

The Clinical Efficacy and Safety of Microneedling Fractional Radiofrequency in the Treatment of Facial Wrinkles: A Multicenter Study with the INFINI System in 499 Patients

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ABSTRACT

Background and Aims: Radiofrequency energy has been reported for the treatment of facial wrinkles but results have been inconsistent. The use of microneedle fractional RF (MFR) to deliver energy selectively to the dermis has recently attracted attention in this field. The INFINI fractional RF system with MFR has become commercially available, and the current multicenter study was designed to assess the efficacy and safety of the INFINI system in various geographic locations and different skin types.

Study Centers and Patients: Five study centers were selected in Italy, India, Korea, Poland and Turkey. The total number of patients treated over all the centers was 499 broken down by country as follows: Italy, 220 (total); India, 155 (total); Korea, 19 (trial population); Poland, 15 (trial population); and Turkey, 90 (total). Patient skin types ranged from Fitzpatrick type I to type V.

Parameters and Treatment Sessions: A topical anesthetic cream (5% to 20%) was used in all centers for all patients, with occlusion times from 20 to 45 min. A large variety of parameters was used, and varied according to both the severity of the condition and the site being treated. Needle depths ranged from 0.5 mm to 3 mm, depending on the anatomical site and pass number. Power levels ranged from 4 to 12 depending mostly on needle depth but also site. Exposure times ranged from 20 ms to 200 ms. Full-face passes per session ranged from 1 to 3, with extra passes being delivered over the wrinkles in some centers. Treatment sessions ranged from 1 to 4, with 4 weeks being the average interval between sessions. Follow-up periods ranged from 3 months to 1 year.

Results: All study centers reported improvements in all patients, ranging from subtle to excellent, with the large majority of the results being more towards the excellent than the subtle. Patient assessments coincided well with the clinicians' findings. Results immediately after the final session were noted to continue to improve with the length of the follow-up period due to collagenesis, stimulated by the dermal deposition of electrothermal damage, being followed by matrix remodeling. All centers reported transient side effects after treatment, with mild edema lasting for around 24-48 hr and erythema lasting from 3-6 days. Mild crusting formed in some patients following pin-point bleeding, but resolved spontaneously in 3-5 days. Patients were extremely happy with the comparative lack of downtime required. Intra-treatment discomfort varied from very mild to moderate, but no patient in any of the centers failed to continue with their treatment program. Mild secondary hyperpigmentation was noted in 5 patients from the Italian center (2.3%) which was controlled completely with hydroquinone, but no serious side effect was reported by any center.

Conclusions: MRF with the INFINI system was effective and safe in the treatment of facial wrinkles in all Fitzpatrick skin types examined from I to V, with no secondary hyperpigmentation seen in the darker Asian

skin types particularly notable in the Indian center with skin types IV to V. The results obtained after the final treatment session continued to improve over time, and patient satisfaction with the procedure was very high with excellent compliance.

INTRODUCTION

The improvement of photoaged skin, especially the removal of wrinkles, has historically posed problems for dermatological aesthetic clinics. Full face ablative laser resurfacing appeared in the early 1990's with CO₂, Er:YAG or combinations of the two wavelengths. Nonablative treatment with a variety of visible and near-infrared laser and intense pulsed light was next proposed, but patient satisfaction tended to be very poor. The next step was nonablative fractional laser technology delivering micronecrotic columns (MNCs) surrounded by normal skin, using Er:Glass lasers. It was still not aggressive enough for the more severely photoaged skin and scarring, however, so ablative fractional laser resurfacing was proposed with the CO₂ and then the Er:YAG lasers, delivering microablative columns (MACs) rather than MNCs, and the wheel has turned back towards ablative laser resurfacing. Radiofrequency (RF) technology for wrinkle reduction was first developed in the early 2000s, but with mixed results. The INFINI system represents the culmination of many years of research into optimum RF delivery.

In the 'monopolar' approach, the delivery electrode is the handpiece, and the large return electrode is fixed elsewhere on the body. Tissue has inherent resistance to an electric current, or impedance. Following Joule's law, when an electric current meets resistance it generates heat as electrothermal reaction. When the temperature is high enough, over around 65°C, tissue is coagulated. This is the basic principle of RF treatment, with the target damage being electrothermal rather than photothermal, as would be the case with laser or IPL energy.

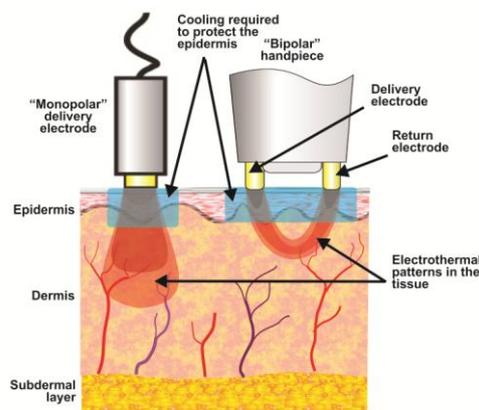


Fig 1: So-called 'unipolar' and 'bipolar' RF effects in tissue shown schematically. The return electrode for the unipolar handpiece is not shown, but would be attached elsewhere on the patient's body.

In the case of so-called ‘bipolar’ RF, both the delivery and return electrodes are incorporated in the handpiece. When the system is activated, the current flows between the handpieces in a kind of ‘U’ shape, the depth of the base of the ‘U’ being limited to one-half of the distance between the electrodes. These approaches are illustrated in Fig 1. In both approaches, as the RF electrodes are associated with hot spots there would be severe electrothermal damage to the epidermis, resulting in burn injuries, and therefore these approaches required aggressive skin cooling to protect the epidermis while allowing electrothermal damage to be created in the dermis. The major problem with these approaches to RF treatment was the limited depth of electrothermal damage into the dermis, limited by the power level in the monopolar and the distance between the electrodes in the bipolar approach. Multiple treatments were necessary, or the power level had to be so high the process was extremely painful.

The concept of using needles as the electrodes allowed the RF energy to be delivered into the dermis was proposed in a pilot study by Hantash and colleagues in 2009, and that was the genesis of microneedling RF. Since the RF energy was fractionated among several delivery and return needles, the terminology became ‘microneedling fractional RF’, MFR in the case of the INFINI. When the shafts of the needles are not insulated, the needles, as electrodes, are active all the way from the epidermis to the needle tips. This necessitated epidermal cooling to protect the epidermis from electrothermal damage, and led to designs incorporating insulation of the needle shaft, restricting RF energy delivery to the very tip of the needle such as in the case of the INFINI system. No epidermal cooling is required in this case (Fig 2), but simple physical needling damage to the epidermis occurs, thereby stimulating regeneration of a young epidermis over the restructured dermis.

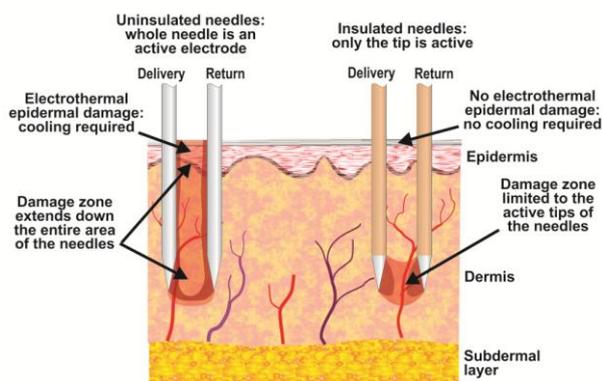


Fig 2: The electrothermal damage pattern compared schematically between uninsulated and insulated needles. With uninsulated needles, epidermal cooling is required to protect the epidermis from electrothermal damage. This is not the case for insulated needles, where epidermal damage is limited to mechanical needling.

Refinement of the microneedling RF principle as embodied in the INFINI system led to the incorporation of user preset needle depths, adjusted with a control

wheel on the system handpiece; and independently variable power levels and exposure times, so that a high power level could be balanced against a short exposure time, and vice versa. Further refinements included a lightweight and ergonomic handpiece to help eliminate user fatigue, and single-use tips with the unique flow needling mechanism whereby the ultrafine 200 µm needles are not inserted all at once into the skin, but are smoothly inserted in rows extremely rapidly then swiftly withdrawn, thereby avoiding the bounce effect and giving more natural stretching of the skin. The present multicenter study was designed to assess the efficacy of the INFINI system for wrinkle treatment in a variety of Fitzpatrick skin types.

INFINI Microneedling: Principles, Mode of Action and Experimental Confirmation

The INFINI microneedle fractional RF (MFR) handpiece tip offers two replaceable single use tips: the 49 needle tip (10 mm x 10 mm, 7 x 7 needles) and the 16 needle tip (5 mm x 5 mm, 4 x 4 needles) the former being



Fig 3: INFINI MFR 49 needle tip.

shown in Fig 3. The microneedles are made from surgical stainless steel, coated with gold for conductivity and then double coated with an insulating silicon compound, except for the first 300 µm of the tip. The needles have a diameter of 200 µm and a point diameter of 20 µm. The insulation of the needle shaft means that the active area of the microneedle electrodes is restricted to the tip, and there is no electrothermal damage delivered to the epidermis (Fig 4,5).

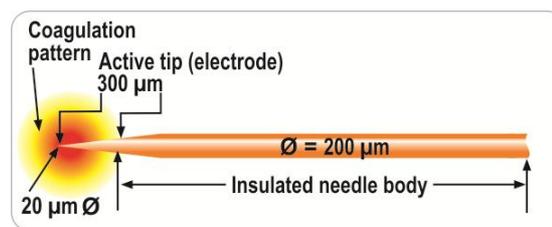


Fig 4: Microneedle characteristics.

Before trials in animal models or human subjects, a skin phantom was devised from saline gel, and experimental needling of the phantom was carried out at the VU Medisch Centrum, Amsterdam, Holland, to test the electrothermal characteristics of the microneedles. RF electrothermal distribution activity from the MFR tips was recorded using high-speed fine plate thermography with Schlieren imaging. Schlieren are optical inhomogeneities in transparent material not visible to the human eye, and in this case were representing electrothermally mediated changes in the skin phantom material. Two different preset needle depths (1.5 mm and 3.5 mm) were compared over a range of power levels and exposure times.

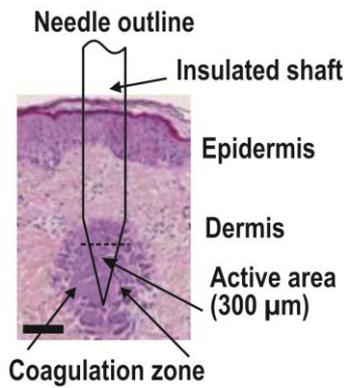


Fig 5: Schematic showing a microneedle (drawn to scale) and 'inserted' in skin (micropig) with an actual zone of coagulation from a real needle. The discrete damage zone is shown at the active tip of the microneedle electrode with no electrothermal damage to the epidermis. (Hematoxylin & eosin, scale bar 200 μm).

The thermography images demonstrated a true fractionation of the energy with the electrothermal effect limited to the very tip of the microneedles, and no damage to the skin phantom material in between the needles, representing undamaged normal epidermis and dermis in actual skin. Fig 6 shows a set of representative Schlieren filtered images for the 3.5 mm depth setting, power level 8 and exposure times as shown. From the results, the needle tracks in the phantom were very clear with good separation, and the thermal effect in the phantom material was very clearly limited to the very tips of the needles, with no thermal blooming seen anywhere else in contact with the shaft especially where the needles entered the phantom, representing the epidermal layer.

Micropigs were used for the next set of experiments, as micropig skin is recognized as a good model for human skin. The animals were handled ethically and humanely and in accordance with the regulations as in the National Research Council's Guide for the Care and Use of

Laboratory Animals (2011). The experiment was performed in a dedicated and accredited animal laboratory (Medi-Kinetics Korea) and all histological specimens were prepared independently in the Clinical Research Center, Yonsei University Severance Hospital (Seoul). Fig 7 shows a set of typical histological specimens illustrating the discrete and fairly consistent areas of coagulation obtained at different needle depths, with the exposure time (100 ms) and power level (4) kept constant. Of some importance is the potential epidermal damage seen at the shallowest setting of 0.5 mm (panel at the far left of the figure). This illustrates the importance of the Lutronic recommendation that the power level and/or exposure times must be reduced as the needle depth is decreased.

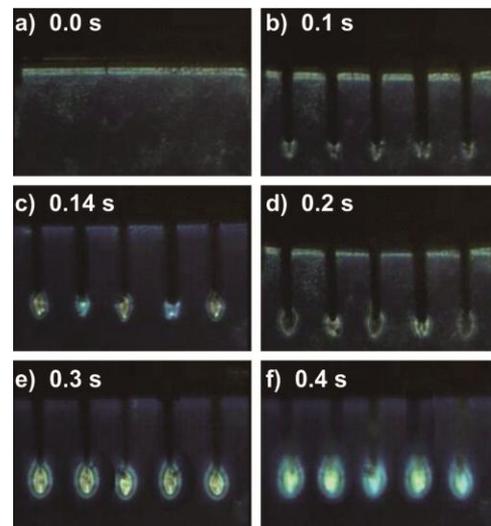


Fig 6: Needle tracks and thermal distribution of RF energy in the skin phantom model for the 3.5 mm depth at power level 8 and with exposure times as shown (in seconds). Images were captured immediately after withdrawal of the microneedles.

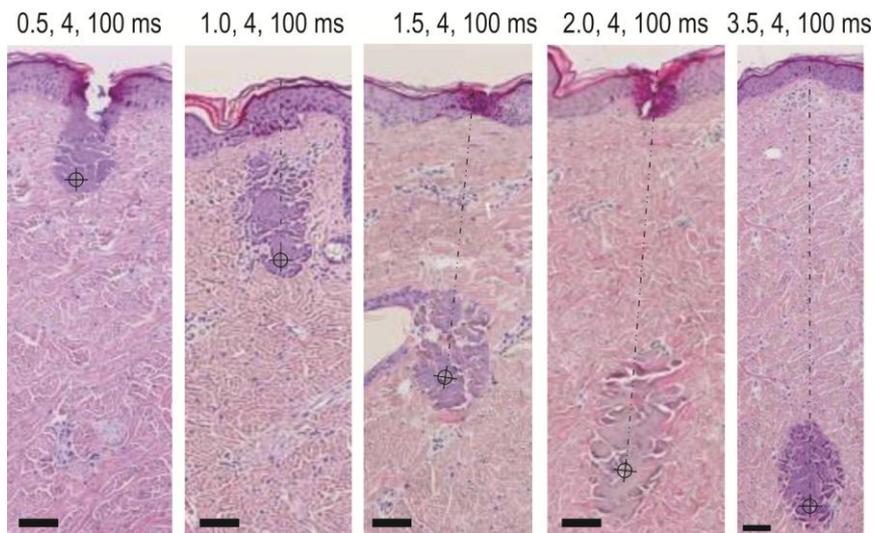


Fig 7: Needle depths of from 0.5 mm to 2.0 mm are illustrated at a constant power level of 4 and an exposure time of 100 ms. Space bar = 200 μm for all, but note that the 3.5 mm depth specimen is at a smaller final magnification to fit the photomicrograph into the figure with the others.

Comparative Characteristics between INFINI and Other Similar Devices

There are some differences in design and parameters between the INFINI and other similar devices, but INFINI has been demonstrated to deliver safe and effective delivery of fractionated RF energy, and in fact the different characteristics could be argued as benefiting patients treated with INFINI.

Needle Diameter: The microneedles of the INFINI MFR tip are thinner than those of some other devices, being 200 μm in diameter. The finer the needle, the less discomfort for the patient as the needle penetrates the target tissue. Thicker needles cause more pain as the physical resistance of the tissue to the needle increases with its diameter. The thinner needles of the INFINI have adequate guidance and support through the design of the tip configuration, ensuring the needles smoothly penetrate the skin without bending. INFINI's finer microneedles are therefore associated with accurate needling combined with increased patient comfort.

Difference in Parameter Range: The INFINI has a maximum power of 50 W at level 20, almost double the maximum power of many other systems. On the other hand, there is a large range of exposure times from the very short 10 ms (0.01 s) to 1000 ms (1 s), so that higher power levels can be balanced by and compensated with short exposure times. More control over tissue damage can be achieved by changing the exposure time than by altering the power level. Although the maximum power level is higher than many other devices, the large range of exposure times, in particular the shorter ones, enables the user to apply safe and consistent levels of coagulation in the dermis to achieve the desired clinical effect.

Needle Depth in the Dermis: The INFINI has a range of needle depths in the dermis, which are preset by the user, from 0.5 mm to 3.5 mm. This ability to set multiple needle depths per pass is an advantage, allowing discrete electrothermal coagulation at different layers of the dermis, while the insulated needles prevent electrothermal damage from occurring anywhere in the dermis but at the very tip of the needle, and never in the epidermis.

Trial Centers and Patient Populations

Five geographically separate centers were selected for the present study (alphabetically, by country): India (Dr. Satish Savant), Italy (Dr. Franco Lauro), Korea (Dr. Boncheol Leo Goo), Poland (Dr. Adam Wronski), and Turkey (Dr. Devrim Gursoy). In the case of the Korean and Polish centers, the patients reported herein formed part of a formal trial, and as such all procedures were conducted with the approval of the respective IRB and

Ethics Committee, and all patients gave written informed consent regarding their participation in the trial and for the use of their clinical photography. In all other centers, the population shown was the total number of patients treated over a given period, but in all cases, having had the treatment, potential results and possible side effects explained to them, patients were not able to receive INFINI treatment without giving written informed consent for the treatment and for the use of their clinical photography. The total number of patients was 499, 419 females and 80 males, ages ranging from 35-72 yr., average age 52.6 yr. Table 1 shows the breakdown of patients by national center.

Table 1: Total patient population broken down by study center.

Center	Gender		Age (Years)	
	Female	Male	Range	Mean
India	117	38	35-58	48
Italy	195	25	35-65	52
Korea	16	3	38-55	49
Poland	13	2	40-66	56
Turkey	78	12	42-72	58
Totals	419	80	–	–

INFINI MFR Method

The general method of application of the INFINI MFR system was the same for all centers. After thorough cleaning of the face, topical anesthetic cream was evenly applied over the face and covered with a polyethylene film in the occlusive dressing technique. Occlusion was from 20 min to 45 min, depending on the severity of the condition to be treated. The occlusive dressing was removed and remaining anesthetic cream was carefully cleaned from the face with alcohol wipes. The needle depth was set for the first pass (individual parameters from the contributing clinicians are covered in detail in the next subsection, but the 7 x 7 49 needle tip was used in all centers), and the power level and exposure time set. The first pass was then carried out at the chosen settings, covering the entire target area with careful abutment of the tip and no overlapping. Any pinpoint bleeding was controlled with pressure or an epinephrine solution and the face wiped clean. The subsequent passes depended on the individual clinician, either a repeated full face pass at lower parameters, or a partial pass concentrating on wrinkles, especially for milder wrinkles, and repeated as required by each clinician's protocol, discussed below. In general, as the needle depth decreased, the power level and exposure times were also reduced to avoid damage to the epidermis from conducted heat when the tip of the needle was set at shallower depths.

Table 2: Summary of the normal treatment regimen and parameters shown by study center.

Center	Passes/Session	Treatment parameters			No of sessions (average)	Inter-Tx interval
		Depth (mm)*	Level*	Exposure time (ms)*		
India	Usually 1	0.5 – 3.0	8 – 12	50 – 150	2 – 4 (2.9)	4 weeks
Italy	Usually 1	0.5 – 2.5	4-5	150	1 – 3 (2.1)	8 weeks
Korea	2 – 3	0.5 – 2.5	4 – 7	80 - 120	2 – 3 (2.7)	2 – 4 weeks
		0.5 – 1.5	3 – 5	60 - 80		
		0.5	3	50		
Poland	3	0.5 – 2.5	4 – 9	20 – 100	4 – 6 (5.1)	2 – 4 weeks
		0.5 – 1.5	4 – 7	20 – 80		
		0.5 – 1.0	4 – 6	20 - 40		
Turkey	2 passes** (fine wrinkles)	0.5 – 2	8 – 12	60 – 100	1 – 3 (2.7)	2-3 weeks
	3 (Others)	0.5 – 3	4 – 12	40 – 120		
		1	14	50		

* The parameter ranges used in the study centers..

** Second pass over wrinkles only

When INFINI treatment was complete, the face was cleaned after control of any pinpoint bleeding and a cooling pack or mask, or some form of forced air cooling was used for patient comfort and to control erythema and edema. Some clinicians then applied LED phototherapy. An antibiotic ointment was finally applied, with or without a mild steroid depending on the clinician’s approach. Patients were then given post-care instructions including the follow-up regimen and returned home or to work. The recommended interval between treatments was at least 2 weeks, and varied by clinician. Immediately post-treatment erythema was relatively mild, and tended to be more pronounced on the day after the procedure.

Treatment Regimens

The treatment regimens varied quite extensively depending on the clinic concerned. Needle depths ranged from 0.5 mm to 3 mm, depending on the anatomical site and pass number. Power levels ranged from 4 to 12 depending mostly on needle depth but also site. Exposure times ranged from 20 ms to 200 ms.

Results

The results from all centers were overall very good to excellent, ranging from mild improvement to excellent in even severe wrinkles. All centers followed the same scoring protocols. Clinician assessment of improvement was based on the clinical photography, determined by two independent and experienced dermatologists per center. Scoring was on a 5-part scale as follows: Little or no improvement, 0%-15%; Some improvement, 16%-50%; Fair, 51%-65%; Good, 66%-85%; and Excellent, 86%-100%. The numbers of patients scoring Good and Excellent were then added and expressed as a percentage

of the total patient number to give overall efficacy (O/A). Patient satisfaction was on a 5-point scale as follows: 1, extremely dissatisfied with very little or no improvement; 2, somewhat dissatisfied with little improvement; 3, somewhat satisfied, with some improvement; 4, satisfied, with marked improvement; and 5, highly satisfied with excellent improvement. The numbers of patients scoring 4 and 5 were then added and expressed as a percentage of the total patient number to give patient satisfaction index (SI). Patients were also asked if they would choose this treatment again if necessary (definitely would not [-], uncertain [- / +], probably [+ / -], definitely would [+]). Clinician-assessed overall efficacy and patient satisfaction index were similar at from 80.7% to 88.9 % and 81.3% to 85.9%. The majority of patients in all 5 centers would probably or definitely return for retreatment when needed.

As for side effects, mild edema was reported for 12-48 hours and erythema from 3-5 days. No persistent erythema was reported by any of the center clinicians. The only cases of secondary hyperpigmentation were reported from the Italian center in 5 out of their 220 patients in the early days of INFINI treatment, and that was rapidly controlled with hydroquinone. Patient compliance was excellent, based on the improvement seen by patients 2 to 4 weeks after their first treatment, improving with subsequent sessions in those centers whose regimen involved several sessions. All clinicians reported continued improvement for 3-5 months after the final treatment, due to the remodeling of the new collagen induced by the selective dermal damage. Figures 8-12 show representative examples from each center.

Clinicians’ Opinions

Specific comments from the center clinicians are as follows.

Dr. Savant (India, 155 patients)

- Good Results: Clinician Overall Improvement (OI), 80.7%; Patient Satisfaction Index (SI), 81.3%
- Particularly impressed with the lack of secondary hyperpigmentation in dark Indian type IV-V skin
- 2-3 sessions, usually 1 pass/session
- Remarkable degree of neocollagenesis compared with other laser-and light-based systems

“The more I use INFINI, the more impressed I am with its ability to deliver good and lasting results in the darker Indian skin types. Although the ability to deliver precise electrothermal damage to the dermis in a multilayer approach is an excellent advantage, I believe that the efficacy of the system hinges on the microneedling of the epidermis without electrothermal damage, giving stimulation of the basal layer keratinocytes and inducing the synthesis of cytokines and growth factors. I feel that the pinpoint bleeding is not at all a problem, but it is rather another possible means to enhance wound healing and collagenesis through the distribution of platelet-associated growth factor release throughout all skin layers.”

Dr. Lauro (Italy, 220 patients, largest patient population)

- Good Results: Clinician OI, 82.7%; Patient SI, 81.8%
- Especially impressed with the superior results in the neck
- Greatest improvement seen in areas with less fat
- Uses a single pass per session (little difference in results between a single pass at his parameters and multiple passes): usually changes only the needle depth for the different anatomical zones
- Two sessions are usually enough but a few patients benefit from a third session
- Uses LED phototherapy (HEALITE II, Lutronic) as a matter of course immediately post-treatment (ameliorates the side effects and improves the overall result)

“I am extremely happy with INFINI, and so are my patients. I like the ease of use, and I call it my ‘Elixir of Youth’. In particular, I can get results which are far superior to any other system I have tried.”

Dr. Goo (Korea, 19 patients, formal in-house study)

- Good Results: Clinician Overall Improvement (OI), 80.7%; Patient Satisfaction Index (SI), 81.3%
- One of the first doctors to use INFINI
- Very Good results (Clinician OI, 89%, Patient SI, 86%)
- Objective assessments: wrinkle size/depth, 36%/29%
- Greatest improvement in areas of least fat deposits
- Uses multiple passes (2-3) depending on the severity of the condition
- 2-3 sessions

- Always applies LED phototherapy (HEALITE II, Lutronic) immediately post-treatment

“I am impressed with the ease of use of the system, in particular the ease with which needle depths is precisely user-set. Taken together with the unique ability to balance the power level and exposure settings to give exactly the volume of coagulation I want to achieve, this allows me to deliver true three-dimensional effect with high patient satisfaction. The ability to work in our darker Korean skin types without inducing secondary hyperpigmentation is an added and important advantage.”

Dr. Wronski (Poland, 16 patients, formal in-house study)

- Good results (Clinician OI, 80%; Patient SI, 80%)
- Greatest improvement in areas with least fat
- Objective assessment gave over 30% improvement in wrinkle length/depth (significant, $P < 0.01$)
- Continued improvement noted for some months after final treatment
- Low settings over several sessions (4-6) gave almost the same results as high settings over fewer settings (2-3)

“The flow needling technology combined with the insulated needle MFR definitely makes INFINI less painful for the patients compared with other needle- and needleless-based RF systems, and the ability to preset treatment depth is a powerful advantage. I was impressed with the good results in my study, especially those measured objectively with machine systems.”

Dr. Gursoy (Turkey, 90 patients)

- Very good results (Clinician OI, 88.9%; Patient SI, 85.9%)
- Able to use INFINI even in darker Turkish skin, and also in tanned skin, common in Turkish patients due to high terrestrial UV levels
- Despite fairly aggressive parameters (uses maximum possible parameters mediated by patient pain tolerance), no cases of secondary hyperpigmentation seen or prolonged erythema.
- Patient compliance excellent due to good results seen early in the regimen
- INFINI excellent as monotherapy, but could be even better in combination with other approaches

“This is a unique RF system delivering really effective wrinkles in severely photoaged skin caused by harsh Turkish solar UV levels. Patients see good results early on, but these continue to improve for some months after the final treatment session. The handpiece is well-designed, and I can treat all day without my hand and arm getting tired.”



Fig 8: Nasolabial and melomental folds at baseline and 6 months after final treatment session in a 46-year-old Indian female. Three sessions, one pass per session: 3 mm, 10, 100 ms. (Courtesy Satish Savant MD)



Fig 9: Perioral wrinkles at baseline and 4 months after one single session in a 48-year-old Italian female. One pass, 2.5 mm, 5, 150 ms. (Courtesy Franco Lauro MD)



Fig 10: Crow's feet lines and glabellar wrinkles in a 45 year-old Korean female at baseline and after 2 sessions, 2 passes per session. Glabella: 2.5 mm, 6, 100 ms; 2 mm, 4, 100 ms. Periocular: 1.5 mm, 4, 100 ms; 1 mm, 3, 50 ms. (Courtesy BC Leo Goo MD)

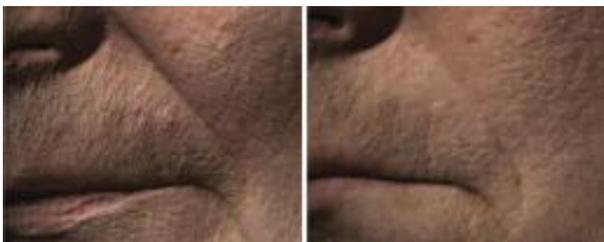


Fig 11: Perioral wrinkles in a 53-year-old Polish female at baseline and 3 months after the final session. Three passes per session: 2.5 mm, 7, 80 ms; 1.5 mm, 6, 60 ms; 0.5 mm, 5, 30 ms. (Courtesy Adam Wronski MD)



Fig 12: Wrinkles of the cheek at baseline and 4 months after the final treatment session in a 65-year-old Turkish female. Three sessions, 3 passes per session. Parameters per pass: 3.0 mm, 10, 120 ms; 2.0 mm, 12, 80 ms; 1 mm, 14, 50 ms. Note the balance between the high power level and short exposure time for the third pass. (Courtesy Devrim Gursoy MD)

Conclusions

The INFINI fractional microneedling RF system was used in 5 geographically distant clinics in 499 patients of Fitzpatrick skin types I – V for the treatment of a variety of wrinkles. Patient downtime was minimal, and patient satisfaction was high with improvement seen early after the first treatment session, and continued improvement being noted for some months after the final session. Edema and erythema were transient, with no prolonged erythema reported by any of the participating clinicians. Post inflammatory hyperpigmentation was seen in only 5 of the 499 patients, and was quickly controlled with hydroquinone. No scarring was reported by any participating clinician. All clinicians were extremely satisfied with the safety and efficacy of the INFINI system. In conclusion, the INFINI MFR approach is safe and effective for the treatment of wrinkles in all skin types .