Surgical Outcome in Patients Taking Concomitant or Recent Intake of Oral Isotretinoin: A Multicentric Study-ISO-AIMS Study

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ABSTRACT

Background: The current standard recommendation is to avoid surgical interventions in patients taking oral isotretinoin. However, this recommendation has been questioned in several recent publications. **Aim:** To document the safety of cosmetic and surgical interventions, among patients receiving or recently received oral isotretinoin. **Materials and Methods:** Association of Cutaneous Surgeons, India, in May 2012, initiated this study, at 11 centers in different parts of India. The data of 183 cases were collected monthly, from June 2012 to May 2013. Of these 61 patients had stopped oral isotretinoin before surgery and 122 were concomitantly taking oral isotretinoin during the study period. In these 183 patients, a total of 504 interventions were performed. These included[1] 246 sessions of chemical peels such as glycolic acid, salicylic acid, trichloroacetic acid, and combination peels;[2] 158 sessions of lasers such as ablative fractional laser resurfacing with erbium-doped yttrium aluminum garnet and CO_2, conventional full face CO_2 laser resurfacing, laser-assisted hair reduction with long-pulsed neodymium-doped yttrium aluminum garnet, diode laser, and LASIK surgery;[3] 27 sessions of cold steel surgeries such as microneedling, skin biopsy, subcision, punch elevation of scars, excision of skin lesion, and wisdom tooth extraction;[4] 1 session of electrosurgery. **Results:** No significant side effects were noted in most patients. 2 cases of keloid were documented which amounted to 0.4% of side effects in 504 interventions, with a significant *P* value of 0.000. Reversible transient side effects were erythema in 10 interventions and hyperpigmentation in 15. **Conclusion:** The study showed that performing dermatosurgical and laser procedures in patients receiving or recently received isotretinoin is safe, and the current guidelines of avoiding dermatosurgical and laser interventions in such patients taking isotretinoin need to be revised.

KEYWORDS: Guidelines, hypertrophic scar, isotretinoin, keloid, side effects

INTRODUCTION

Oral isotretinoin has been in use since 1982, for "severe, nodulocystic acne, refractory to treatment, including oral antibiotics" and since 2000 with expanded indication to include acne which causes physical scarring and psychological impact.[1] With this expanded recommendation, nearly 1.2 million prescriptions were

Access this article online

Quick Response Code:

Website: www.jcasonline.com

DOI: 10.4103/0974-2077.184054

How to cite this article: Mahadevappa OH, Mysore V, Viswanath V, Thurakkal S, Majid I, Talwar S, *et al.* Surgical outcome in patients taking concomitant or recent intake of oral isotretinoin: A multicentric Study-ISO-AIMS study. J Cutan Aesthet Surg 2016;9:106-12.

captured from December 2005 to February 2011, through PLEDGE Registry in the US.[2]

Even though the benefits outweigh the risks, isotretinoin has its share of side effects. Of all the side effects, three are significant and subject to much debate-depression and suicidal ideation,[3,4] inflammatory bowel disease,[5] and finally hypertrophic scar and keloid formation.[6]

Of the above, the hypertrophic scar and keloid formation are the focus of this paper. The present established standard preoperative surgical care, so far advises the stoppage of oral isotretinoin 6–12 months before any dermatosurgery.[7] This was based on the early reports of keloids or delayed wound healing, in patients on isotretinoin during surgery documented in 1980's.[8,9] Surprisingly, this recommendation stemmed from 9 cases reported from different authors.

However in 1985, Roenigk *et al*. had performed dermabrasion in nine patients on isotretinoin and reported normal "initial" skin healing.[10] However, despite this observation, for nearly two decades, stopping oral isotretinoin before dermatosurgery was the medico-legal standard practice, unchallenged.

Between 2004 and 2012, a few case series and prospective studies were published documenting the safety of dermatosurgery and laser therapy in patients on oral isotretinoin. These included laser hair removal with diode laser,[11,12] long-pulsed neodymium-doped yttrium aluminum garnet (Nd: YAG) laser,[13] diamond fraise dermabrasion,[14] and chemabrasion.[15] The data are summarized the Table 1. However the studies were small and not significant enough to alter the recommended guideline, and larger studies were needed. The recommendation however put restrictions on physicians while performing procedures in these patients as it would have medicolegal implications and also often denied the right treatment to them.

In view of this, to establish proper evidence for a change in the guidelines and facilitate evidence-based practice, in 2012, the Association of Cutaneous Surgeons India, ACS (I) proposed to start a multicentric study to establish the safety of procedures in such patients. The study was named as per acronym ISO-AIMS study which stood for "Isotretinoin and Surgical Outcome: ACS (I) Multicentric Study." 11 investigators from across India took part in the multicentric trial [Figure 1].

MATERIALS AND METHODS

The study was prospective, interventional, and nonblinded in nature. The scope of the study is shown in Table 2.

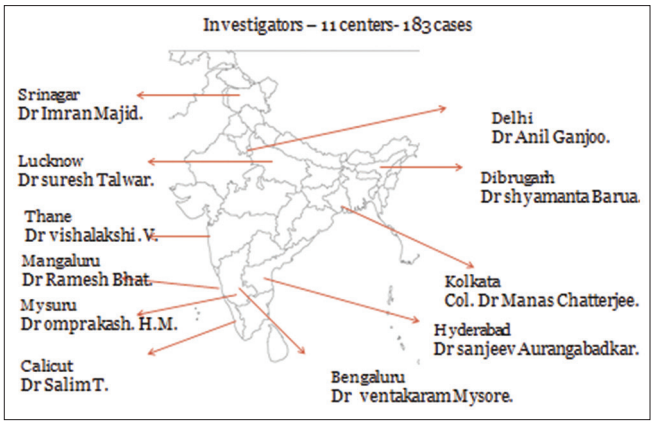


Figure 1: Centers participating in the multicentric trial

A total of 183 cases were enrolled across 11 centers. The age, sex, and Fitzpatrick skin types are shown in Table 3. The indications for oral isotretinoin are shown in Table 4. Of these patients, 61 had stopped oral isotretinoin intake before surgical intervention and 122 were taking concomitantly isotretinoin during surgical intervention. Dosage range was 2–110 mg/kg (180–9160 mg) [Table 5].

In the 183 cases, a total of 504 interventions were performed as shown in [Table 6]. The devices and parameters used are shown in Table 7. The data were statistically analyzed using descriptive statistics, contingency coefficient test, and Chi-square test.

Of the 183 cases, 82 cases (44.8%) were of skin type IV, and 72 cases (39.3%) were of skin type V. Furthermore, significant was 122 (66.66%) cases were on concomitant oral isotretinoin. The skin type, age group, and indication for isotretinoin had a significant $P < 0.000$ except the gender distribution.

Of the interventions, chemical peel – 246 sessions (48.9%) – was the most common performed, followed by different lasers – 184 sessions (37.6%).

RESULTS

Two sets of adverse events were documented [Table 8]. Keloid formation was noted in 2 cases. The second set of adverse events was were transient like-erythema, pigmentation, acne, and hemorrhage. However, 93.8% cases did not have any adverse events.

Laser-diode/long-pulsed Nd: YAG or IPL-assisted hair reduction and acne therapy totaling 38 sessions had no adverse outcome. Salicylic acid peel performed in 30 sessions was without side effects. Microdermabrasion, 44 sessions was also safe. 8 skin biopsies also were safe. One wisdom tooth extraction healed well, despite patient

Table 1: Oral isotretinoin intake and scarring postintervention - review of literature

Year of publication	Journal	Purpose of publication	Number of patients treated	Oral isotretinoin	Skin type	History of hypertrophic scar present	Duration of follow-up	Site of dermabrasion/ laser	Pre- and post-operative complications	Limitations of study
1985[10]	J Dermatol Surg Oncol; 11:396-8	Acne, retinoids, and dermabrasion	9	Concomitant isotretinoin	?		9 days	Rhinophyma dermabrasion	No complications	Case series
1986[8]	J Am Acad Dermatol; 15 (2 Pt 1):280-5	Dermabrasion on face	3	Patients on isotretinoin during dermabrasion started almost 4-14 months duration before intervention	?		1-3 months	Face	1-3 months noted keloids on the face. Resolved in 2 patients with interventions	Case report
1988[9]	Br J Dermatol; 118:703-6	Delayed wound healing and keloid formation following argon laser therapy or dermabrasion	Patient1 Patient 2 Patient 3	On isotretinoin concomitant Concomitant oral isotretinoin Postprocedure oral isotretinoin	?	Yes Yes	8 months 6 months 2 months	Face, argon laser for rosacea Traumatic scar Rhinophyma dermabraded	Delayed scarring Delayed scarring	Case report
2004[11]	Dermatol Surg. 30:1205-7	Diode hair reduction in patients on oral isotretinoin	7	Concomitant 63 mg/day isotretinoin mean of 4 months duration	II-III		1 month	Axilla and bikini hair reduction	One patient had blister, by week 1, which resolved	Case series
2005[12]	Dermatol Surg. 31:380-1	Diode hair reduction and oral isotretinoin	6	Concomitant	II-III		4 years	Facial hair reduction	Erythema immediate, crusting which resolved in few days	Case series
2009[13]	J Cosmet Laser Ther 2009;11:56-60	Long- pulsed Nd: YAG laser reduction in patients taking oral isotretinoin, concomitantly	11	Concomitant, but stopped during the laser therapy day	III-V	No	12 weeks postlaser	Face and extrafacial site hair reduction	No adverse events	Retrospective case series
2010[14]	Dermatol Surg 2010;36:483-9	Outcome of diamond fraise dermabrasion in patients taking oral isotretinoin	7	On the drug during intervention	I-VI	Yes in one patient	6 months postsurgery	Face	Nil in all and even in the case with history of hypertrophic scarring	Interventional type. No control group
2012[15]	Dermatol Surg 2012;38:1521-6	Outcome after chemabrasion, in patients who had stopped isotretinoin	10	Stopped isotretinoin 3 months prior	II-V	Yes is 3 patients	6 months postsurgery	Face	No hypertrophic scarring	Interventional prospective study

being on isotretinoin. The wisdom tooth extraction outcome in our study concurs with the currently documented experience in literature of 26 cases, which is safe.[16]

Of the other procedures carried out – in glycolic peel [Figure 2], of 147 cases, 6 had erythema. All had one coat of peel applied. One case on Refinity 70% buffered glycolic peel, had immediate erythema which started with in a minute, which was neutralized and resolved without sequelae (manufacturer recommended contact time 4–10 min). The second case of glycolic acid peel had erythema which resolved only with tacrolimus ointment 0.01% by 2 weeks. The third case had facial keloid formation at the site of glycolic acid application [Figure 3] and interestingly developed keloid later on truncal zone too (cumulative dose in this case - 2100 mg of isotretinoin). This was managed by intralesional steroids. In other procedures, 2 cases of combination peel developed erythema lasting for 5 days.

In the ablative fractional erbium-doped yttrium aluminum garnet (Er: YAG) series, one had postinflammatory

Table 2: Scope of study

The trial is prospective in nature.
The investigators are ACS (I) members
The investigator can enroll any number of patients
Informed consent to be taken as appropriate either to start oral isotretinoin and later to do dermatosurgery and publish the images in journal
Ethical committee clearance as appropriate can be taken by the investigator
The scope of dermatosurgery encompasses
Chemical peels: Superficial or deep with any alpha or beta hydroxy acids
Laser resurfacing: Conventional and fractional
Microdermabrasion: First and second degree
Laser-assisted hair reduction
Cold steel surgeries such as punch excision of acne scars, skin biopsies for coincidental skin pathologies
The timing of dermatosurgery could be during oral isotretinoin intake or after stopping the same
Pro forma for collection of data is given [Appendix 1]
The study period is for 1 year - June 2012 to May 2013
Kindly keep us updated about the number of cases enrolled on the first of every month, online. If no cases have been enrolled - "Nil" enrolled should be communicated
The data collected could be periodically called for, online, to update, our central database

pigmentation, which resolved in 3 weeks. The second case of fractional Er: YAG laser had prolonged redness requiring topical steroids for 2 weeks. The third case in this intervention had a flare of acne treated with adapalene 0.1% gel night daily.

Interestingly, a case with acne vulgaris with a history of keloid on the trunk, who was on isotretinoin, did not develop keloid on the face when fractional Er: YAG laser was used to treat scar on the face [Figure 4].

Conventional ablative CO_2 laser resurfacing was done in 19 cases on face. Of these 14 cases developed post inflammatory hyperpigmentation, which resolved with sunscreen and hydroquinone by 3 months. However, none developed keloid or delayed wound healing.

The only microneedling case enrolled and subjected to 7 sessions of therapy had pigmentation which resolved.

A single case of acne vulgaris with nevus of Hori underwent 4 sessions with Q-switched Nd: YAG laser had erythema twice posttherapy which lasted for few minutes and resolved.

Subconjunctival hemorrhage post-LASIK surgery (laser-assisted *in situ* keratomileusis) in a case resolved without permanent sequelae. It is known that isotretinoin causes corneal xerosis, so does LASIK surgery. LASIK surgery is contraindicated during isotretinoin. A gap of 6 months has been advocated before surgery. Furthermore, post-LASIK, isotretinoin should not be prescribed for nearly 6 months.[17]

Table 3: Patient profile

Investigator ASC (I) code	Total cases	10-20 years		21-30 years		31-40 years		>40 years		Total cases		Skin types-Fitzpatrick type				
		Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	II	III	IV	V	VI
1	37		1	20	3	7	0	3	3	30	7		5	12	18	2
2	9			2	6		1			2	7			3	6	
3	7	1		3	3					4	3		1	4	2	
4	6			4	2					4	2			2	4	
5	29	2	2	5	12	2	2	2	2	11	18			9	20	
6	17	2	2	5	6		2			7	10	2	3	10	2	
7	14			1	12		1			1	13		9	5		
8	9			3	6					3	6		2	6	1	
9	9	2	2	3	2					5	4		3	3	3	
10	11		1	3	4	1	2			4	7		2	7	2	
11	35	4	11	7	11	1	1			11	24			26	9	
Total	183	11	19	56	67	11	9	5	5	84	99	2	25	82	72	2
Percentage		22.4	22.4	61.2	61.2	10.9	10.9	5.5	5.5	45.9	54.1	1.1	13.7	44.8	39.3	1.1
Chi-square test		138.858	138.858	138.858	138.858	138.585	138.858	138.858	138.58	1.230	1.230	159.650	159.650	159.650	159.650	159.650
P		0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.268	0.268	0.000	0.000	0.000	0.000	0.000

Table 4: Oral isotretinoin indications data

Investigator ASC (I) code	Total cases	Acne vulgaris	Rosacea	Seborrheic dermatitis	Hidradenitis suppurativa/ acne inversa	Acne nuchae
1	37	29	4	3	1	
2	9	9				
3	7	7				
4	6	6				
5	29	25	1		1	2
6	17	17				
7	14	14				
8	9	9				
9	9	9				
10	11	11				
11	35	35				
Total	183	171	5	3	2	2
Percentage		93.4	2.7	1.6	1.1	1.1
χ^2		617.052	617.052	617.052	617.052	617.052
P		0.000	0.000	0.000	0.000	0.000

Table 5: Isotretinoin - cumulative dosage and usage profile

Investigator - ACS (I) code	Total cases	Isotretinoin before	Isotretinoin during	Dosage range (mg/kg)	Cumulative dose range (mg/kg)
1	37	18	19	10-40 - daily	40-70
2	9	1	8	10-20 - daily	10-48
3	7	5	2	10-30 - daily	40-50
4	6	4	2	20 - daily	5-48
5	29	14	15	5 - daily or 1-week medication in a month	2-60
6	17	12	5	20 - daily	3-48
7	14	7	7	20-10 - daily	40-50
8	9		9	20 - daily	40-60
9	9		9	10-40 - daily	36-110
10	11		11	20-40 - daily	40-60
11	35		35	20 - daily	36-50
Total	183	61	122	10-40 - daily	2-110

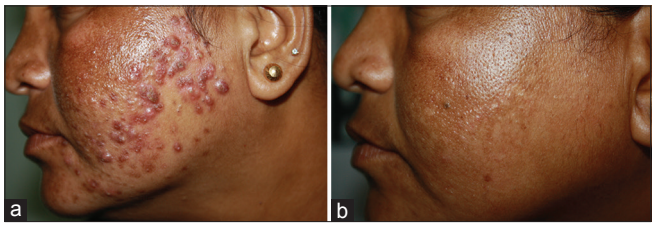


Figure 2: Glycolic acid peel in topical steroid induced acne with centrofacial melasma. 70% buffered glycolic acid peel done in a patient with 1800mg of oral isotretinoin intake. (a) Pre peel (b) Post peel

In this study, not only facial fractional resurfacing but also extrafacial fractional resurfacing was done. One case of Er: Yag fractional laser and one case of CO_2 fractional resurfacing were done on trunk region without any side effects.

Radiofrequency ablation of compound nevi on the face was done, in a case, with a cumulative dose of 4000 mg of isotretinoin. This patient developed a keloid.

Two cases of keloid were documented, which amounted to 0.4% of side effects in 504 interventions, with a significant *P* value of 0.000.

Table 6: Table of procedures

	Total number of cases	Total number of procedures
Glycolic acid peel	147	55
Salicylic acid peel	30	10
TCA peel	4	1
Combination peel	65	13
Fractional Co_2 laser	19	12
Conventional Full face Co_2 laser	19	19
Fractional Er: YAG laser	102	27
Long pulsed Nd: YAG laser hair reduction	4	1
Long pulsed Diode laser hair reduction	13	5
IPL hair reduction	9	6
IPL acne reduction	12	5
Q switched Nd YAG laser	5	1
LASIK	1	1
Microneedling	7	1
Mcrodermabrasion-aluminum	44	18
Subcision	7	7
Skin biopsy	8	8
Dental extraction	1	1
Excision	2	2
Punch elevation	2	2
Comedone extraction	1	1
Electrosurgery	1	1
Cryosurgery	1	1

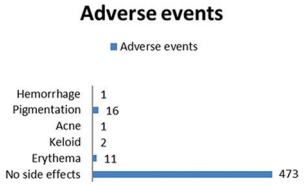
Table 7: Devices/interventions and some parameters used

Intervention	Parameters
Long-pulsed Nd: YAG laser	1064 nm, 9 mm spot, 30 ms, 40 J/cm^2
Fractional Er: YAG laser	2940 nm, long pulse, 7×7 × spot, 1200 mj
Fractional Er: YAG laser	2940 nm, scanner, 250 μ spot size, 100 J/cm^2, 600 μs pulse duration
Fractional CO_2 laser	30 mj, pulse 0.04 s, 100 pixel
Intense pulse light for acne	320 mm spot, 4 ms pulse, 16.8 J/cm^2
Full face conventional CO_2 resurfacing	3 mm spot, ultrapulse, 500 Hz, 250 μs
Q-switched Nd: YAG laser	1.5 mm spot, 400 mj
Microdermabrasion	130-180 μ particle size
Combination peel/ trichloroacetic acid easy peel	15 min to 8 h

Nd-YAG: Neodymium-doped yttrium aluminum garnet, Er: YAG: Erbium-doped yttrium aluminum garnet

Table 8: Adverse events

Adverse events	Frequency	Percentage
No side effects	473	93.8
Erythema	11	2.2
Keloid	2	0.4
Acne	1	0.2
Pigmentation	16	3.2
Hemorrhage	1	0.2
Total	504	100.0



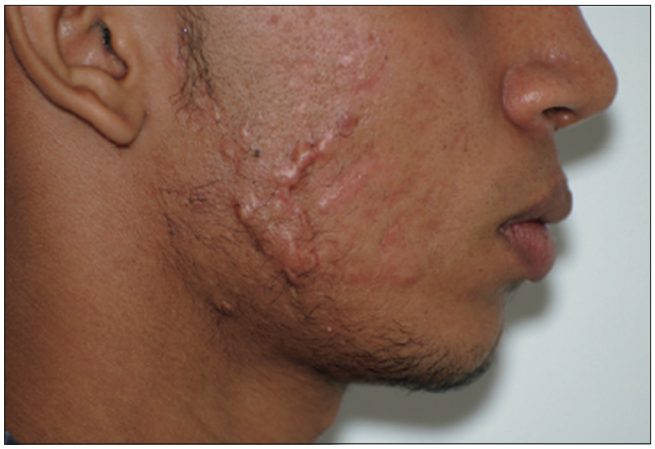


Figure 3: Keloid formation at site of peel and even distant site. Oral isotretinoin 1800 mg intake with postglycolic acid peel keloid

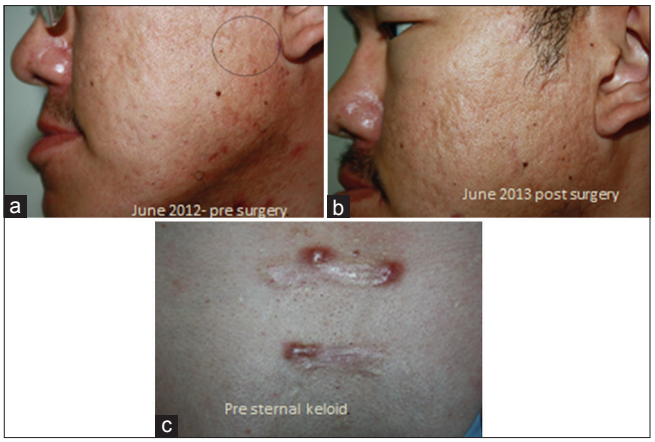


Figure 4: Pre- and post-fractional erbium-doped yttrium aluminum garnet laser resurfacing in a case of preexisting keloid. (a) Pre surgery (b) Post surgery (c) Pre sternal keloid

DISCUSSION

Of interest, in this prospective interventional study – "102 Fractional Er: YAG laser resurfacing, 19 conventional full face CO_2 laser resurfacing, 19 Fractional CO_2 laser resurfacing, 8 skin biopsies;" had no keloid/hypertrophic scar formation or delayed healing. All the above were collagen-specific interventions.

Laser or IPL-assisted hair reduction, being performed in 38 sessions, being more melanin specific, had no keloid/hypertrophic scar formation.

Thirty sessions of salicylic acid peels, 65 sessions of combination peels had no keloid/hypertrophic scar formation. However, of 147 sessions of glycolic acid peel, one case developed keloid at the site of peel and distant site postprocedure. This event of distant site keloid could be idiosyncratic.

The second case of keloid on the face followed radiofrequency ablation of compound nevi.

However, there were minor reversible outcomes such as pigmentation, erythema, and acne. If one compares our study and literature, which could serve like control data, the occurrence of reversible events in isotretinoin group is comparable [Table 9].

In a recent retrospective study,[22] about 55 patients undergoing laser-assisted hair reduction and postacne scar reduction in patient taking oral isotretinoin; the authors found no keloid or hypertrophic scar or delayed wound healing.

CONCLUSION

This study with 504 interventions done in patients taking oral isotretinoin with – glycolic/salicylic/combination acid peels, fractional Er: YAG laser resurfacing/fractional CO_2 laser and conventional CO_2 laser resurfacing, microdermabrasion had a single documented keloid in glycolic peel group. This was probably idiosyncratic. The second case of keloid following radiofrequency ablation of compound nevi however could not be explained.

Table 9: Comparison of adverse events in ISO-AIMS study and literature review

Intervention	Complication	Present study-ISO-AIMS study (with isotretinoin) (%)	Literature review (without isotretinoin) (%)
Glycolic peel	Erythema	4.08	0 - Garg *et al*.[18]
Ablative fractional Er: YAG laser	Erythema	0.98	0 - Manuskiatti *et al*.[19]
Ablative fractional Er: YAG laser	Acne	0.98	2-10 - Metelitsa *et al*.[20]
Conventional full face CO_2 resurfacing	Pigmentation	73	100 - Alster *et al*.[21]

Er: YAG: Erbium-doped yttrium aluminum garnet

The results of this study, further enhance the already accumulating evidence, about the safety of procedures in patients receiving isotretinoin and further provide additional evidence that the current recommendations for avoiding procedures may not be valid and need revision.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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APPENDIX 1

(Abridged version)

Demographic data

Name: _____ Age: _____ Sex: _____

Patient identification number (hospital registration number): _____

Address: _____

_____

Contact phone numbers: _____ E-mail id if present: _____

Occupation: _____ Patients skin Fitzpatrick type: _____

ACS (I) reporting code:_____

Indication for oral isotretinoin (kindly tick the indication)

1. Acne vulgaris
2. Acne rosacea
3. Other indications _____ (kindly write)

Table 1: Isotretinoin current dosage, duration, and frequency (kindly fill the data in detail)

Date	Dosage	Daily	Intermittent

Table 2: Isotretinoin, past dosage, and duration since stopping

Date of stopping isotretinoin	Duration after stopping the drug	Dosage administered cumulative dose

Relevant patient history

History of keloids/hypertrophic scars_____ (yes/no)

Procedures indications

1. Acne scar- atrophic/ hypertrophic
2. Postacne macules - hyperpigmentation
3. Hair reduction
4. Scars - posttraumatic, chicken pox
5. Excision of scars/biopsy

Procedure performed

Chemical peel

Agent used (write the ingredients, concentration, pH, buffered or not)

Glycolic acid
TCA
Salicylic acid
Combination

Date	Time of contact	Site of peel-face, back, upperlimbs	Immediate side effects* (within 3 days)	Delayed side effects	Time of resolution of complications, and how it was managed.

Hair reduction - laser assisted

Device – Long-pulsed Nd:YAG, diode laser, IPL, diode with radiofrequency, IPL with radiofrequency

Date	Site-face, trunk, limbs	Spot size	Pulse duration	Fluence	Cooling system	Immediate complications	Delayed complication	Time of resolution of complications and how it was managed

Fractional - ablative/nonablative

Indications - acne scarring, photoaging, rejuvenation

Device - Wavelength: _____, Laser source - Er:YAG, CO2, Er:glass, diode, Nd:YAG

Date	Site of therapy	Spot size/ pixel size	Fluence/ Energy	Pulse duration	Pixel density –ex 7×7=49	Immediate complications	Delayed complications	Time of resolution of complications and how it was managed