area.

Case – Combined Imiquimod and HIFU on Condyloma Acuminata (genital warts)



Dermoscope
Before HIFU



Dermoscope
Directly after HIFU



Dermoscope
5 weeks after HIFU



Before treatment

Recalcitrant condylomas after
7 weeks treatment with 5% imiquimod

Clinical Note:

*The focused ultrasound method does not
generate fumes or aerosols.
Risks for transferring HPV virus from
patient to operator is therefore eliminated*



5 weeks after HIFU

No condyloma in treated area.

Case - Cutaneous NF1 Neurofibromas – Management of growing tumors

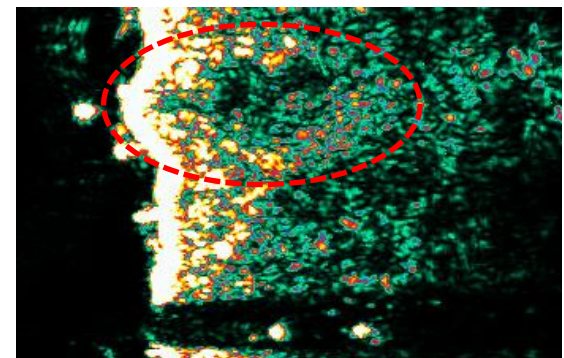
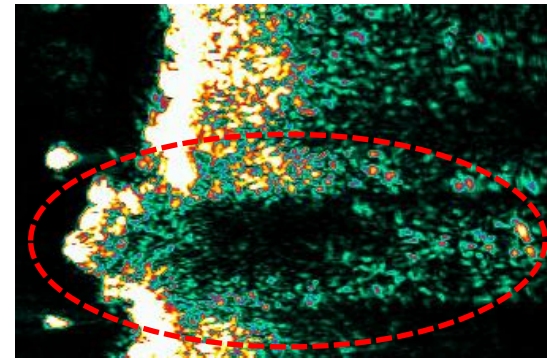
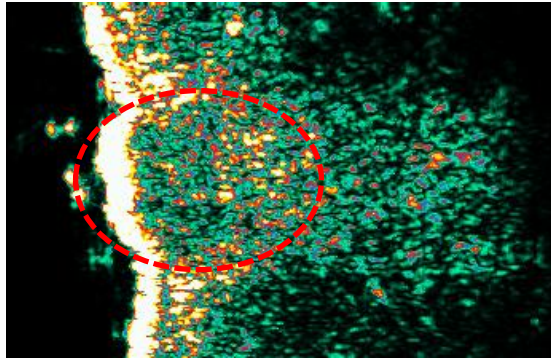
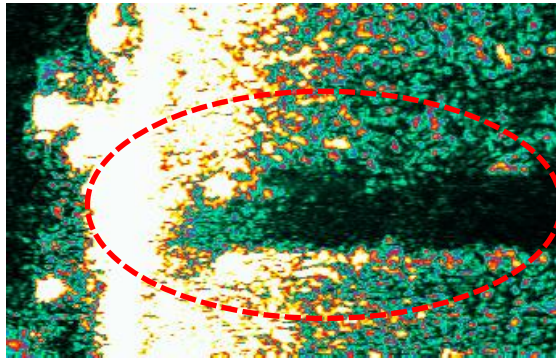
- NF1 is the most common genetic defect in humans
- 1 in 3000 people are diagnosed with NF1
- Cutaneous neurofibromas (cNFs) appear from adolescence
 - Numbers vary from a few to thousands dispersed over the entire body



Before and 6 months after treatment

[Link to Video](#)

Cases - Cutaneous NF1 Neurofibromas – Management of growing tumors



Before HIFU

3 months after HIFU

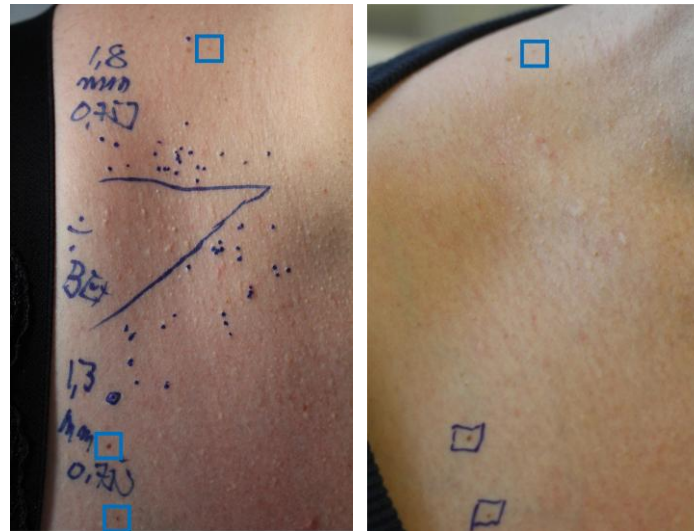
Before HIFU

3 months after HIFU

Flattening of tumors are typically the primary success criteria for the patient



Fox Fordyce Disease



Birt Hogg Dubé Disease



Squamous cell carcinoma in-situ
(off-label)



Cystic Acne



Apocrine hidrocystoma

Ongoing demonstrations:

- Radiation-induced BCC
- Granuloma annulare
- Kaposi Sarcoma
- Steatocystoma multiplex
- Vulvar Lichen Sclerosis

Peer-reviewed articles – From theoretical background to GCP Studies

Theory

- ⌘ Numerical modelling
- ⌘ Transducer design and manufacturing
- ⌘ Measurement methods

Pre-clinical studies

- ⌘ In-vitro measurements
- ⌘ Ex-vivo studies
- ⌘ Animal studies (mini-pigs)

Clinical treatments

- ⌘ Clinical Trials
 - Basal Cell Carcinoma
 - Actinic Keratosis
 - Cutaneous Neurofibroma

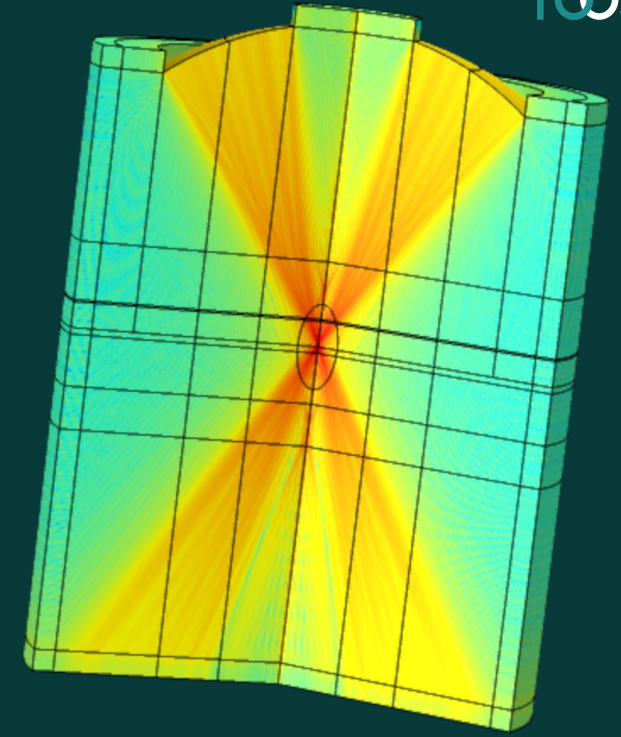
Case series and reports

- ⌘ Case series and reports
 - Rare diseases and lack of therapeutic options
 - Aesthetic treatments with improved healing and final outcome
 - Tattoo removal for smaller stigmatic cases

Link



About TOOsonix



- Company located in Copenhagen, Denmark
- All products are "Country of Origin Denmark"
- Founded in 2017
- ISO 13485 certified since 2018
- MDR CE-marked devices since 2024

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TOOsonix

Thank you

