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(54) Title: COMPOSITION COMPRISING RESVERATROL AND MELATONIN FOR REDUCING HAIR LOSS AND/OR INCREASING HAIR REGROWTH

(57) Abstract: The invention relates to a composition comprising 0.01% to 15% resveratrol and 0.01% to 15% of melatonin. In a preferred embodiment, the composition comprises 5% resveratrol and 0.1 % melatonin. The invention also relates to the use of the said composition to reduce hair loss and/or increase regrowth of hair in a human subject.

**COMPOSITION COMPRISING RESVERATROL AND MELATONIN FOR REDUCING
HAIR LOSS AND/OR INCREASING HAIR REGROWTH**

FIELD OF INVENTION

The inventor has discovered that a composition comprising resveratrol and melatonin shows improved properties in terms of reducing hair loss and increasing hair regrowth when compared to conventional therapies, such as the topical application of a solution of 5% minoxidil.

BACKGROUND OF THE INVENTION

Androgenetic alopecia(AGA) is hair loss (at scalp level) caused by the thinning of hair follicles. It is very common in men between the age of 19 and 70 years. Notably, more than 50% of Caucasian men in their fifties are affected by it. Women's hair loss mostly becomes an issue after menopause.

Individuals affected by androgenetic alopecia (AGA) show a diminution of their self-esteem that can affect negatively many facets of their lives. The inventor has discovered that a composition for topical administration comprising resveratrol and melatonin is effective in reducing hair loss and increasing hair regrowth.

There are several hair loss prevention products on the market. By way of example, minoxidil has been in use since the 1990s in topical form at 2% concentration (without prescription) and at 3% and 5% concentration (with prescription). While studies demonstrate the efficiency of 5% minoxidil over the 2% concentration, minoxidil is less than 40% effective in promoting regrowth of the hair. Minoxidil is considered the topical gold standard available for treatment of hair loss.

Another hair loss prevention product is finasteride. It is administered orally usually at a dosage of 1 mg/day. There are a number of side effects associated with the administration of finasteride including lowered libido, impotence, ejaculation disorders, allergic reactions, testicular pain, male infertility, male breast cancer and depression. At higher concentrations (5 mg), finasteride can cause benign prostate hyperplasia.

The inventor has discovered that a composition comprising resveratrol and melatonin for topical application to the scalp reduces hair loss and increases hair regrowth. Such a composition shows superior improvements to those seen for each of the components of the composition taken individually

and to a composition comprising 5% minoxidil and the results obtained to date suggest that the improvements may be superior to those of the sum of the said components.

SUMMARY OF INVENTION

The invention relates to a composition comprising 0.01% to 15% resveratrol and 0.01% to 15% of melatonin. In another embodiment, the composition comprises 5% resveratrol and 0.1% melatonin. The invention also relates to the use of a composition comprising 0.01% to 15% resveratrol and 0.01% to 15% of melatonin to reduce hair loss and/or increase regrowth of hair in a human subject.

BRIEF DESCRIPTION OF THE FIGURES

Figures 1A to 1C are a series of photographs showing the scalp of participant 1 prior to treatment on the first day of month one (Fig. 1A) and at months three (Fig. 1B) and six (Fig. 1C) of a six month treatment with a solution of 5% resveratrol and 0.1% melatonin;

Figures 2A to 2C are a series of photographs showing the scalp of participant 2 prior to treatment on the first day of month one (Fig. 2A) and at months three (Fig. 2B) and six (Fig. 2C) of a six month treatment with a solution of 5% resveratrol and 0.1% melatonin;

Figures 3A to 3C are a series of photographs showing the scalp of participant 3 prior to treatment on the first day of month one (Fig. 3A) and at months three (Fig. 3B) and six (Fig. 3C) of a six month treatment with a solution of 5% resveratrol and 0.1% melatonin;

Figures 4A to 4C are a series of photographs showing the scalp of participant 4 prior to treatment on the first day of month one (Fig. 4A) and at months three (Fig. 4B) and six (Fig. 4C) of a six month treatment with a solution of 5% resveratrol and 0.1% melatonin;

Figures 5A to 5C are a series of photographs showing the scalp of participant 5 prior to treatment on the first day of month one (Fig. 5A) and at months three (Fig. 5B) and six (Fig. 5C) of a six month treatment with a solution of 5% resveratrol and 0.1% melatonin;

Figures 6A to 6C are a series of photographs showing the scalp of participant 6 prior to treatment on the first day of month one (Fig. 6A) and at months three (Fig. 6B) and six (Fig. 6C) of a six month treatment with a solution of 5% resveratrol and 0.1% melatonin;

Figure 7A to 7C are a series of photographs showing the scalp of participant 7 prior to treatment (Fig. 7A) and at months three (Fig. 7B) and six (Fig. 7C) of a six month treatment with a solution of 5% minoxidil only;

Figure 8A to 8C are a series of photographs showing the scalp of participant 8 prior to treatment (Fig. 8A) and at months three (Fig. 8B) and six (Fig. 8C) of a six month treatment with a solution of 5% minoxidil only;

Figure 9A to 9C are a series of photographs showing the scalp of participant 9 prior to treatment (Fig. 9A) and at months three (Fig. 9B) and six (Fig. 9C) of a six month treatment with a solution of 5% minoxidil only;

Figure 10A to 10C are a series of photographs showing the scalp of participant 10 prior to treatment (Fig. 10A) and at months three (Fig. 10B) and six (Fig. 10C) of a six month treatment with a solution of 5% minoxidil only;

Figure 11A to 11C are a series of photographs showing the scalp of participant 11 prior to treatment (Fig. 11A) and at months three (Fig. 11B) and six (Fig. 11C) of a six month treatment with a solution of 5% resveratrol only;

Figure 12A to 12C are a series of photographs showing the scalp of participant 12 prior to treatment (Fig. 12A) and at months three (Fig. 12B) and six (Fig. 12C) of a six month treatment with a solution of 5% resveratrol only;

Figure 13A to 13C are a series of photographs showing the scalp of participant 13 prior to treatment (Fig. 13A) and at months three (Fig. 13B) and six (Fig. 13C) of a six month treatment with a solution of 5% resveratrol only;

Figure 14A to 14C are a series of photographs showing the scalp of participant 14 prior to treatment (Fig. 14A) and at months three (Fig. 14B) and six (Fig. 14C) of a six month treatment with a solution of 0.1% melatonin only;

Figure 15A to 15C are a series of photographs showing the scalp of participant 15 prior to treatment (Fig. 15A) and at months three (Fig. 15B) and six (Fig. 15C) of a six month treatment with a solution of 0.1% melatonin only;

Figure 16A to 16C are a series of photographs showing the scalp of participant 16 prior to treatment (Fig. 16A) and at months three (Fig. 16B) and six (Fig. 16C) of a six month treatment with a solution of 0.1% melatonin only;

Figure 17A to 17C are a series of photographs showing the scalp of participant 17 prior to treatment (Fig. 17A) and at months three (Fig. 17B) and six (Fig. 17C) of a six month treatment with a solution of 0.1% melatonin only; and

Figure 18A to 18C are a series of photographs showing the scalp of participant 18 prior to treatment (Fig. 18A) and at months three (Fig. 18B) and six (Fig. 18C) of a six month treatment with a solution of 0.1% melatonin only;

DETAILED DESCRIPTION OF THE INVENTION

The invention relates to a composition comprising resveratrol and melatonin which shows improved properties for the reduction of hair loss and for the increase of hair regrowth in human subjects when compared to minoxidil.

Resveratrol is a natural product in topical form derived from *polygonum multiflorum*, an Asian cane.

Melatonin is mostly used to treat insomnia. The FDA classifies melatonin as a dietary supplement.

An exemplary composition of the invention comprises 0.01% to 15% resveratrol and 0.01% to 15% of melatonin. In another embodiment, the composition comprises 5% resveratrol and 0.01% melatonin.

In order to demonstrate the improved properties of a composition suitable for topical application comprising resveratrol and melatonin, the composition was compared to compositions comprising 5% minoxidil only, 0.1% melatonin only and 5% resveratrol only. The various compositions were prepared as follows.

Example 1:**Preparation of Composition Comprising Resveratrol and Melatonin**

The composition comprises 5% resveratrol and 0.1% melatonin as the active ingredients and propylene glycol and absolute ethyl alcohol as non-active ingredients. The alcohol also serves as the final preservative in the composition.

Various modifications for the preparation of the composition of the invention will be apparent to the skilled worker. Furthermore, other pharmaceutically acceptable additives such as suspending agents, emulsifying agents, non-aqueous vehicles and preservatives can be added. The techniques for the preparation of these compositions are well known in the art and reference may be had to Remington's Pharmaceutical Sciences, 18th edition, Mack Publishing Co., Easton, Pennsylvania, USA 18042.

Example 2:**Preparation of Composition Comprising Minoxidil**

A composition comprising 5% minoxidil was prepared. Absolute ethyl alcohol was mixed with propylene glycol and heated to 55° to 65°C. The minoxidil powder was added to the alcohol/propylene glycol mixture. Ethoxy diglycol was added and the solution was stirred. The final solution was brought to volume with absolute ethyl alcohol to obtain a solution comprising 5% minoxidil.

Example 3:**Preparation of Composition Comprising Resveratrol**

A composition comprising 5% resveratrol was also prepared. Absolute ethyl alcohol was mixed with propylene glycol. Resveratrol was added to the alcohol/propylene glycol mixture to obtain a solution having a concentration of 5% resveratrol. Absolute ethyl alcohol also serves the function of preservative.

Example 4:**Preparation of Composition Comprising Melatonin**

A solution comprising 0.1% melatonin was prepared. Absolute ethyl alcohol was mixed with propylene glycol. The melatonin was added to the alcohol/propylene glycol mixture. The final solution was brought to volume with absolute ethyl alcohol in order to obtain a solution having a concentration of 0.01% melatonin. The absolute ethyl alcohol also serves the function of preservative in this composition.

Example 5:**Treatment of Participants With Composition of Invention and Comparators – Analysis and Measurements**

Each participant had androgenetic alopecia.

For each participant, the distance between the base of the nose and the middle of the hair crown was noted, as well as the distance separating the most distal part of the helix and the hair crown. A square area of two centimeters by two centimeters was measured around the middle point of the hair crown (marked by a washable felt crayon).

The participants were seen at monthly intervals over a six-month period and their hair was analysed in the manner described above.

Results**A. Treatment With Composition Comprising Resveratrol and Melatonin**

Each participant first had his hair analysed as described above. Following the first analysis, each participant was provided with a solution comprising 5% resveratrol, and 0.1% melatonin prepared as described in Example 1 above. The participants applied 1 ml to the scalp, once a day after cleansing. The 1 ml was applied as 10 metered dose sprays of 0.1 ml.

The results for six participants are provided. Particulars of each participants are provided in Table 1 below. All six participants had androgenic alopecia, as did the participants of their comparator groups.

Table 1

Participant	Gender	Age
1	Male	38
2	Male	38
3	Male	36
4	Male	45
5	Male	32
6	Male	57

Figures 1 to 6 clearly show a decrease of hair loss and an increase in hair regrowth in all six participants.

Each participant completed a self-assessment questionnaire (Barber, Kaufman, Kozloff, Girman and Guess, A Hair Growth Questionnaire For Use In The Evaluation Of Therapeutic Effects In Men, Journal of Dermatological Treatment, Volume 9, Issue 3, 1998). All participants agreed that they could see their bald spot getting smaller after receiving treatment. 84% of the participants saw an improvement in the appearance of their hair. 83% of the participants saw a slight to moderate increase in the growth of their hair while all participants found that the treatment had been somewhat to very effective at slowing down hair loss.

A marked decrease of hair loss and an increase in hair regrowth was observed for each participant.

B. Comparison with Treatment With Minoxidil, Resveratrol and Melatonin

Each participant first had his hair analysed as described in part A above. Following the first analysis, each participant was provided with a solution comprising either 5% minoxidil, 5% resveratrol, or 0.1% melatonin. The compositions were prepared as described in Examples 2 to 4 above. The participants applied 1 ml to the scalp, once a day after cleansing. The 1 ml was applied as 10 metered dose sprays of 0.1 ml.

a) 5% Minoxidil Comparator

Four participants were provided with a solution of 5% minoxidil. The particulars of the participant are provided in Table 2 below.

Table 2

Participant	Gender	Age
7	Male	64
8	Male	45
9	Male	52
10	Male	48

Only a slight improvement in hair regrowth is observed for the minoxidil group and the results are inferior to those seen with the composition of the invention.

The four participants completed the self-assessment questionnaire described above. Half of the participants agreed that their bald spot decreased in size and that the appearance of their hair was a little better. 75% of the participants saw a little increase in the growth of their hair and found the treatment somewhat effective in slowing down hair loss.

b) 5% Resveratrol Comparator

Three participants were provided with a solution of 5% resveratrol. Particulars of the participants are provided in the Table 3 below.

Table 3

Participant	Gender	Age
11	Male	38
12	Male	31
13	Male	42

Only a slight improvement in hair regrowth is observed for the resveratrol only group. The results are inferior to those seen with the composition of the invention.

Two of the participants disagreed that their bald spot had gotten smaller and the other participants had no opinion. Two of the participants thought that the appearance of their hair was the same as before treatment and one thought that it was worse. All participants saw a slight increase in the growth of their

hair. Two out of the three participants thought that the treatment was somewhat effective at slowing down hair loss while the other participant thought it was not very effective.

c) 0.1% Melatonin Comparator

Five participants were provided with a solution of 0.1% melatonin only. The particulars of these participants are provided in Table 4 below.

Table 4

Participant	Gender	Age
14	Male	35
15	Female	36
16	Male	45
17	Male	42
18	Male	40

Only a slight improvement in hair regrowth was observed for the melatonin only group. The results obtained are inferior to those observed with the composition of the invention.

The self-assessment questionnaire reflected the fact that 80% of the participants either disagreed or strongly disagreed that their bald spot had gotten smaller and the remaining 20% had no opinion. 60% of the participants were of the view that the appearance of the hair remained unchanged, 20% believed it had gotten worse while 20% thought it was a little better. 80% of the participants saw no change in the growth of their hair while 20% saw a slight increase. 80% of the participants were of the view that the treatment was not very affective at slowing down hair loss and 20% thought it was not effective at all.

The composition comprising resveratrol and melatonin shows improved properties in terms of reduction of hair loss and increase of regrowth of hair when compared to a solution of 5% minoxidil alone, a solution of 5% resveratrol alone or a solution of 0.1% melatonin alone. The improvements shown in the reduction of hair loss and the increase of regrowth hair for the composition of the invention are superior to the improvements seen for each of the components of the composition taken

individually and the results obtained to date suggest that the improvements may be superior to those of the sum of the said components.

While the composition of the invention has been tested on males, similar results are expected on females as the mechanism of hair growth is the same for both genders.

While the present invention has been described in connection with specific embodiments thereof and in a specific use, various modifications will occur to those skilled in the art. The scope of the claims should not be limited by the preferred embodiments or the examples but should be given the broadest interpretation consistent with the description as a whole.

What is claimed is:

1. A composition comprising 0.01% to 15% of resveratrol and 0.01% to 15% of melatonin.
2. The composition according to claim 1 comprising 5% of resveratrol and 0.01% of melatonin.
3. The composition according to claim 1 or 2 for use in reducing hair loss and/or increasing regrowth of hair in a human subject.
4. The composition of claim 3, wherein the human subject is a male.
5. The composition of claim 3, wherein the human subject is a female.
6. The composition according to any one of claims 1 to 5 for topical administration.
7. The composition according to claim 6 which is in the form of a spray.
8. Use of the composition as defined in claim 1 or 2 to reduce hair loss and/or increase regrowth of hair in a human subject.
9. Use of the composition as defined in claim 1 or 2 in the manufacture of a medicament to reduce hair loss and/or increase regrowth of hair in a human subject.
10. The use according to claim 8 or 9, wherein the human subject is a male.
11. The use according to claim 8 or 9, wherein the human subject is a female.
12. The use according to any one of claims 8 to 11, wherein the composition is for topical administration.
13. The use according to claim 12, wherein the composition is in the form of a spray.



Figure 1A

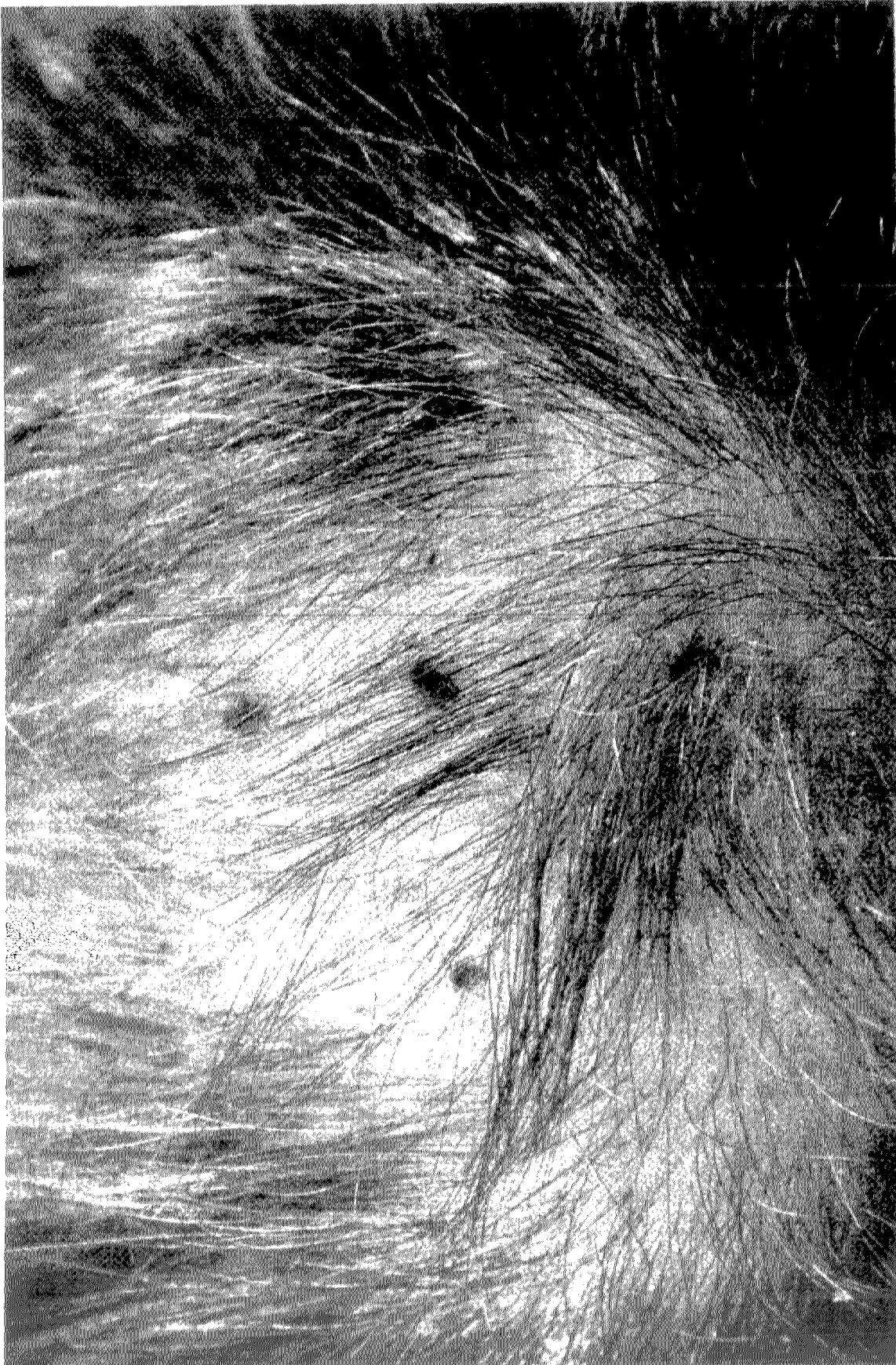


Figure 1B



Figure 1C

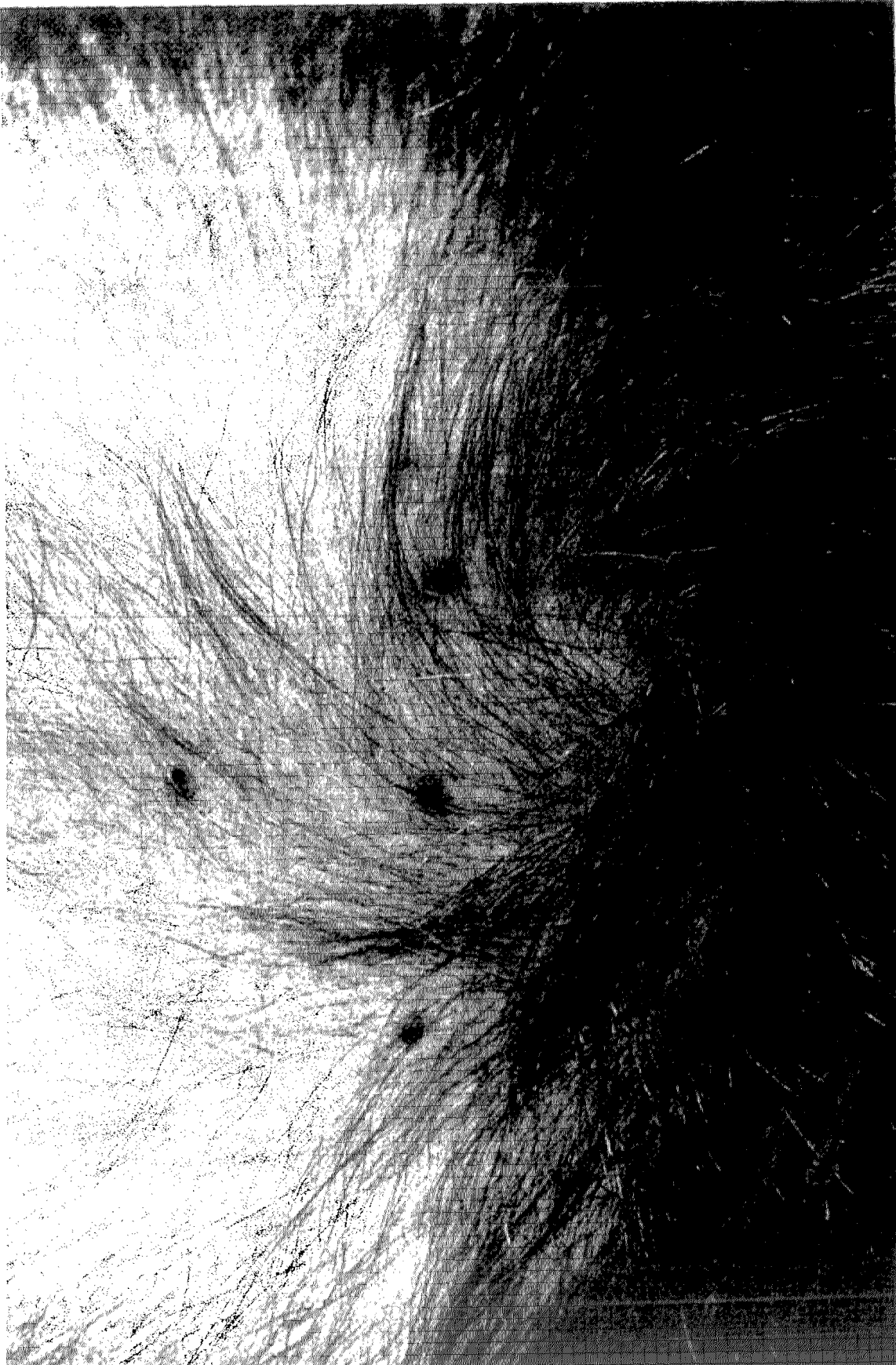


Figure 2A

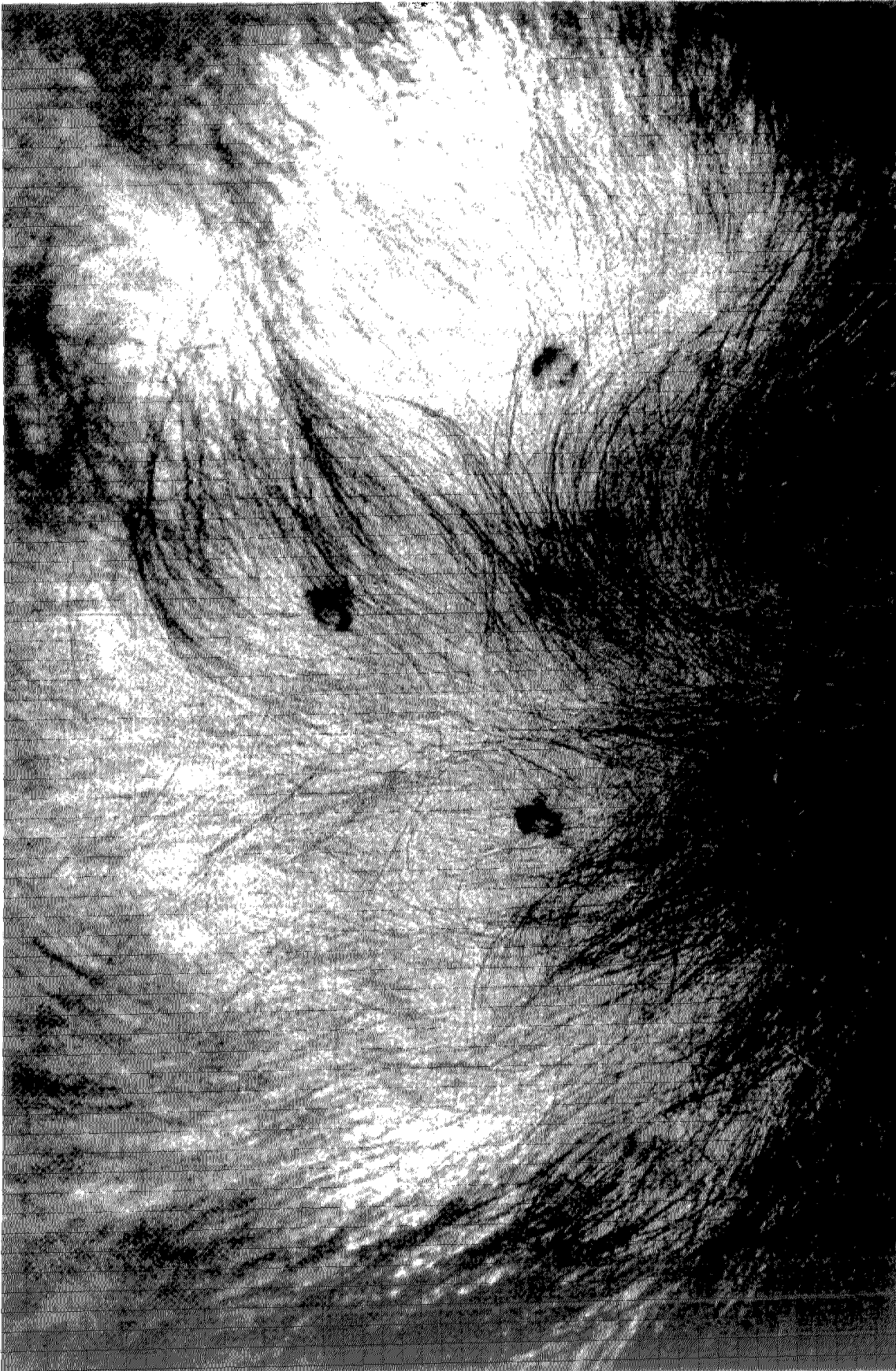


Figure 2B



Figure 2C

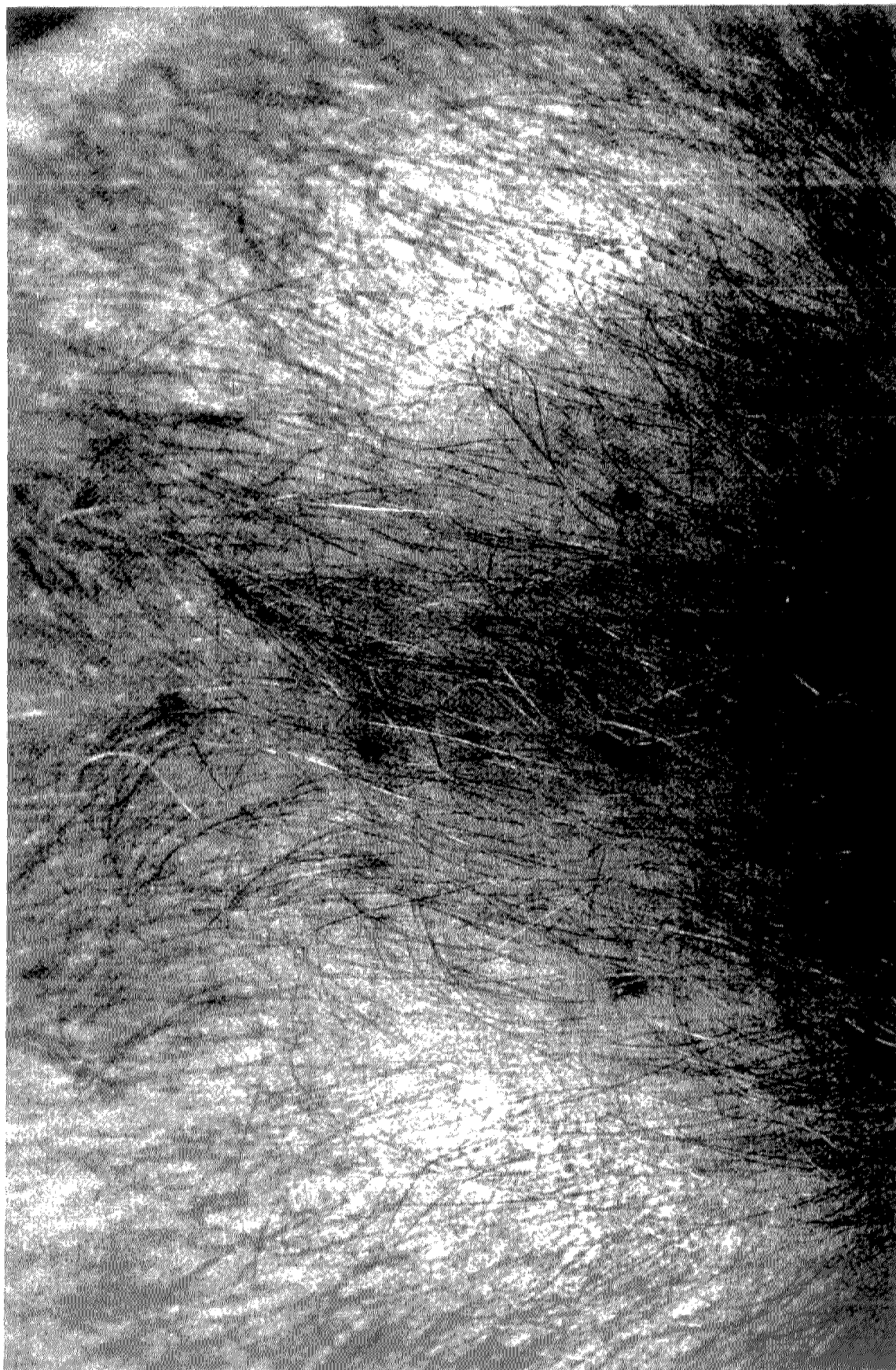


Figure 3A

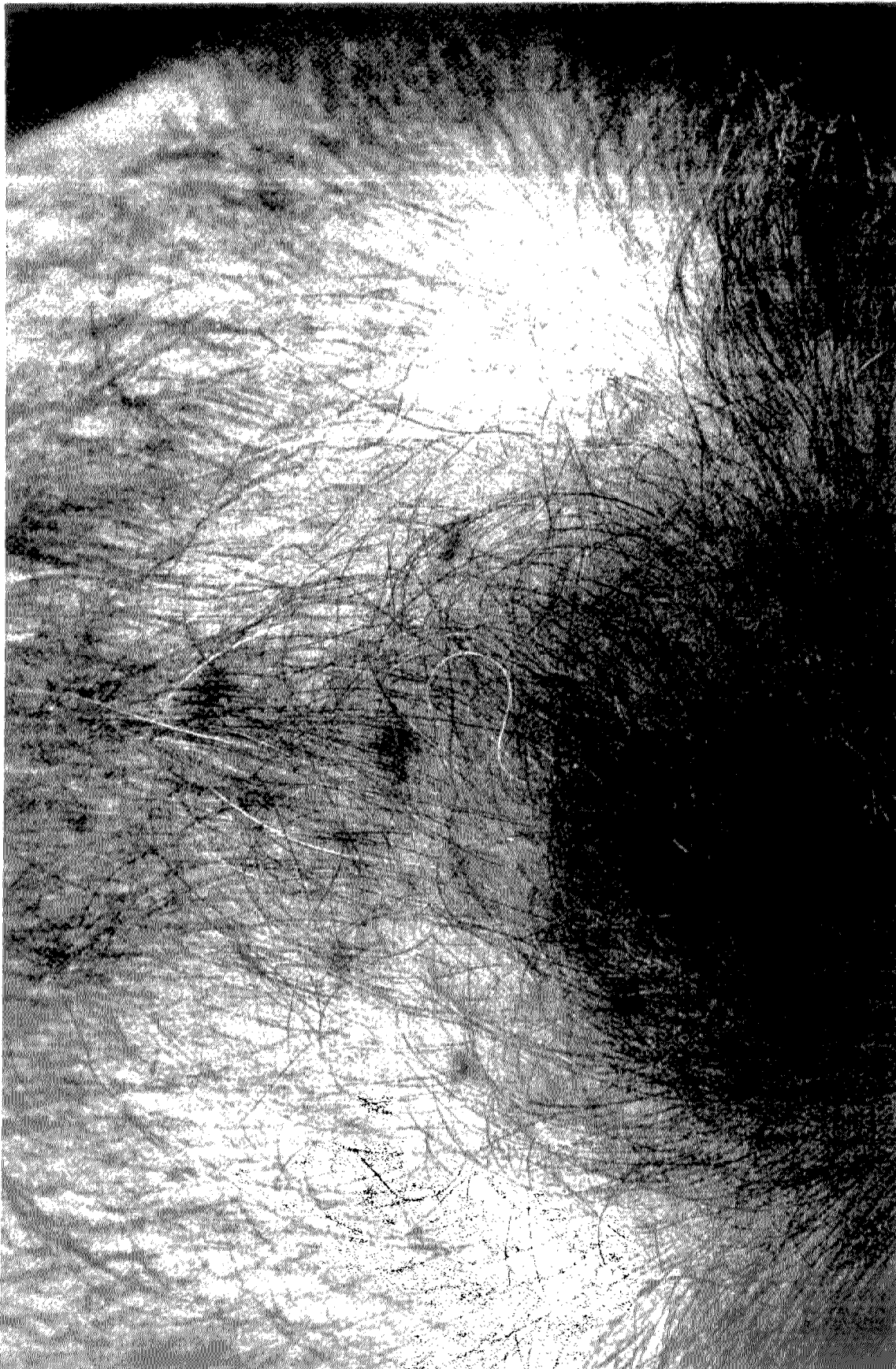


Figure 3 B

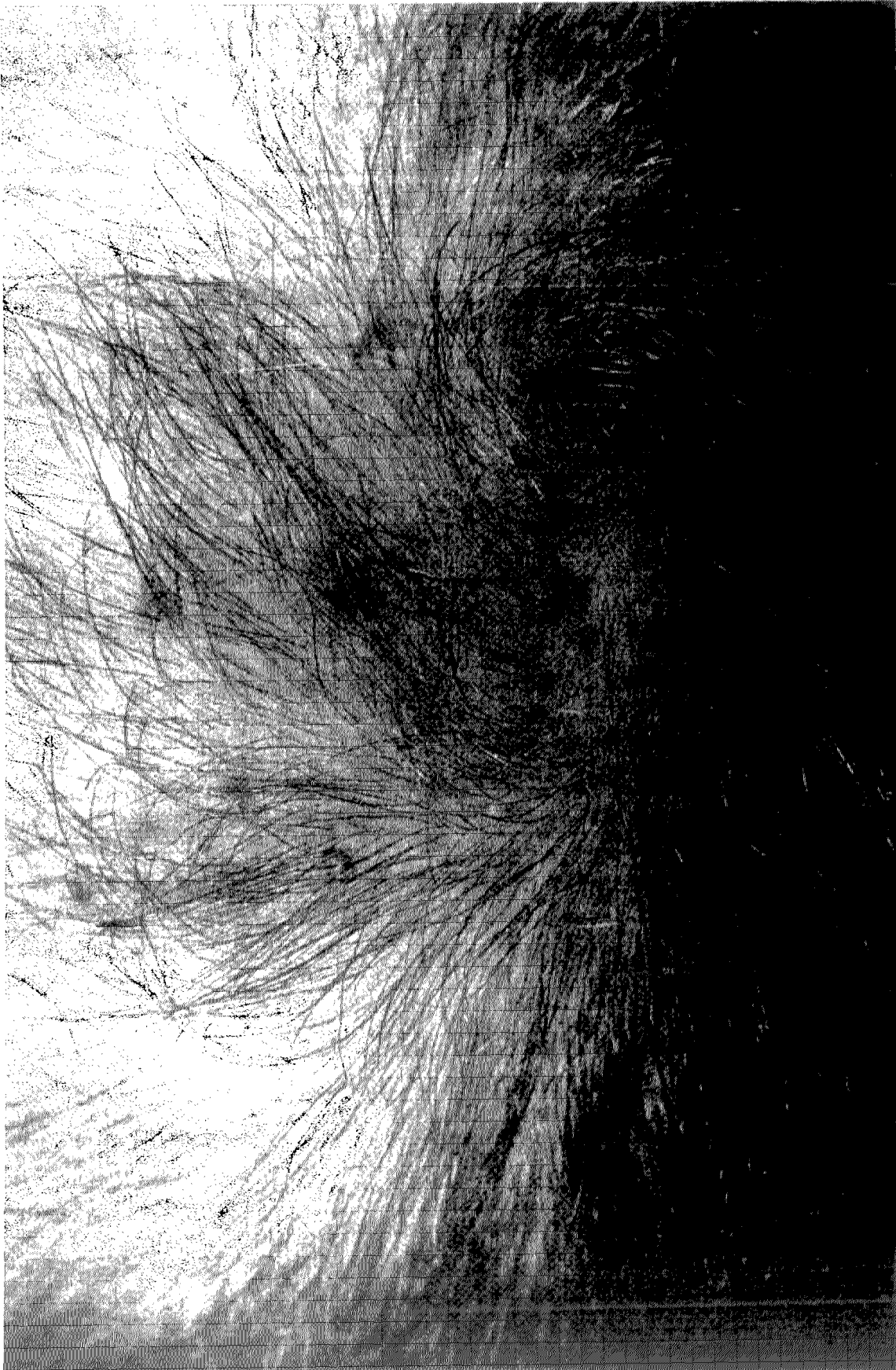


Figure 3C

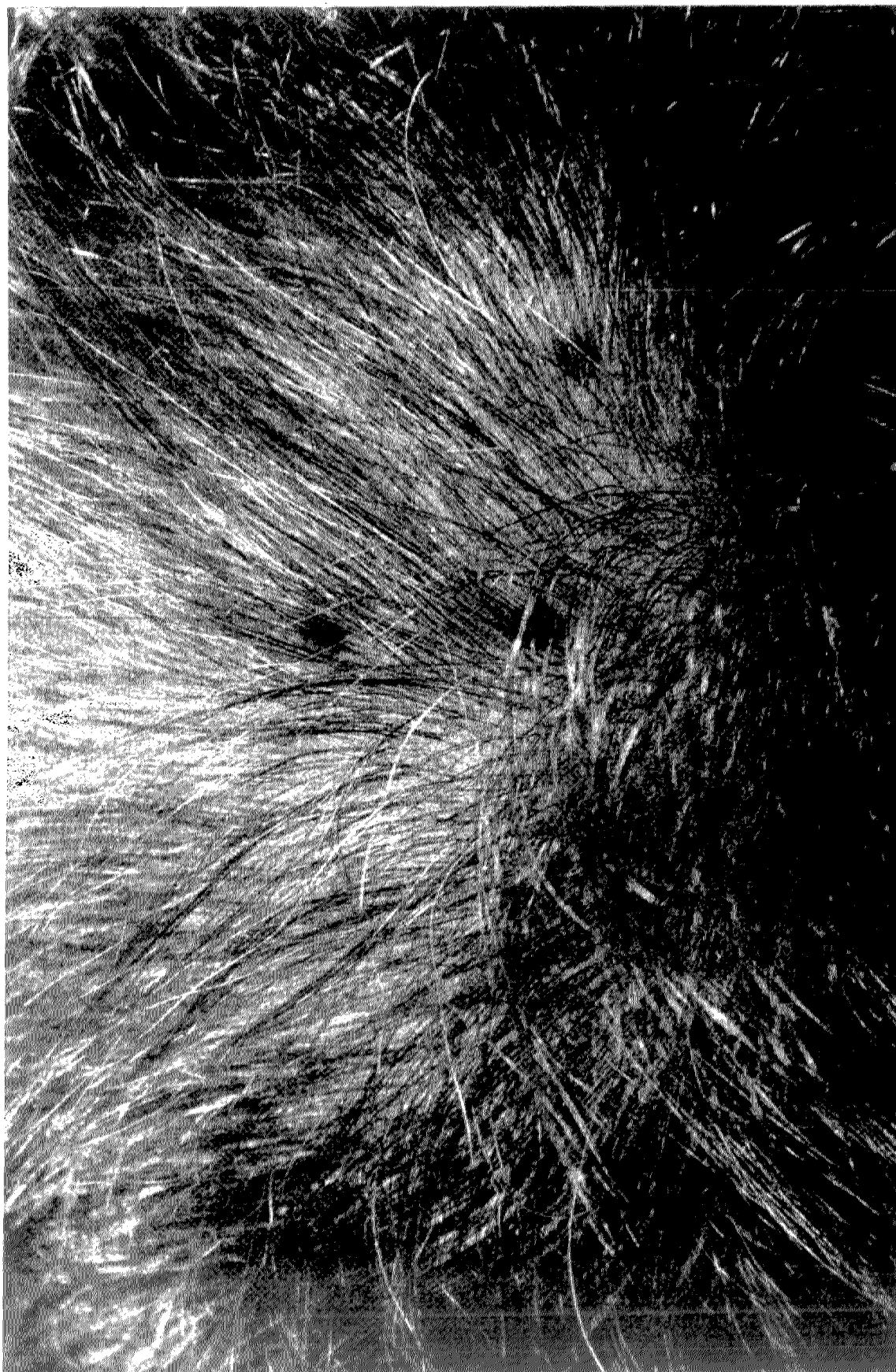


Figure 4A

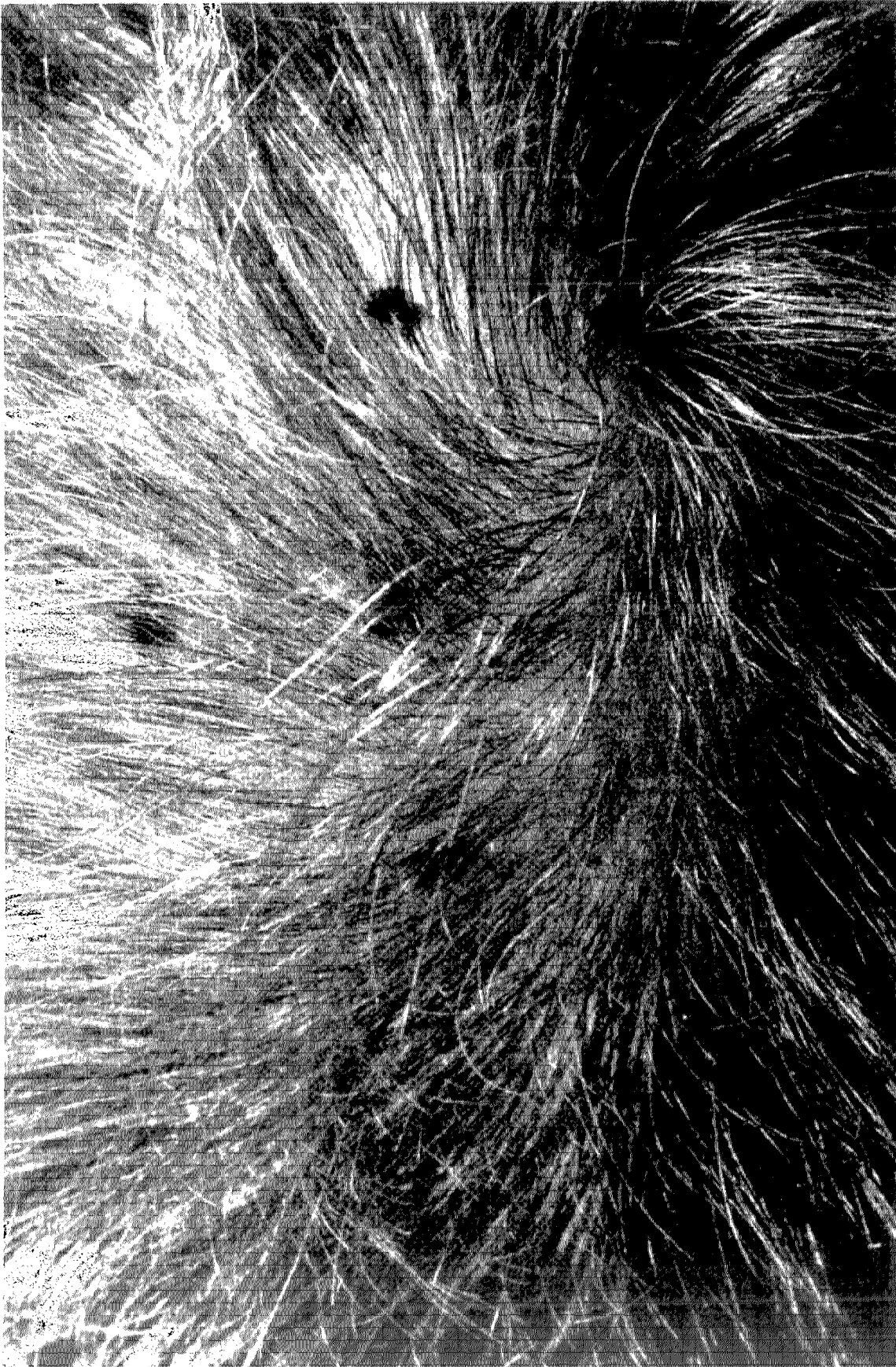


Figure 4B



Figure 4C

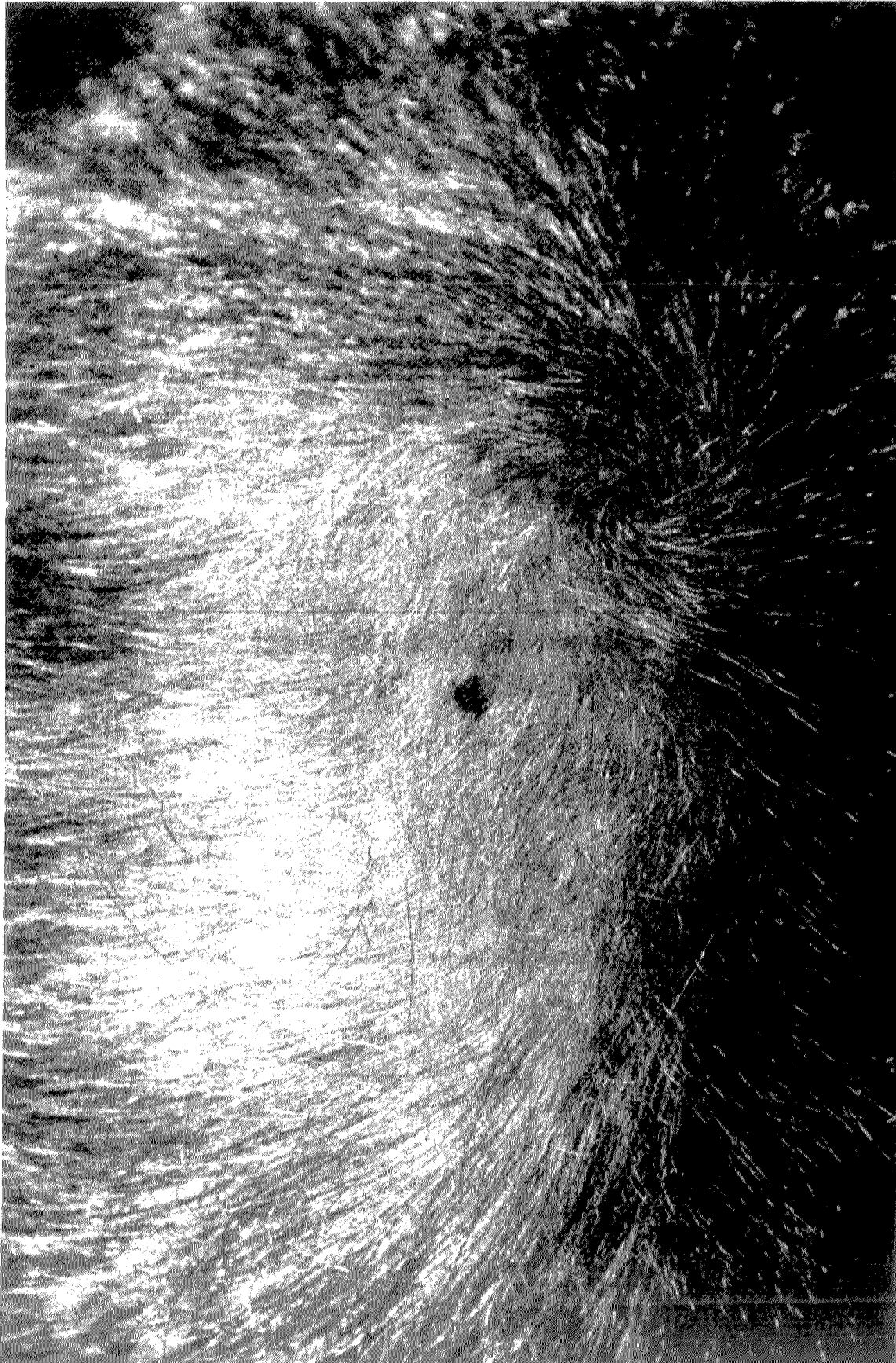


Figure 5A

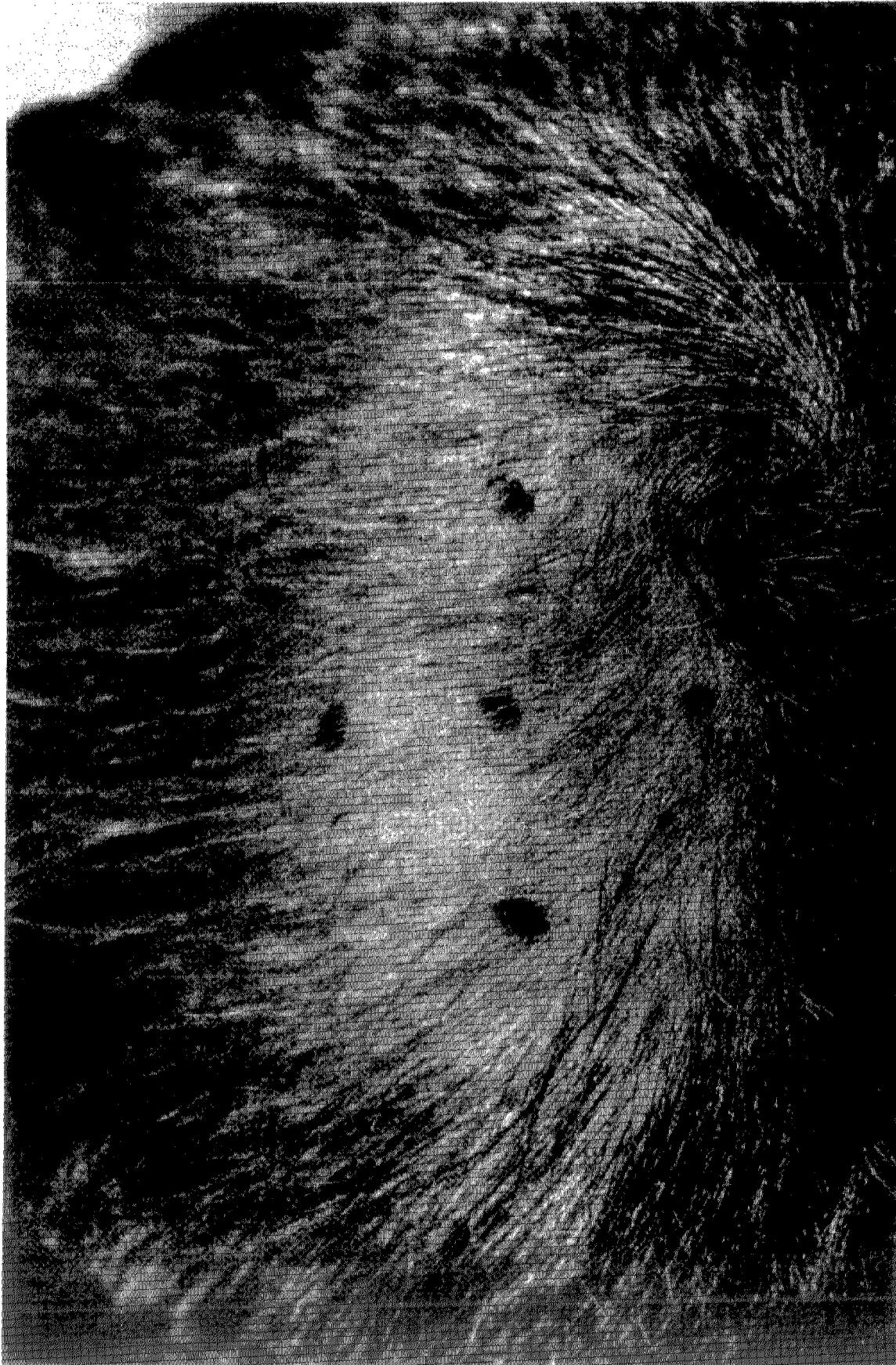


Figure 5B



Figure 5C

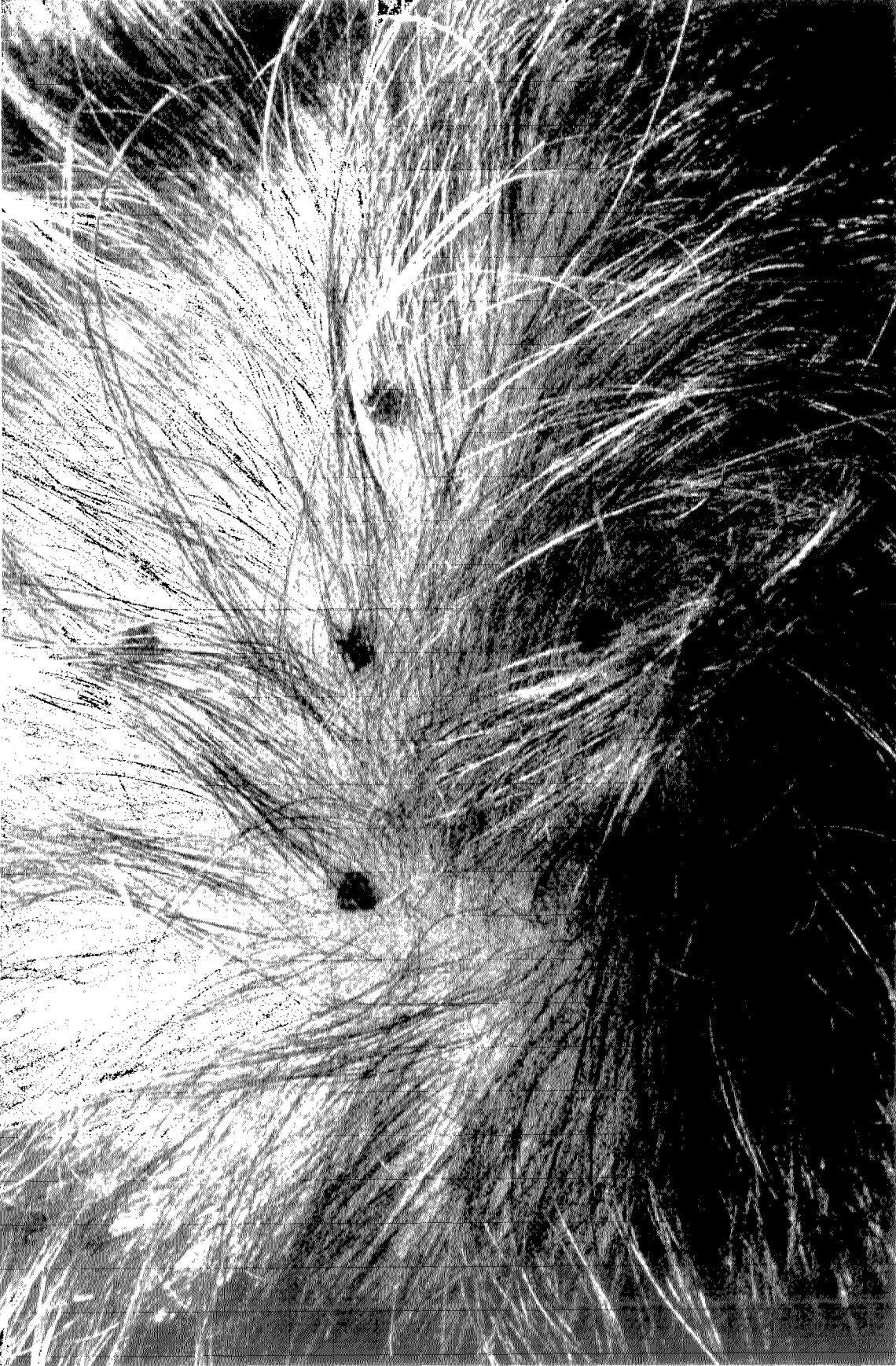


Figure 6A

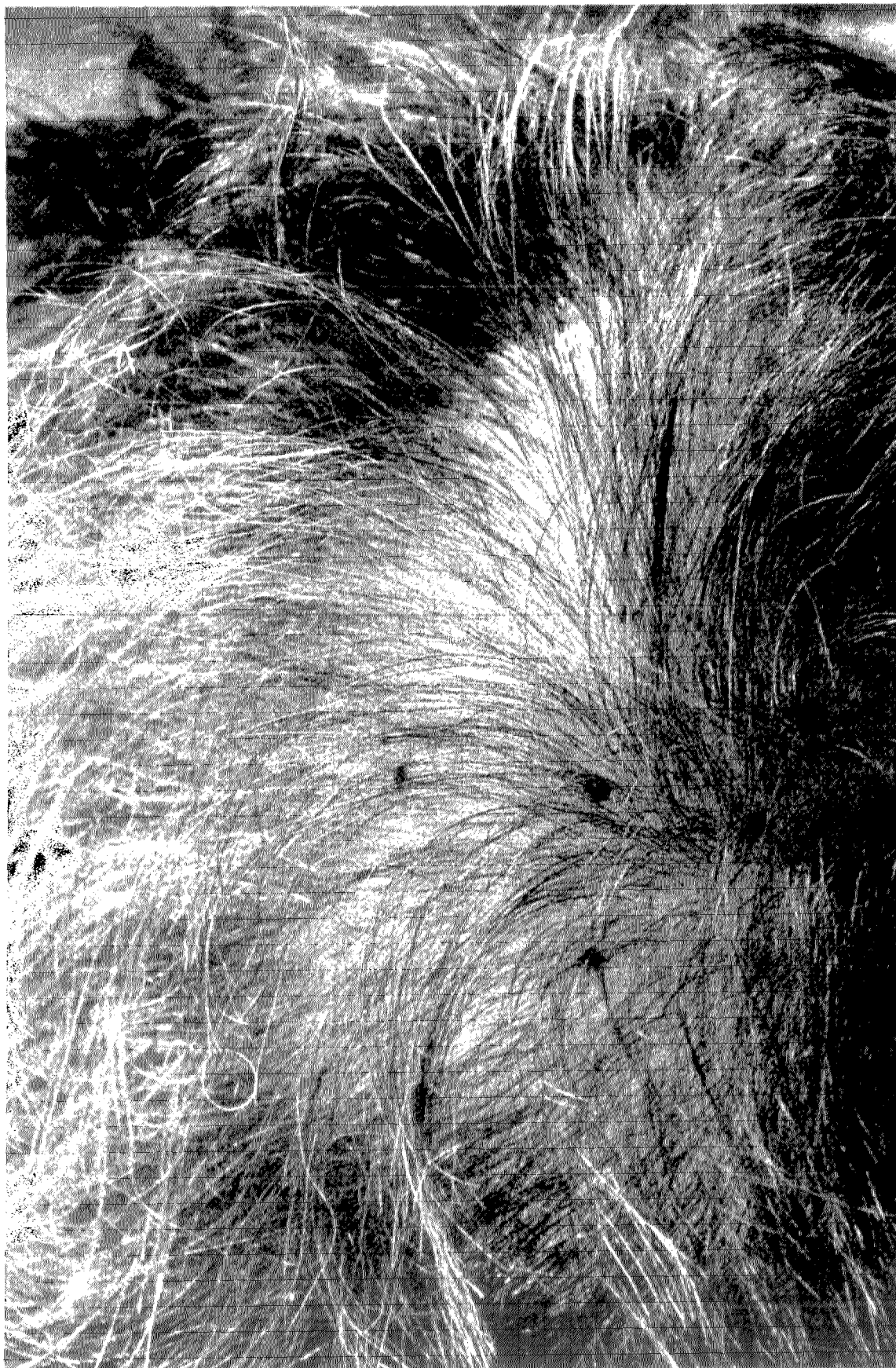


Figure 6B

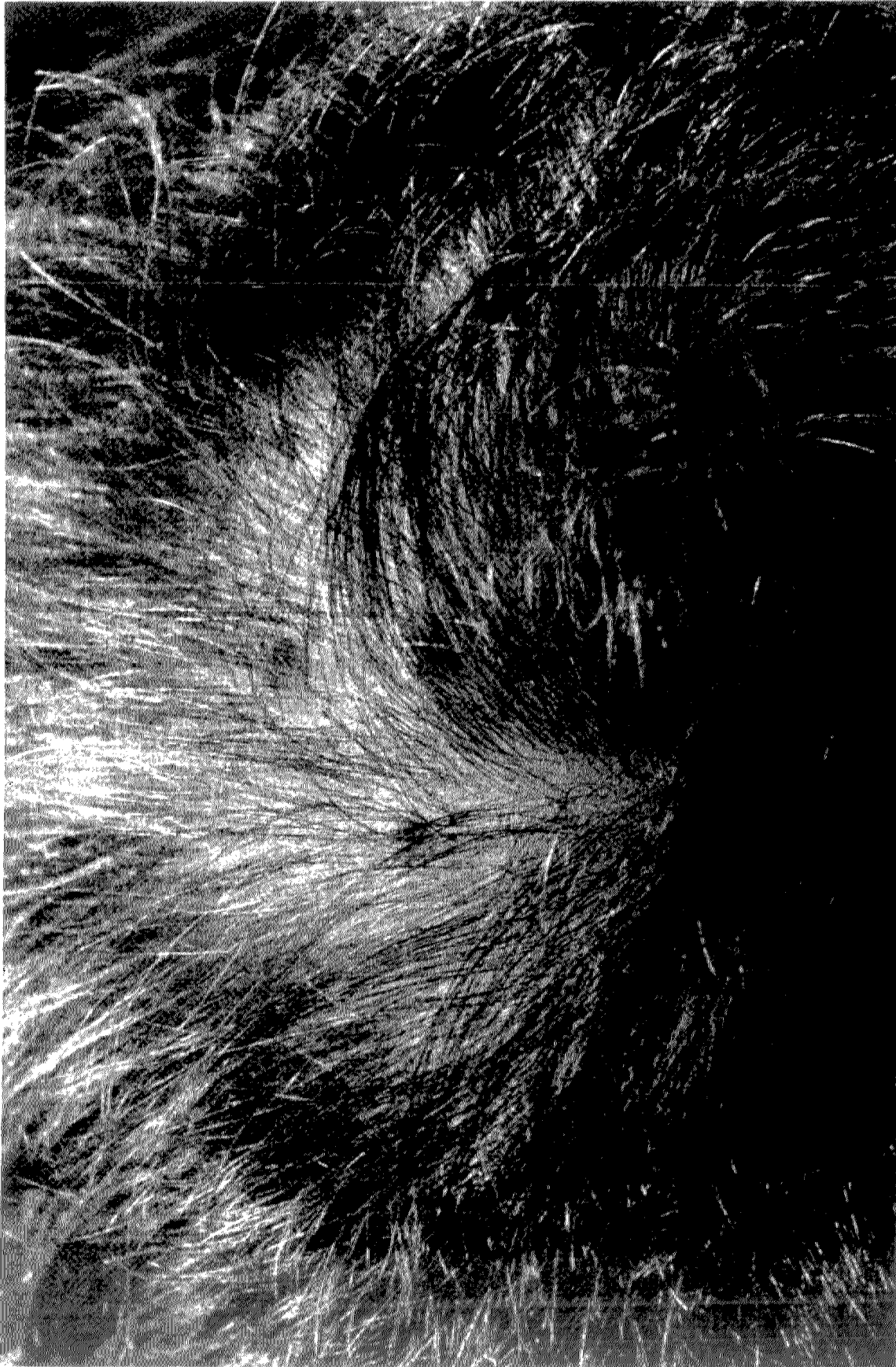


Figure 6C

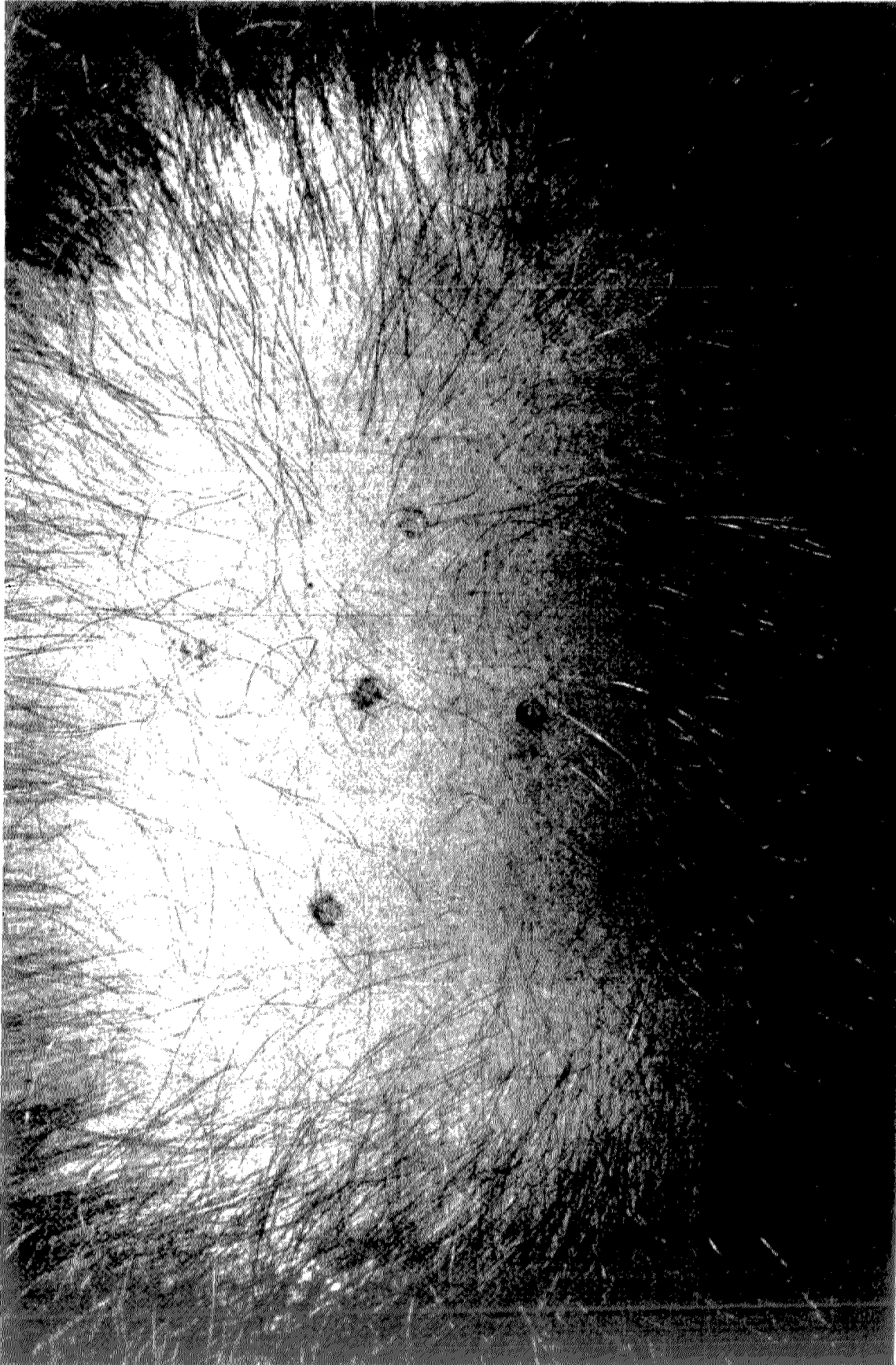


Figure 7A

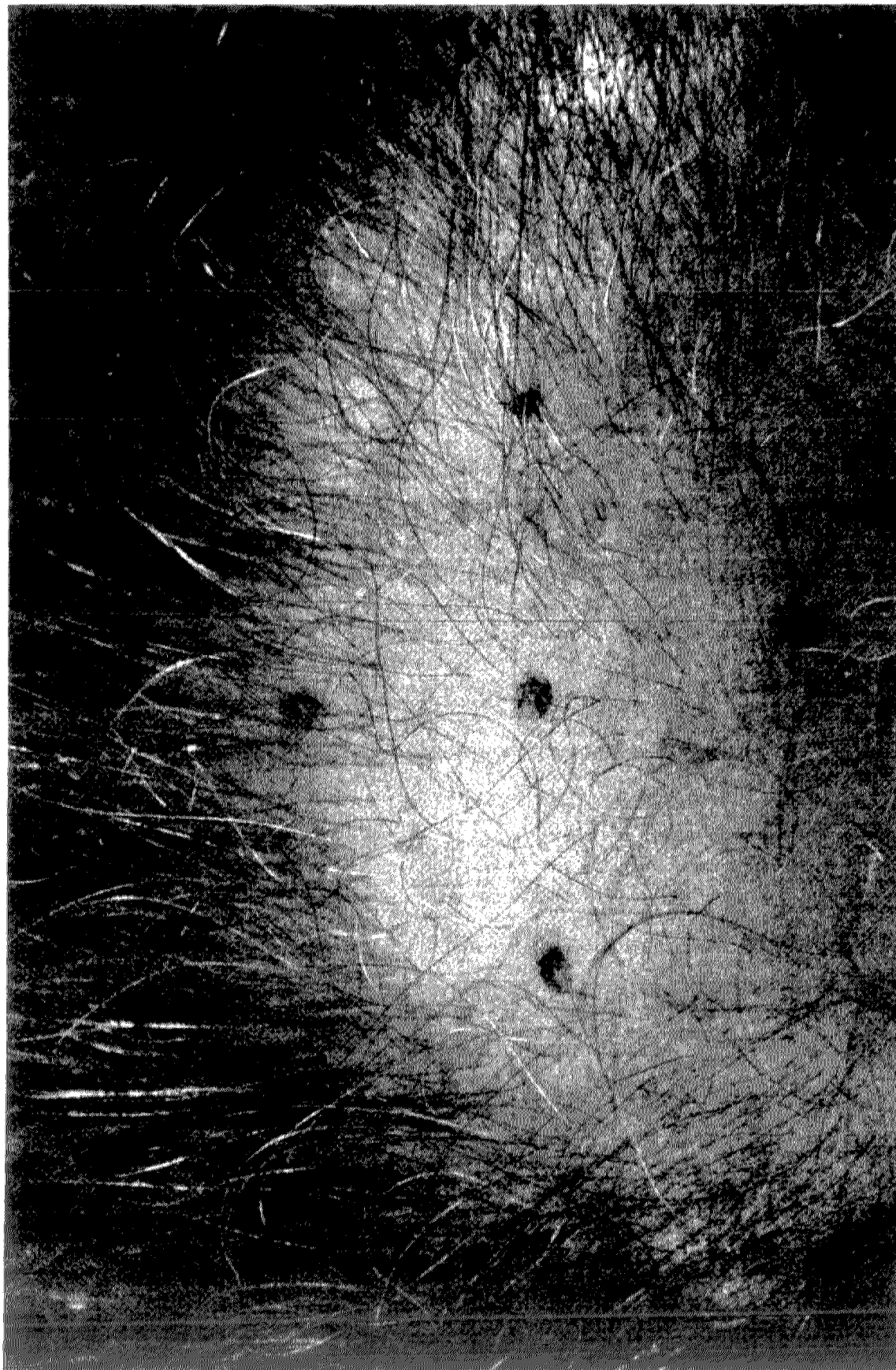


Figure 7B

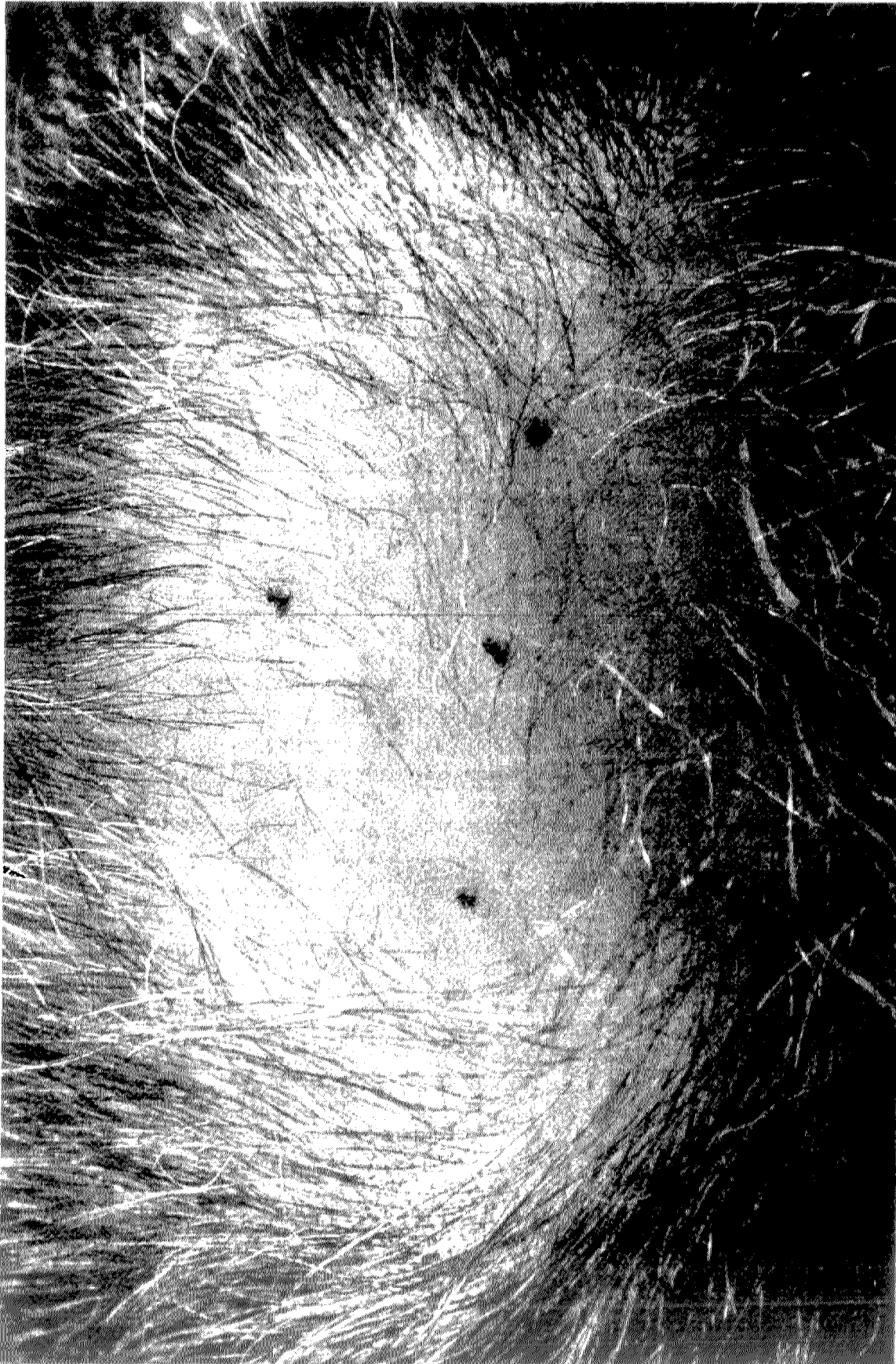


Figure 7C

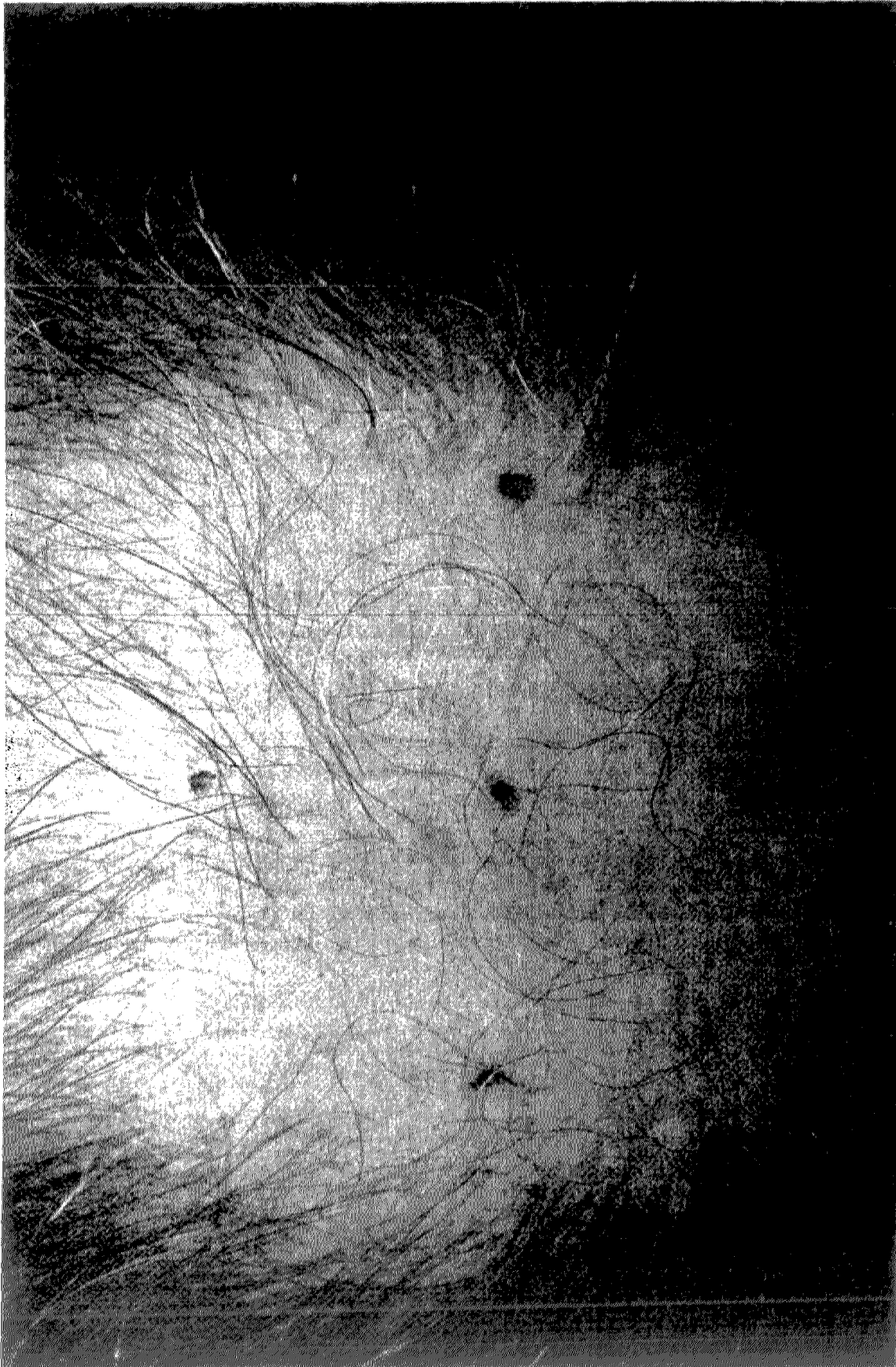


Figure 8A

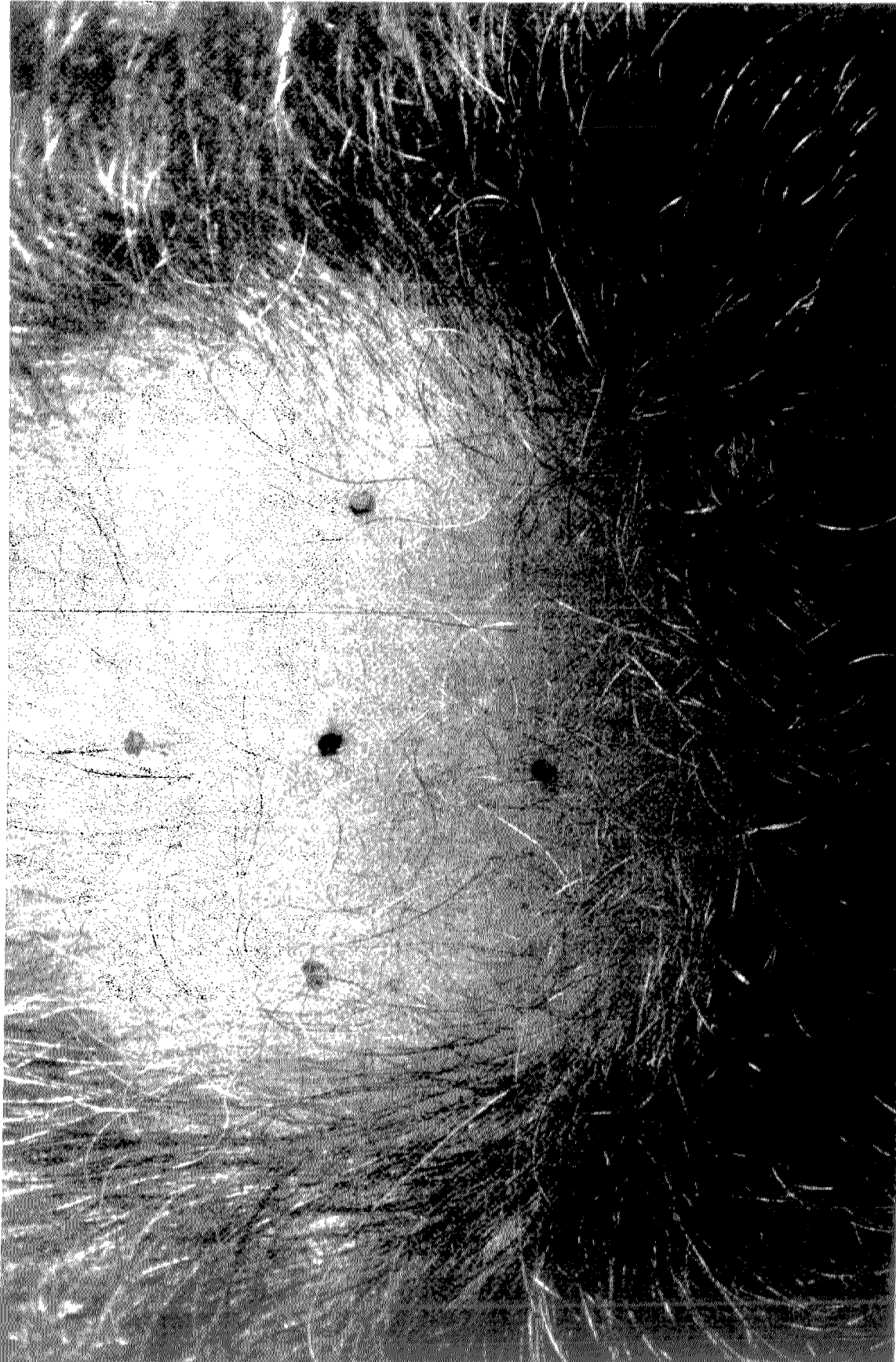


Figure 8B

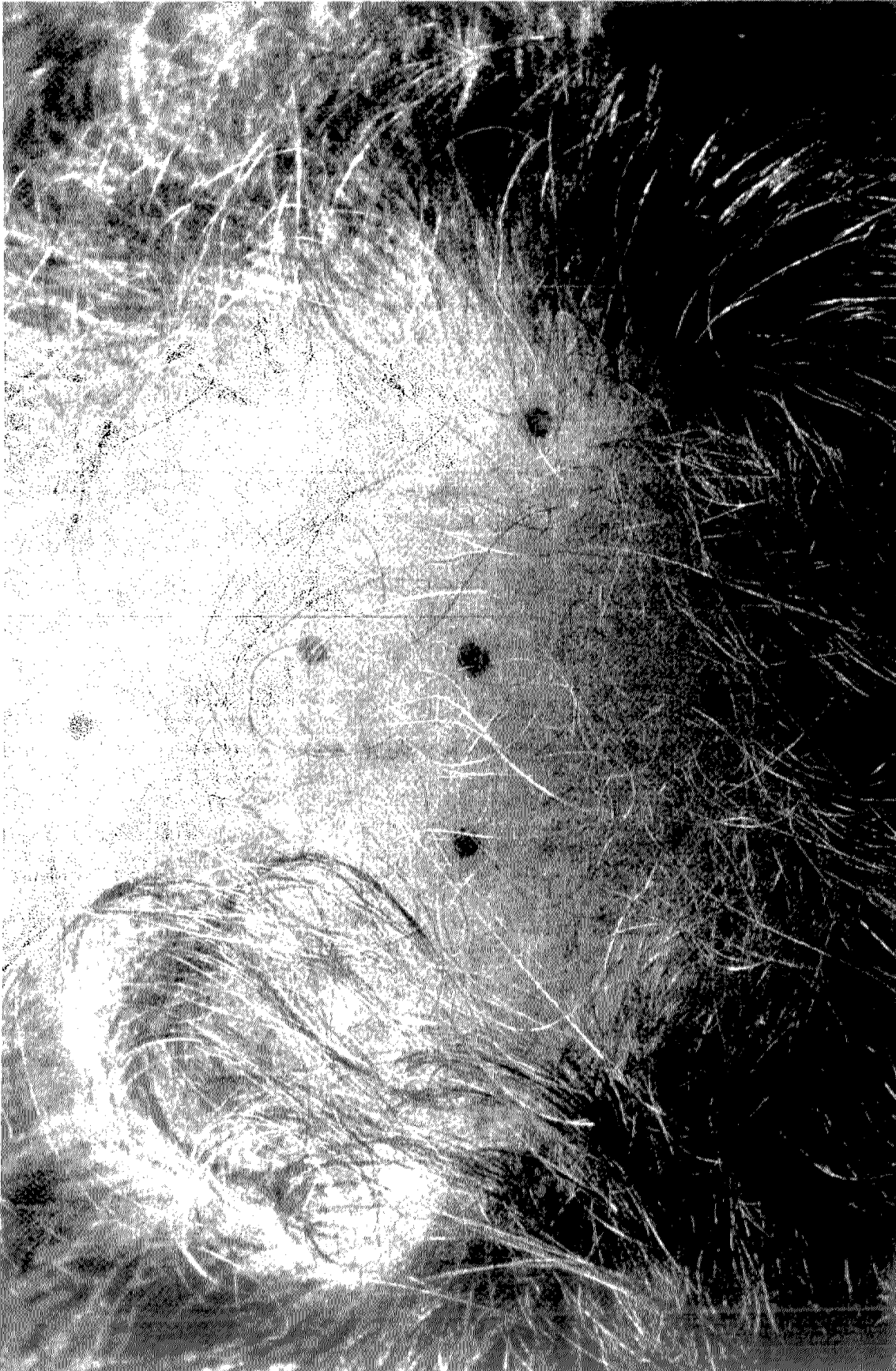


Figure 8C



Figure 9A



Figure 9B

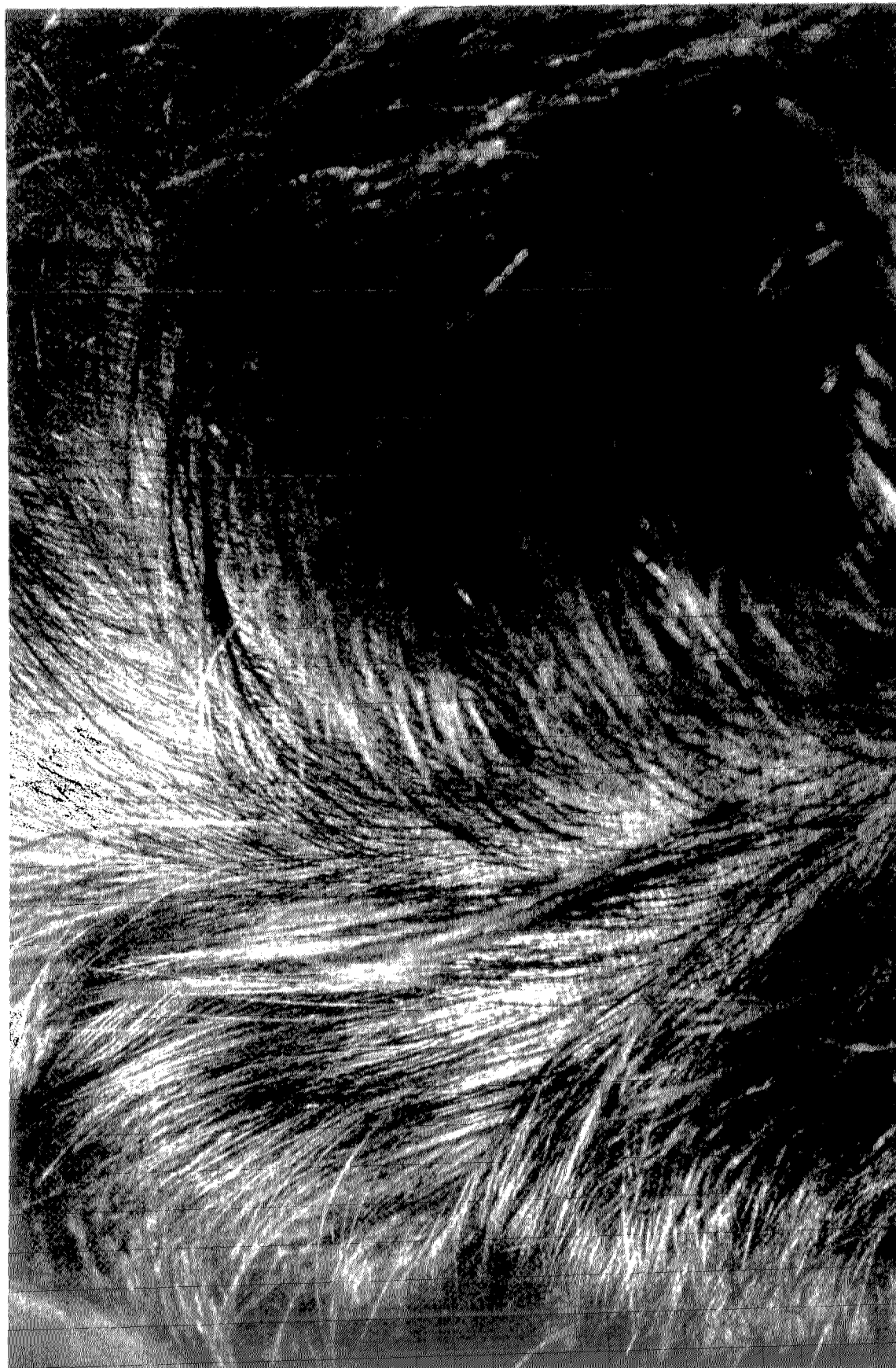


Figure 9C



Figure 10A

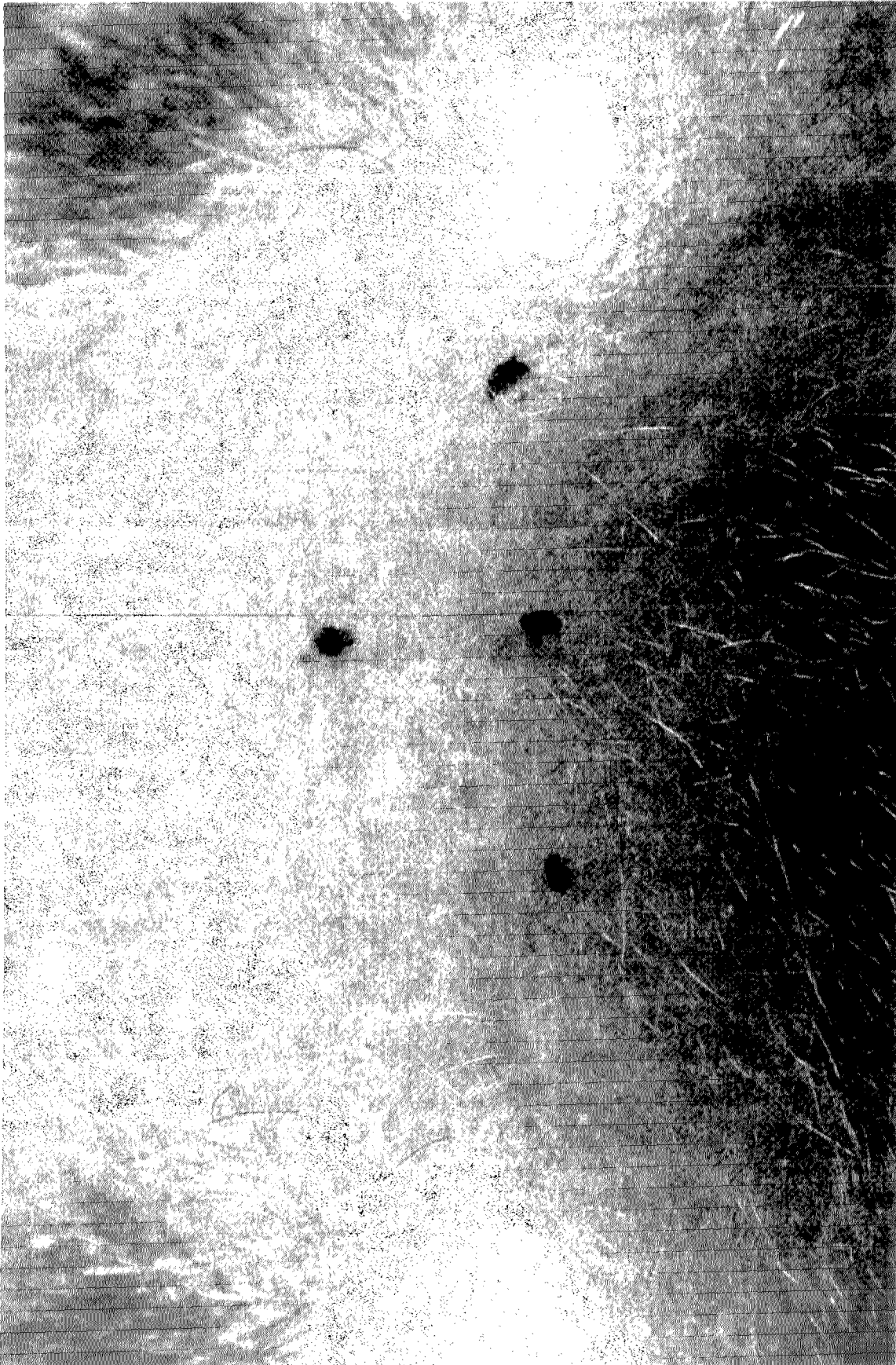


Figure 10B

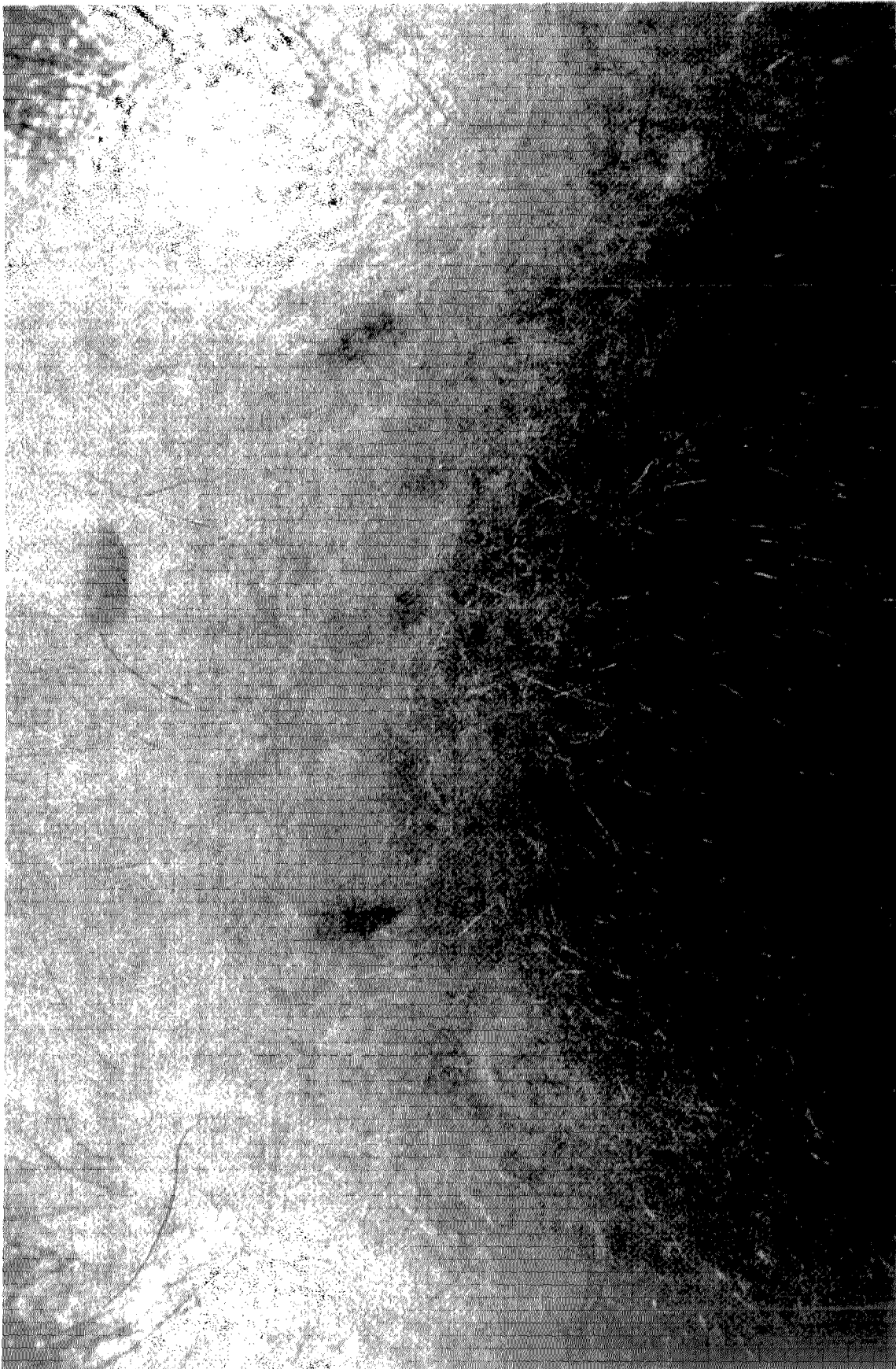


Figure 10C



Figure 11A

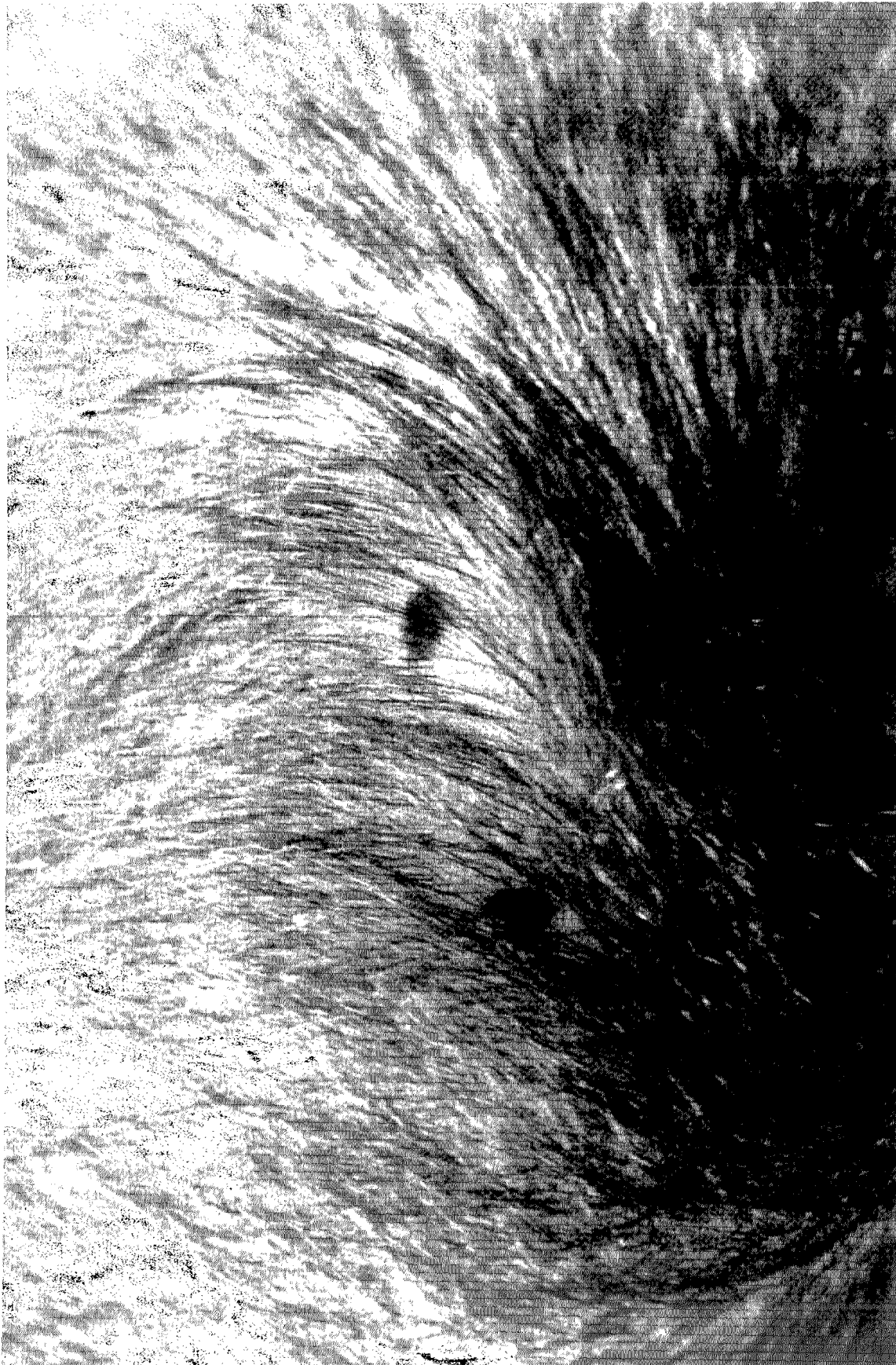


Figure 11B



Figure 11C



Figure 12A

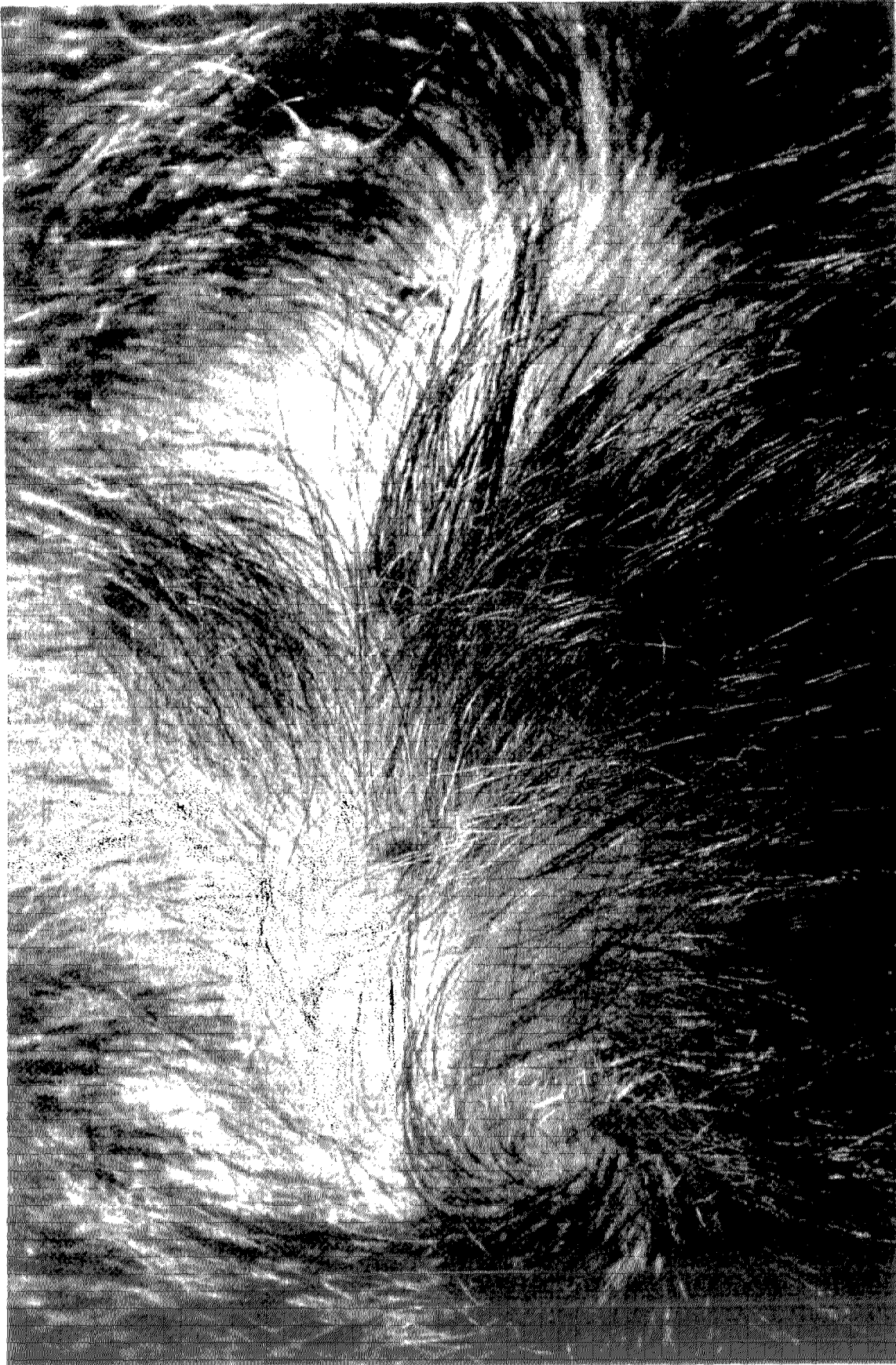


Figure 12B

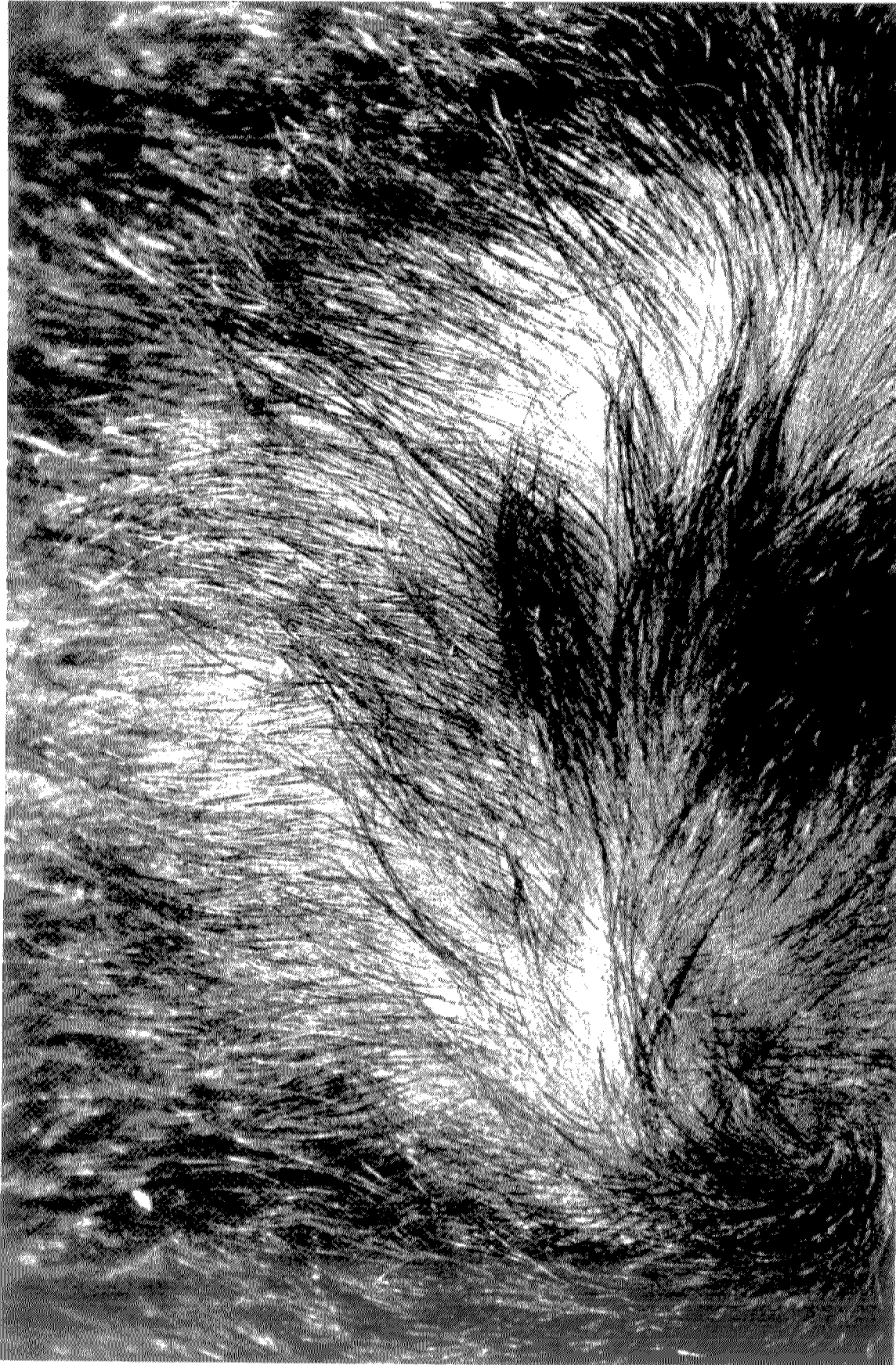


Figure 12C

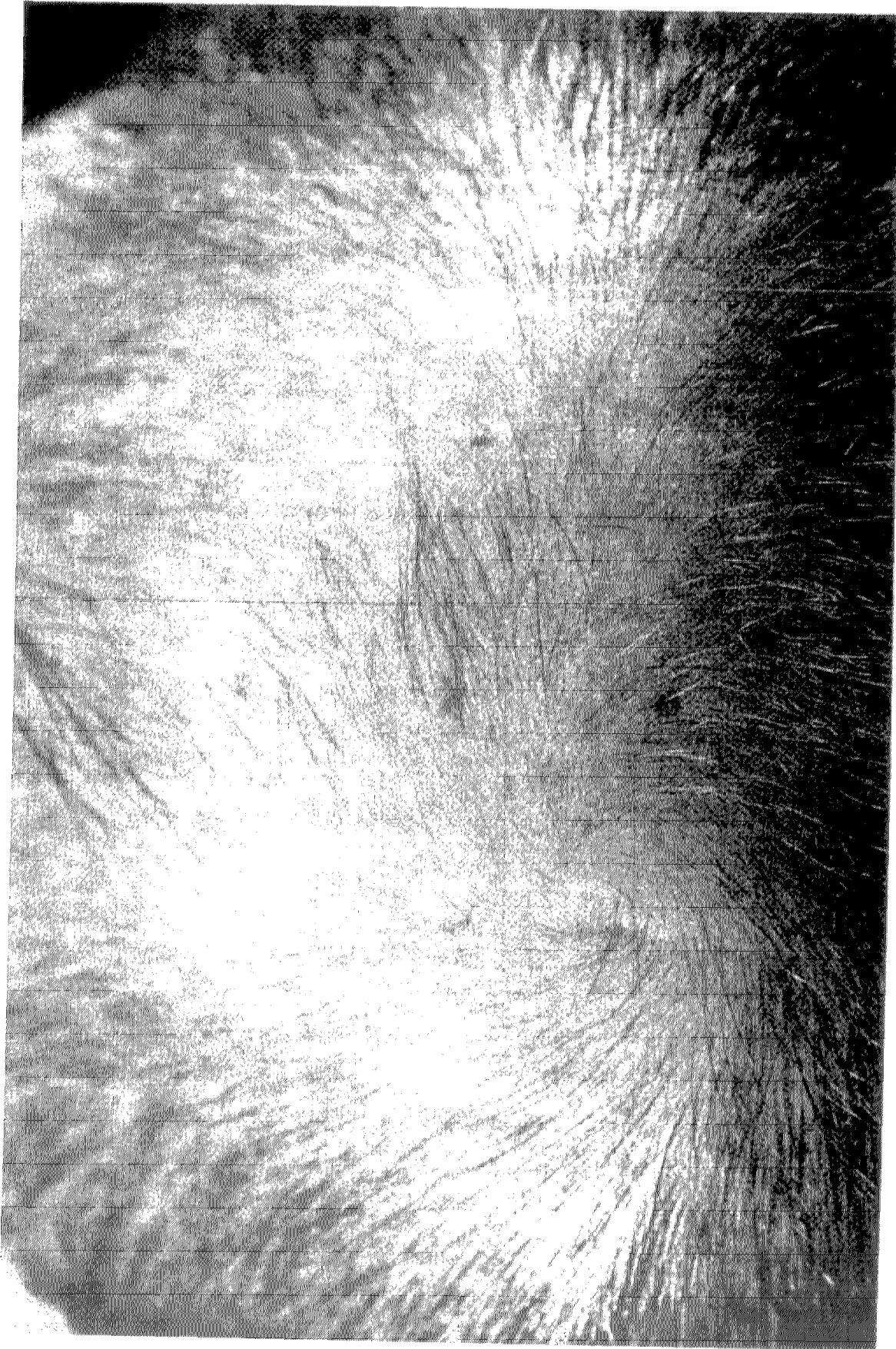


Figure 13A

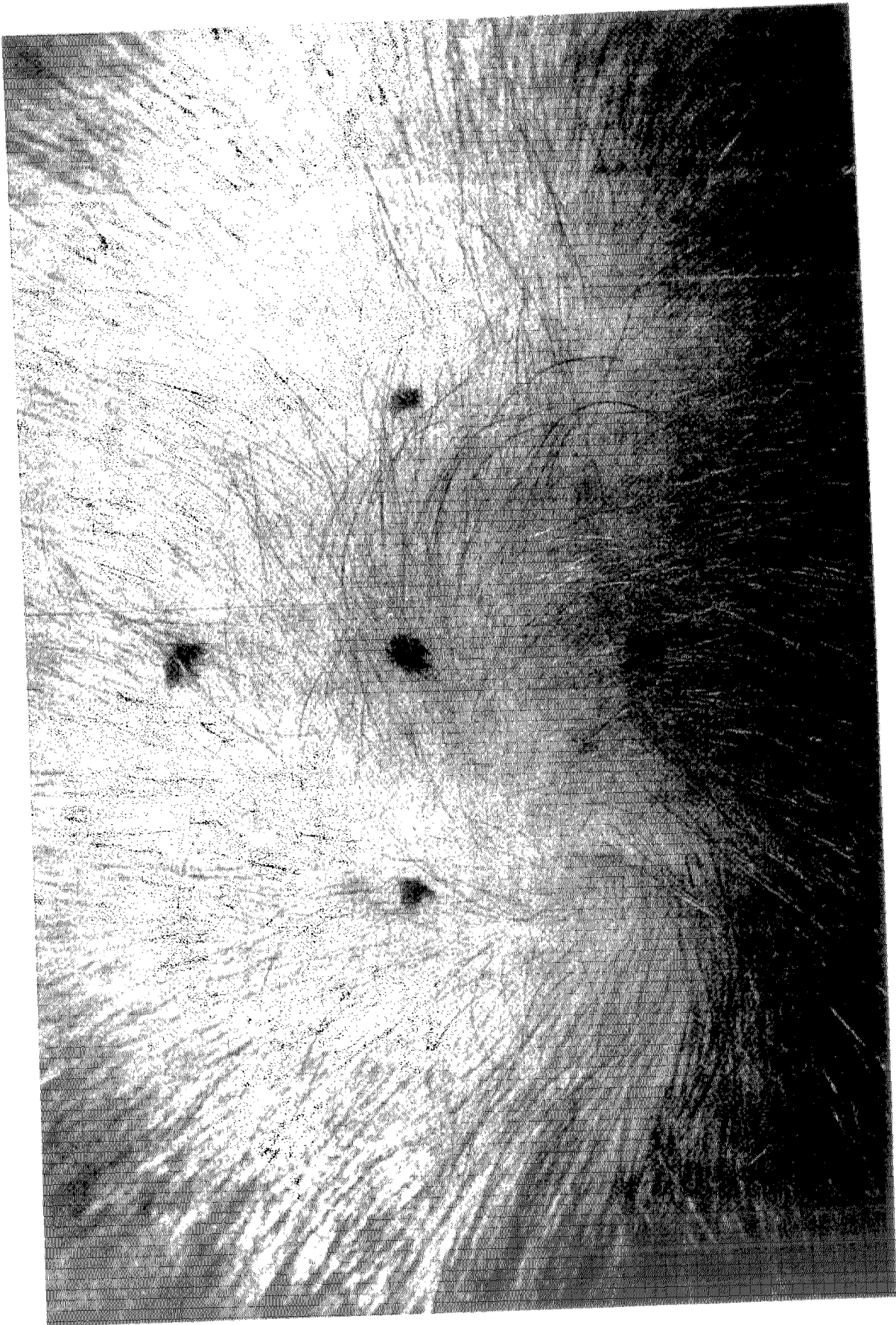


Figure 13B

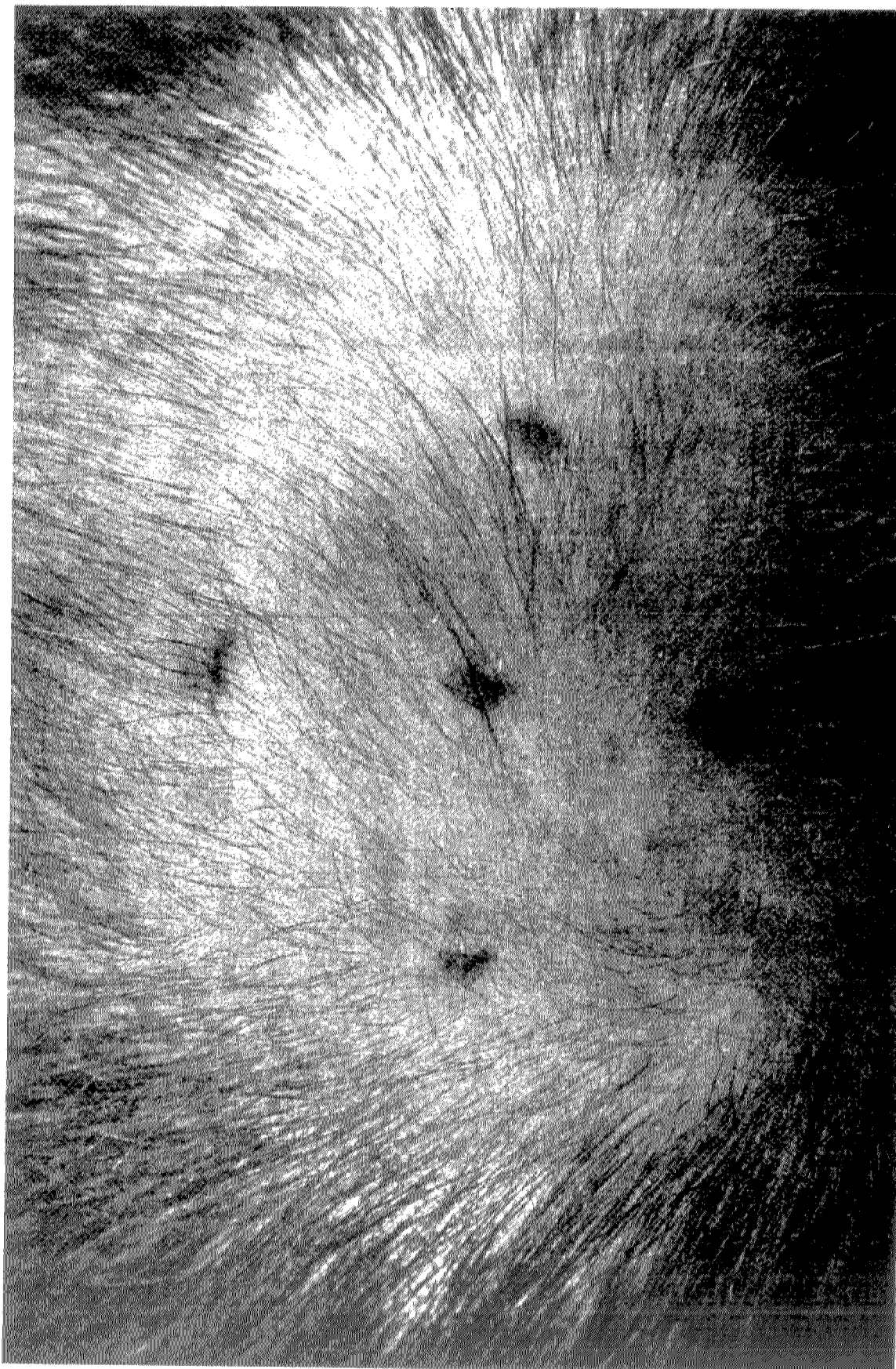


Figure 13C

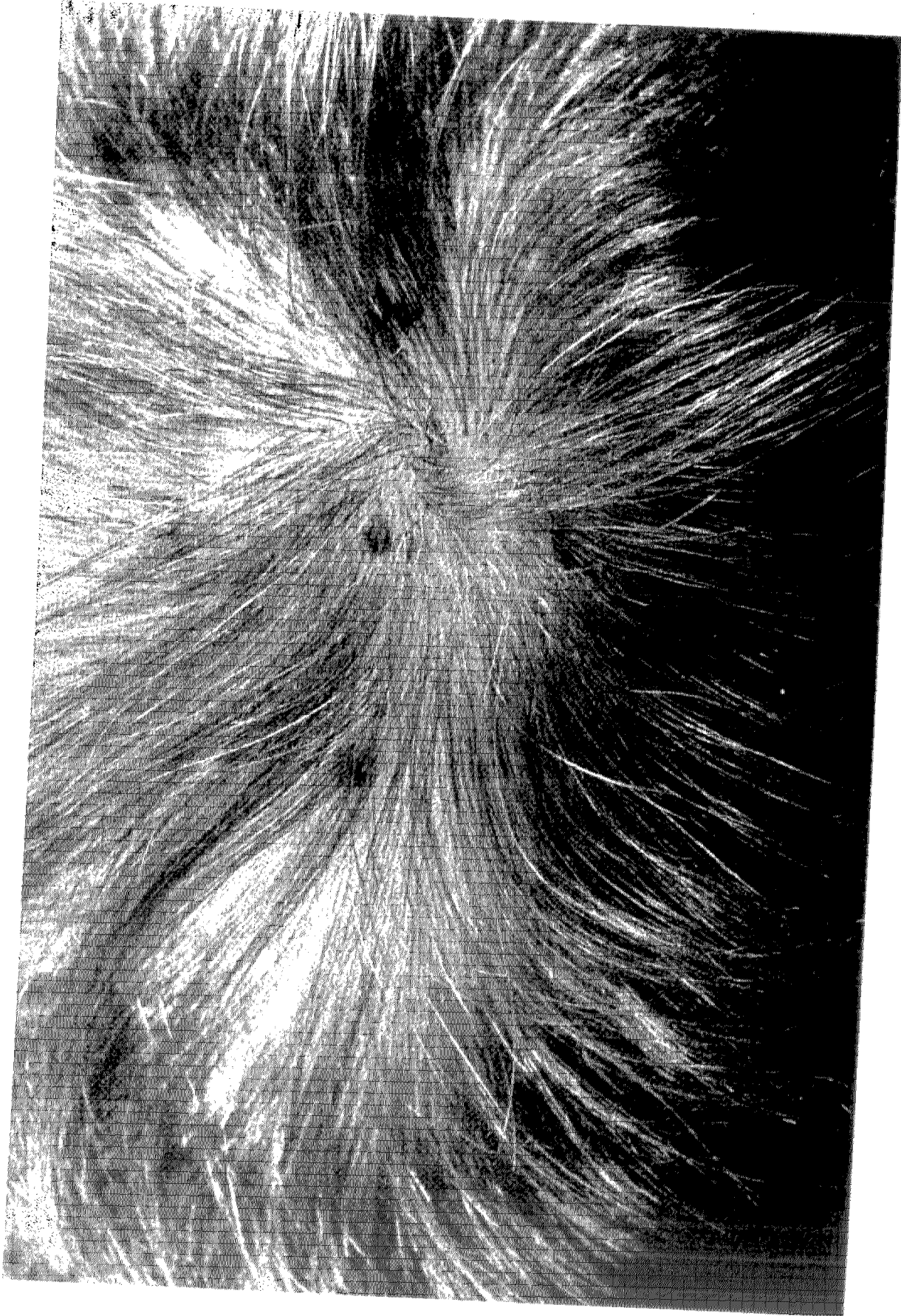


Figure 14A

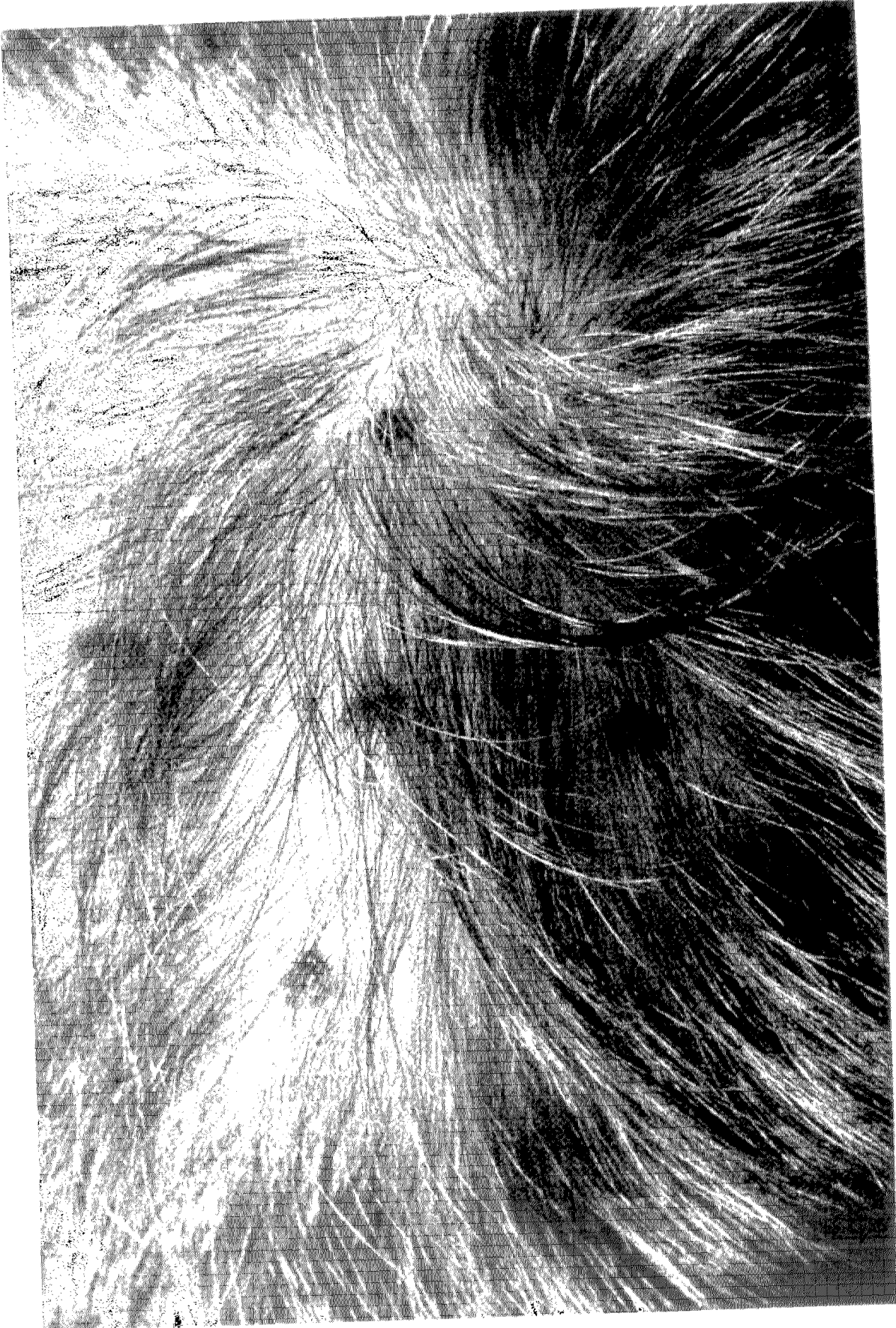


Figure 14B

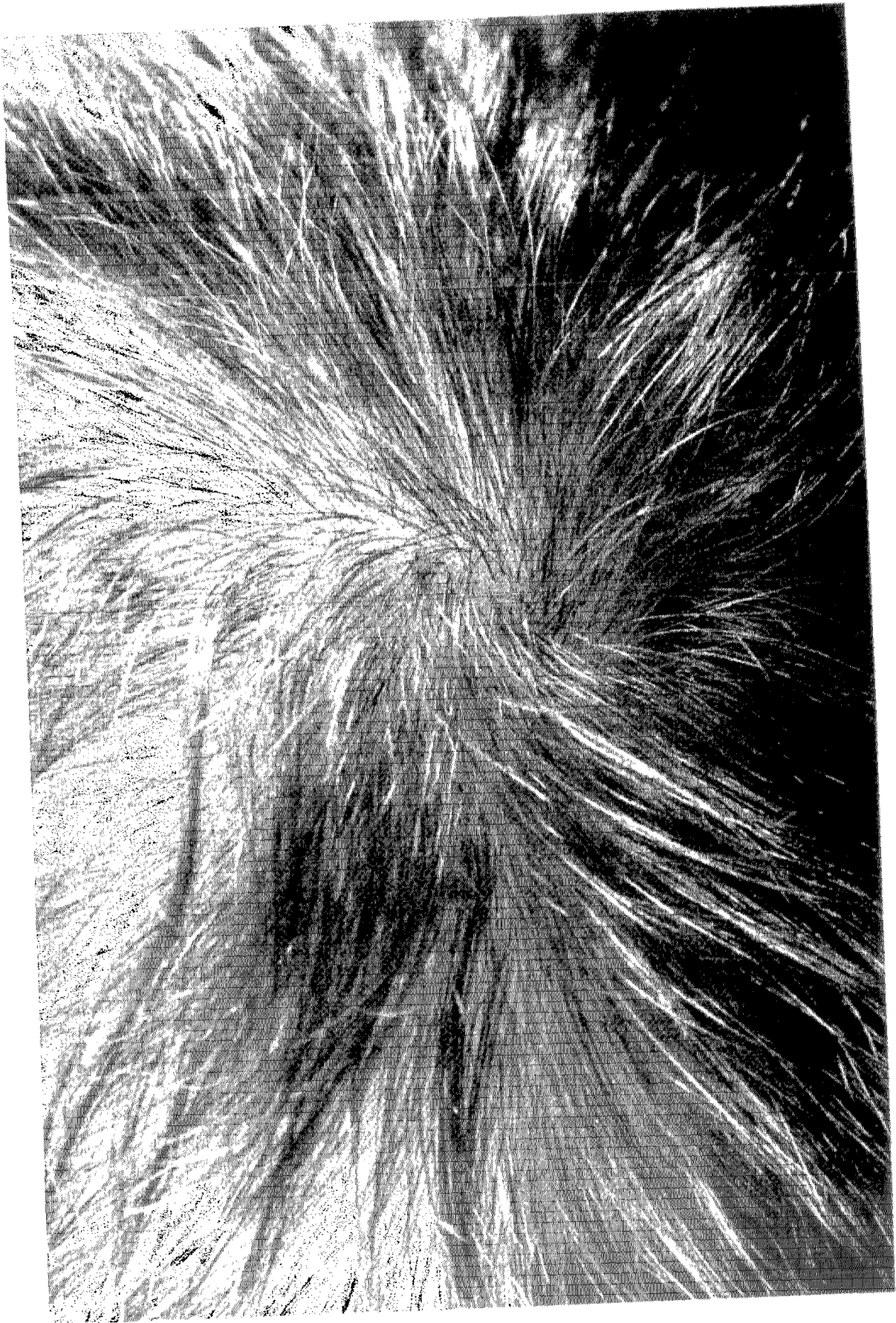


Figure 14C



Figure 15A



Figure 15B

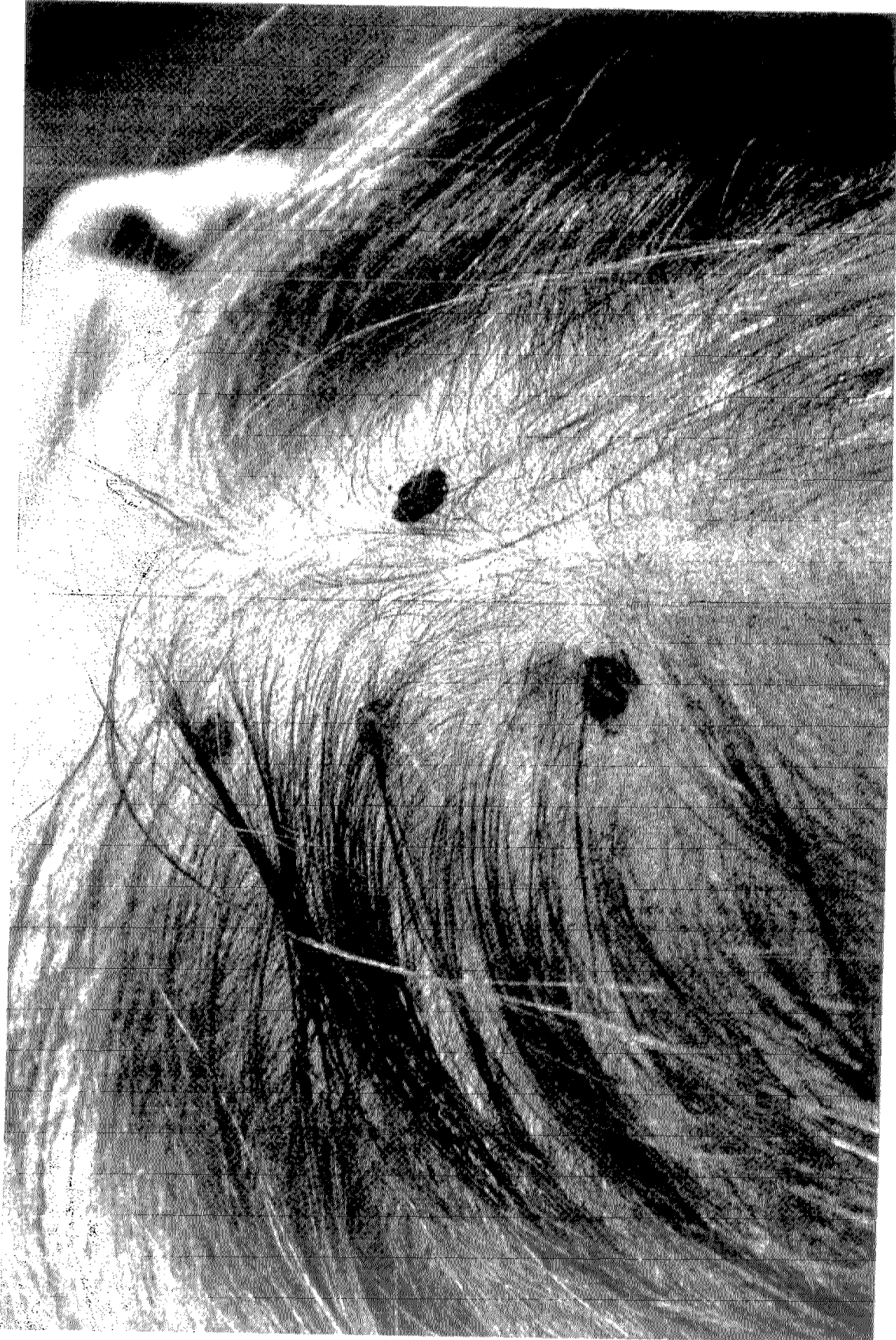


Figure 15C



Figure 16A



Figure 16B

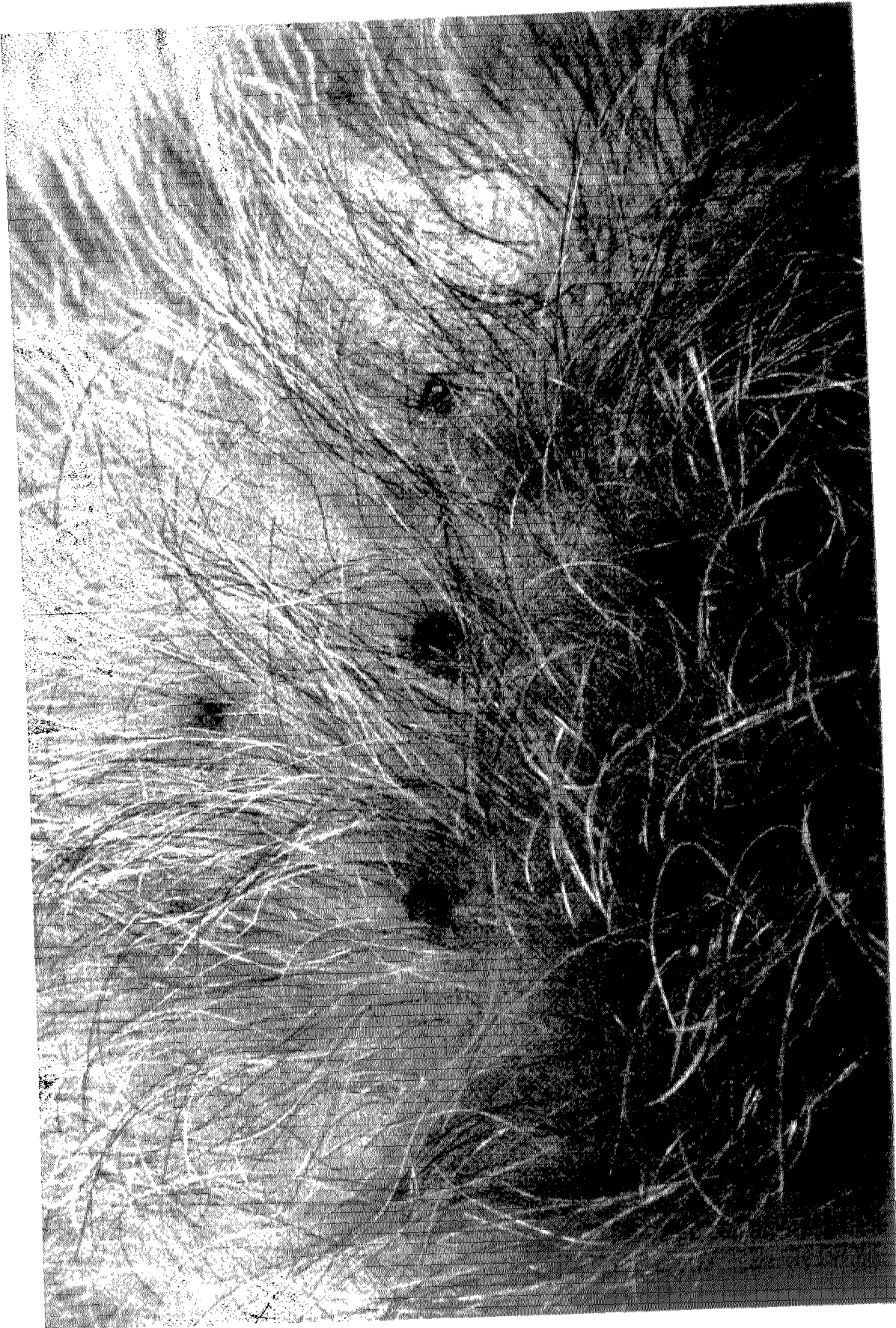


Figure 16C

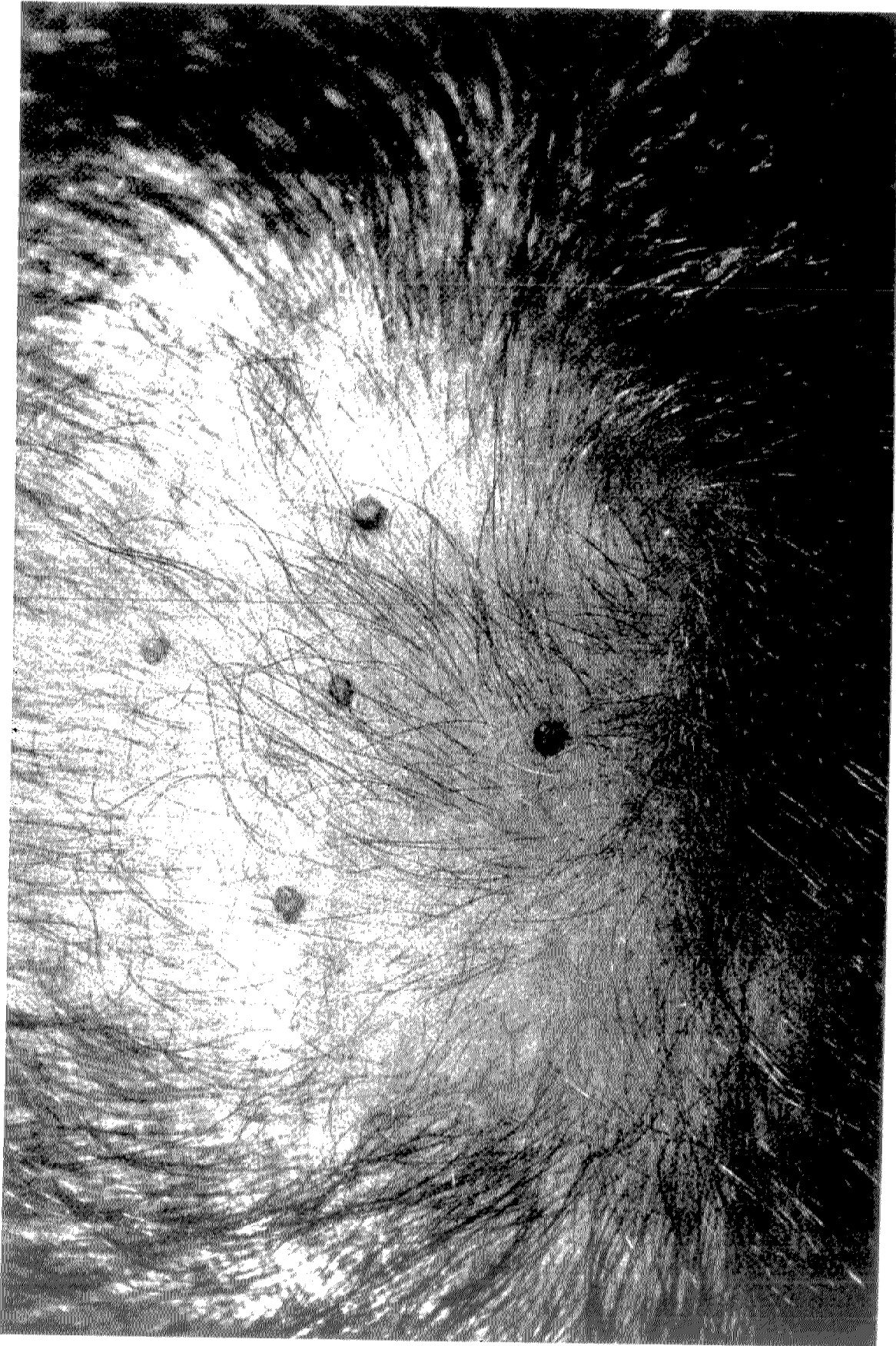


Figure 17A

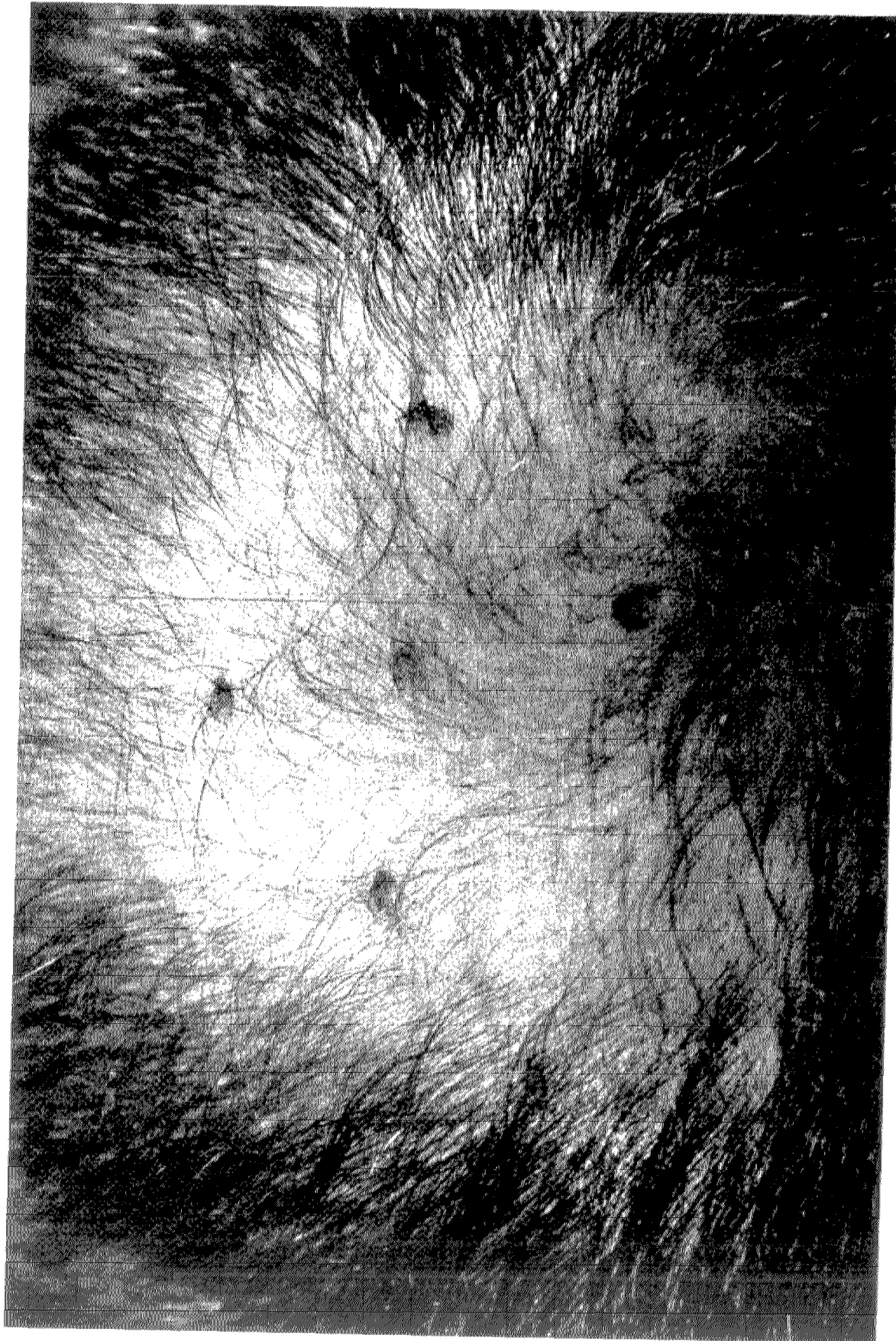


Figure 17B

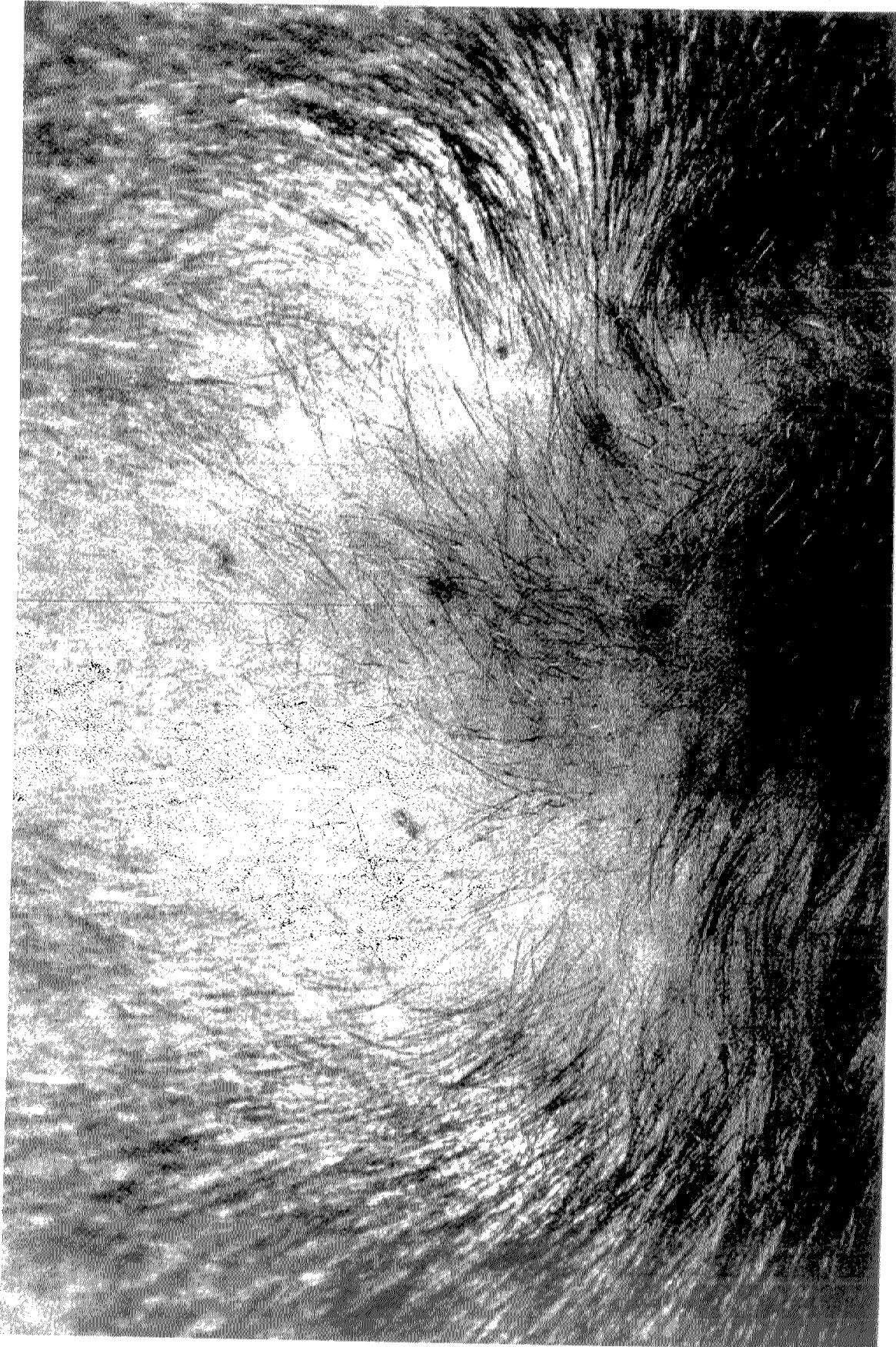


Figure 17C

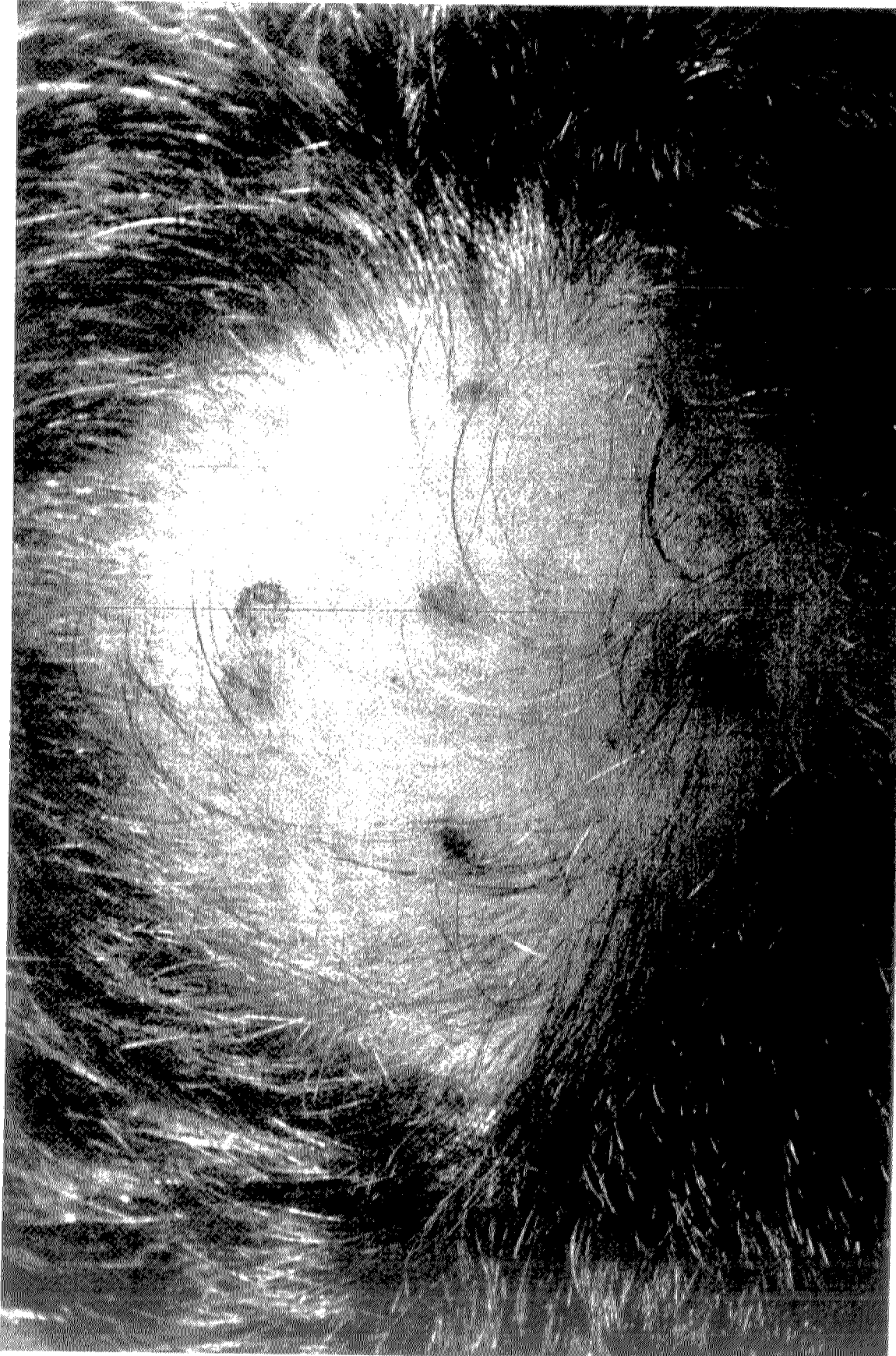


Figure 18A

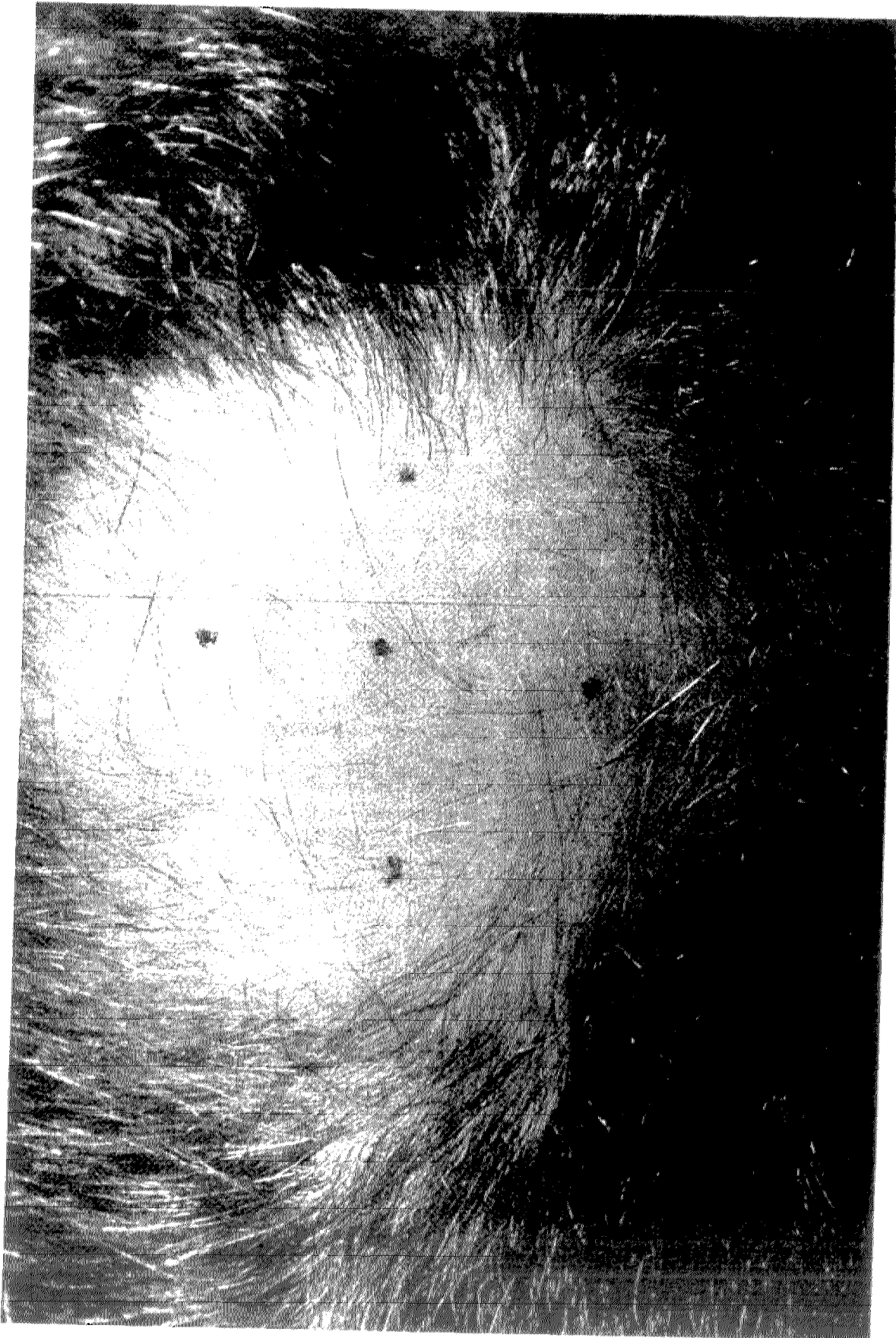


Figure 18B

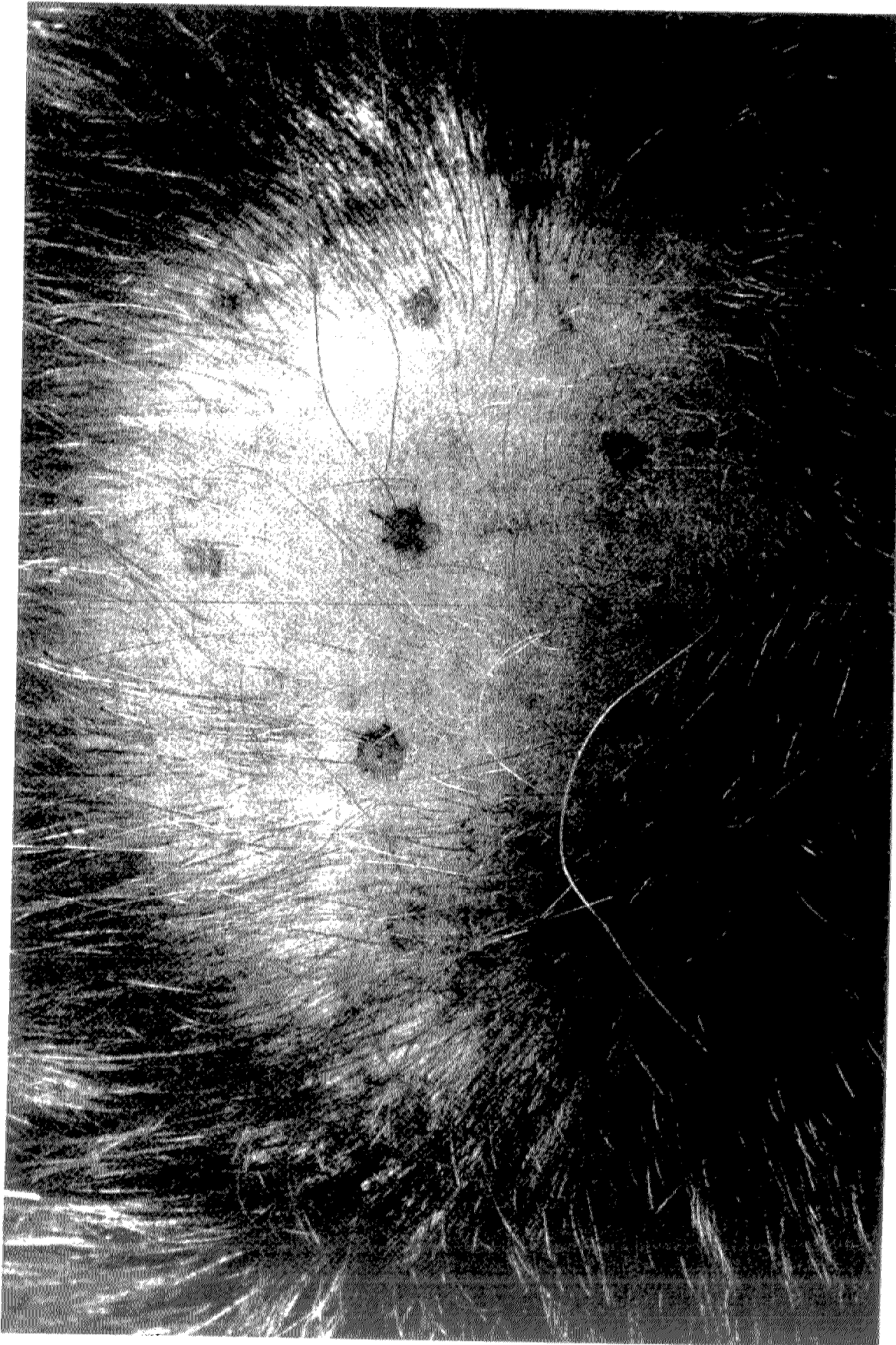


Figure 18C

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA2016/000132

A. CLASSIFICATION OF SUBJECT MATTER

IPC: *A61K 31/4045* (2006.01), *A61K 31/05* (2006.01), *A61P 17/14* (2006.01), *A61Q 7/00* (2006.01),*C07C 35/21* (2006.01), *C07D 209/16* (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61K 31/4045 (2006.01), *A61K 31/05* (2006.01), *A61P 17/14* (2006.01), *A61Q 7/00* (2006.01),
C07C 35/21 (2006.01), *C07D 209/16* (2006.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)

Databases: Google, Canadian Patent database, Questel-Orbit, Pubmed

Keywords: melatonin, resveratrol, hair, hairloss, hair growth

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CA2838646 (WOOD and WONG) 25 April 2013 (25-04-2013)	1-13
X	D2: KISKOVA ET AL, " <i>A combination or resveratrol and melatonin exerts chemoprotective effects in N-methyl-N-nitrosourea-induced rat mammary carcinogenesis</i> ". EUROPEAN JOURNAL OF CANCER PREVENTION, 2012, Vol. 12, pp. 163-170.	1
Y	D3: FISCHER, "Melatonin increases anagen hair rate in women with androgenetic alopecia or diffuse alopecia: results of a pilot randomized controlled trial." BRITISH JOURNAL OF DERMATOLOGY, 2004, Vol. 150, pp. 341-345.	1-6, 8-12
Y	D4: SARDI, " <i>ATTENTION ALL BALDING MALES: RESVERATROL TO YOUR RESCUE</i> ". RESVERATROL NEWS, 2 April 2012 (02-04-2012), [online] [retrieved on 14 June 2016 (14-06-2016)]. Retrieved from the Internet: http://www.resveratrolnews.com/attention-all-balding-males-resveratrol-your-rescue/520/	1-6, 8-12

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
19 July 2016 (19-07-2016)Date of mailing of the international search report
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INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/CA2016/000132

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
CA2838646A1	25 April 2013 (25-04-2013)	CA2838646A1	25 April 2013 (25-04-2013)
		AU2012325370A1	30 January 2014 (30-01-2014)
		EP2717866A2	16 April 2014 (16-04-2014)
		EP2717866A4	19 November 2014 (19-11-2014)
		US2014329785A1	06 November 2014 (06-11-2014)
		US9289428B2	22 March 2016 (22-03-2016)
		WO2013058838A2	25 April 2013 (25-04-2013)
		WO2013058838A3	12 September 2013 (12-09-2013)
