



COSMETOLOGY CENTER
UNIVERSITY OF FERRARA

EFFICACY EVALUATION OF
42 WHITENING BODYWAVE
FOR TREATING
SKIN SPOTS



PRODUCT	DATE	COMPANY
42 WHITENING BODYWAVE	12.2013	QUADRA MEDICAL SRL

**EVALUATION OF PLEASANTNESS AND
TREATMENT EFFICACY
BASED ON USE TEST**

DEVICE: 42 WHITENING BODYWAVE

COMPANY: QUADRA MEDICAL SRL

**Place and date of editing:
Cosmetology Center
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EXPERIMENTAL PROTOCOL

THE TEST WAS CONDUCTED FOR THE PURPOSE OF ASSESSING WHITENING EFFICACY ON SKIN HYPERMELANOSIS OF THE DEVICE:

42 WHITENING BODYWAVE

QUADRA MEDICAL SRL - STRADA CARTIGLIANA 143B, BASSANO DEL GRAPPA (VI) ITALY

EVALUATION CAME THROUGH **USE TEST**.

MATERIAL AND METHOD

SELECTION OF THE VOLUNTEERS: IN THE TEST WERE INCLUDED 12 VOLUNTEERS, AGE OVER 18 YEARS WITH LOCALIZED SKIN HYPERMELANOSIS NON-NAEVUS TYPE.

EXCLUSION CRITERIA: USE OF ORAL CONTRACEPTIVE
PREGNANCY
KNOWN HYPERSENSIVITY REGARDING THE EQUIPMENT
U.V. EXPOSURE DURING TEST
ACTIVE DERMATITIS WHERE TREATED

MATERIAL USED FOR THE TEST: 42 WHITENING BODY WAVE DEVICE.

EXECUTION SCHEME OF USE TEST: 2 SESSIONS A WEEK, 15 MINUTES FOR SESSION (LIGHT THERAPY + VIBRATION PLATE).

DURATION OF THE TREATMENT: 8 WEEKS.

EVALUATION TIMES: BEFORE THE BEGINNING OF THE TREATMENT (T₀), IN THE MIDDLE (T₄) AT THE END OF THE TREATMENT (T₈).

INSTRUMENTAL AND CLINICAL EVALUATION

Volunteers were subject to preliminary objective examination to evaluate their phototype and following skin alterations:

- melasma
- solar lentigo
- Hyper-melanosis post-inflammatory
- Other Hyper-melanosis

Before the beginning of the treatment (T₀), treated areas have been photographed with the instrument

KODAK EasyShare Z740 digital camera

MedicalSCOPE microcamera HR and acquisition software MedicalSCOPE v. 1.0.6 – company

FastBrain Engineering srl

Photographic monitoring of treated areas were repeated in subsequent periods of study (T₄ e T₈).

Pictures were subjected to computerized colorimetric analysis. The colour was expressed through system of **coordinates CIELab** through three numerical values: L* (brightness), a* (erythema), b* (pigmentation), by software: **Corel Photo-Paint X3, vers. 13.0.0.576**

STATISTICAL PROCESSING: data obtained were treated with the t test, considered to be significant for p values $< 0,05$ e and very significant for p values $< 0,01$.

TOLERABILITY: at each control, every possible occurrence of adverse reactions were reported (burning, itching or other intolerance cases) eventually occurred during the session.

RESULTS

All volunteers, aged between 39 and 55 (average age 47,9), completed the test.

Following pigment alterations have been submitted to treatment: solar freckles on the back of the hands, solar freckles on the face.

The variation of the colour was expressed through system of **coordinates CIELab** through three numerical values: **L* (brightness), a* (erythema), b* (pigmentation)**.

Table 1 shows, for each volunteer, values of L*a*b* resulted from the colorimetric analysis of the pictures obtained in time T₀ , T₄ e T₈.

Table 1.

Vol.	Lesion								
	t ₀			t ₄			t ₈		
	L	a	b	L	a	b	L	a	b
1	75,5	15	22	68,50	12,50	17,00	60,50	8,00	7,00
2	62	10,5	15	62,50	9,00	12,00	57,50	11,00	12,00
3	45	19,5	21	56,00	16,00	18,00	56,00	11,00	9,50
4	47	12,5	14,5	40,50	10,50	11,50	51,00	12,00	9,00
5	54	15	15	51,00	12,00	10,00	50,00	9,50	9,00
6	52,5	17	27,5	54,00	9,00	10,00	65,00	8,00	10,00
7	46,5	14,5	11	59,00	10,00	6,00	69,00	6,50	4,00
8	56,5	12,5	12	44,00	11,00	10,00	44,00	11,00	10,00
9	49,5	14	16	58,00	10,00	11,00	51,00	11,50	7,50
10	51,5	11	14	53,50	12,50	14,00	51,00	11,00	11,00
11	74	5	5	64,00	9,00	8,00	73,00	7,00	4,00
12	46	12	21	45,00	12,00	17,50	45,00	2,50	2,50
Average	55,0	13,2	16,2	54,7	11,1	12,1	56,1	9,1	8,0
<i>t Test:</i>				0,444		0,007	0,363		0,0003
Δ%:				-0,606		-25,258	1,970		-50,773

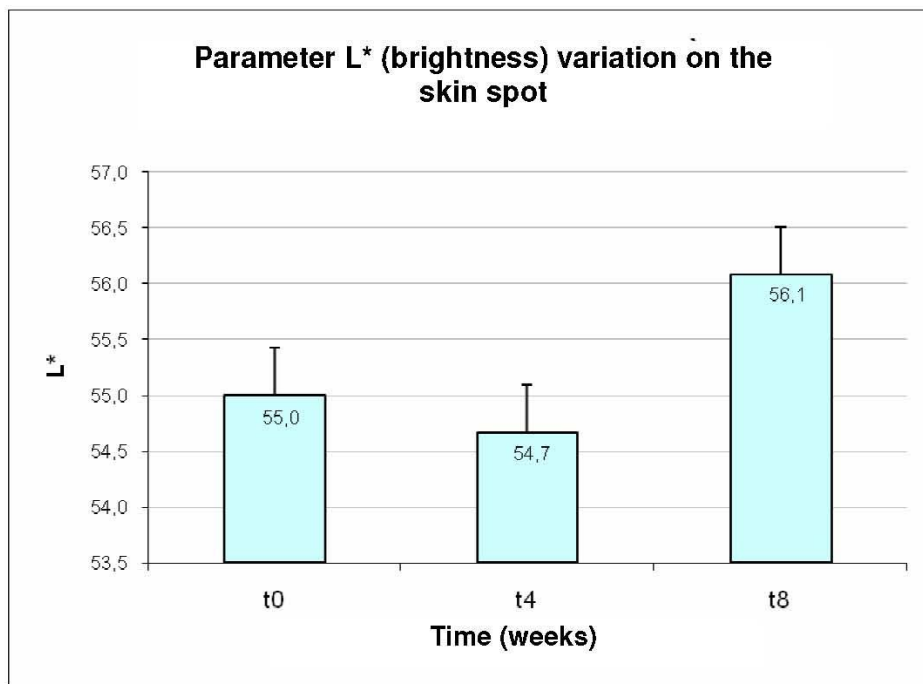
L* (luminosity) parameter.

Graphic 1a shows trend over the time of the average parameter L* (luminosity). The comparison among the initial average brightness (T0:55,0) and the average brightness in following times of evaluation, has underlined a progressive increase of such parameter (T4:54,7 - T8:56,1).

The variation obtained at the end of the period of study isn't statistically meaningful ($p < 0,05$). (T4: $p=0,444$ - T8: $p=0,363$).

Graphic 1a

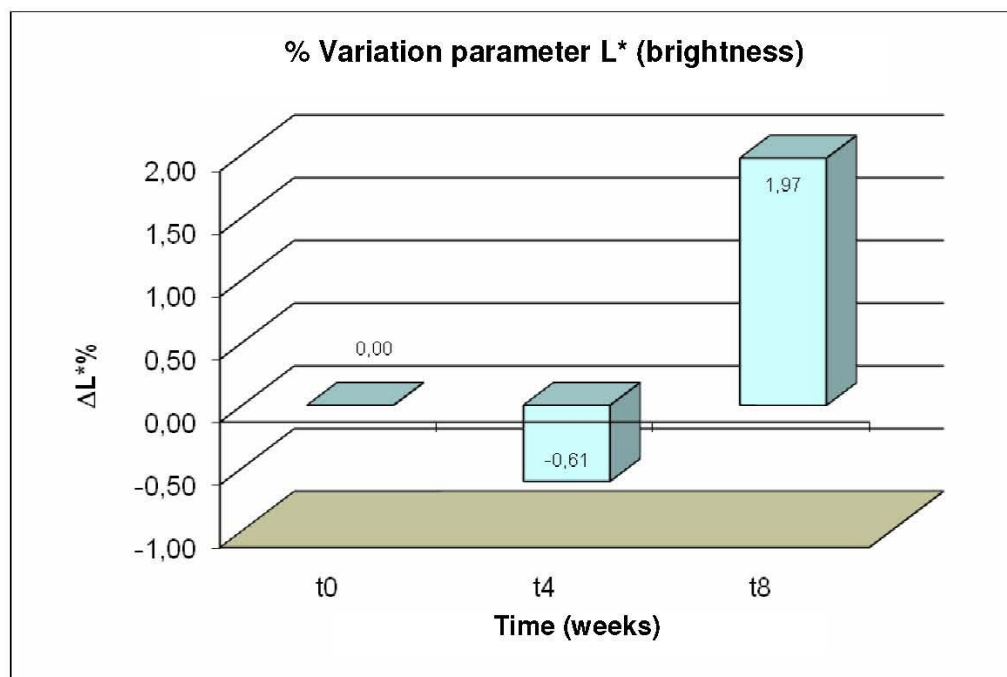
t ₀	55,0
t ₄	54,7
t ₈	56,1



Graphic 1b shows percentage increase over the time of the parameter L* (T₄:-0,61% - T₈:1,97%).

Graphic 1b

t ₀	55,0	t ₀	0,00
t ₄	54,7	t ₄	-0,61
t ₈	56,1	t ₈	1,97

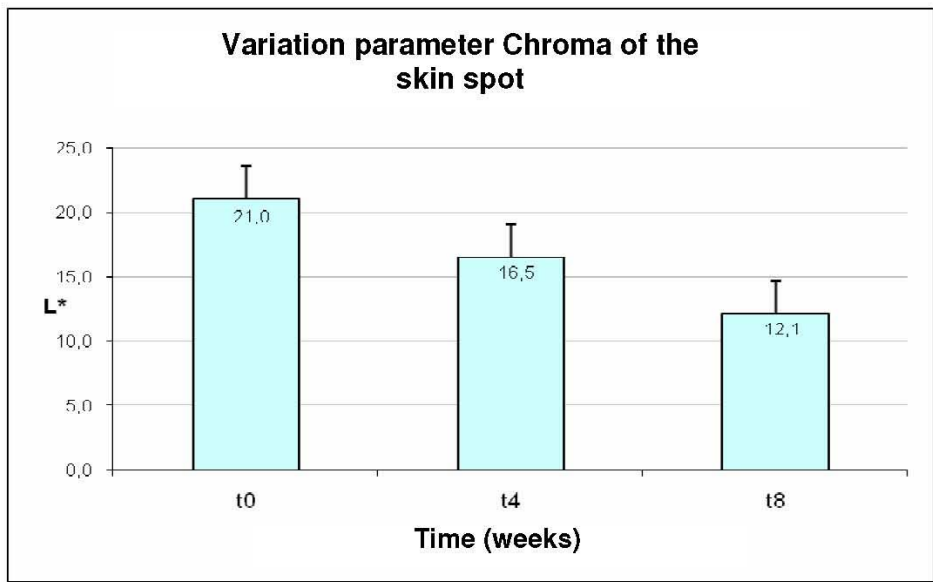


Chroma (colour).

Graphics 2a and 2b show trend over time of absolute and percentage values of skin Chroma (colour) of the hyper-pigmented area.

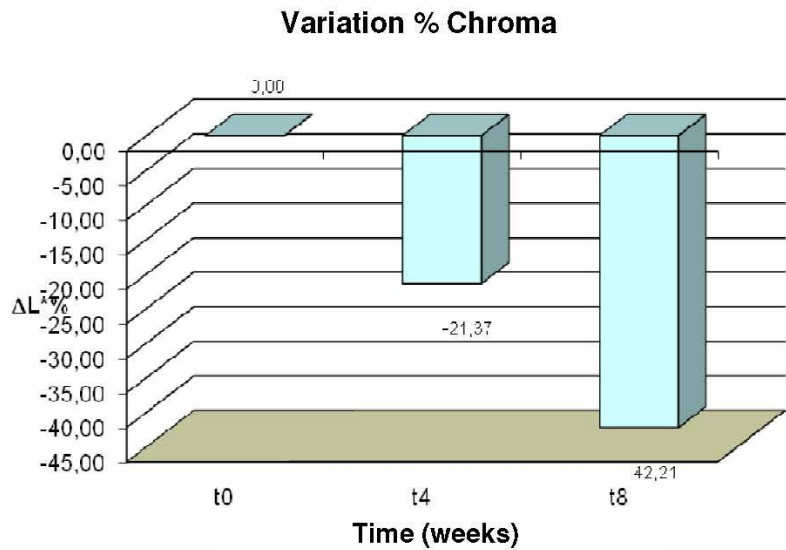
Graphic 2a

t ₀	21,0
t ₄	16,5
t ₈	12,1



Graphic 2b

t ₀	21,0	t ₀	0,00
t ₄	16,5	t ₄	-21,37
t ₈	12,1	t ₈	-42,21

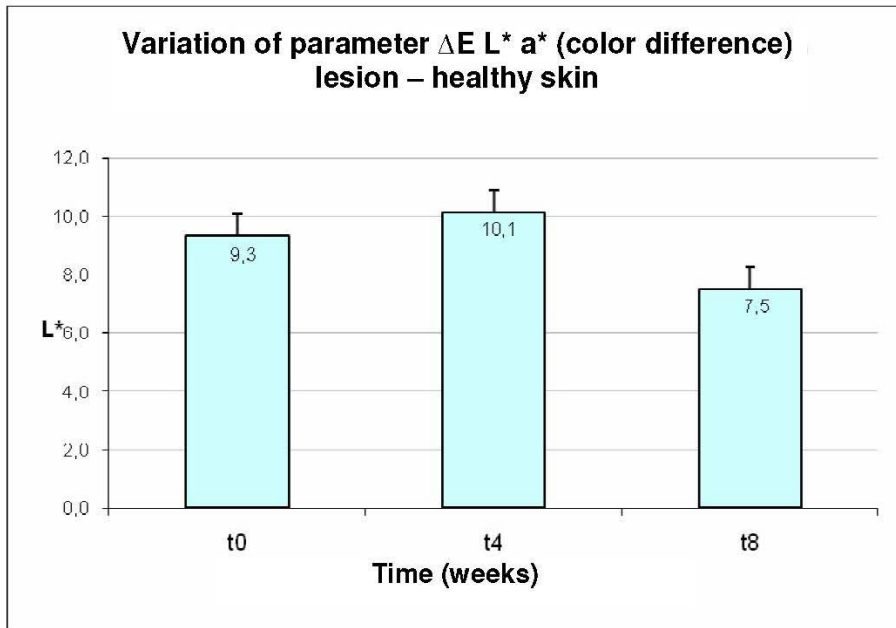


Colour difference ($\Delta E L^*b^*$)

Graphics 3a e 3b show colour difference ($\Delta E L^*b^*$) between healthy skin and hyper-pigmented lesion.

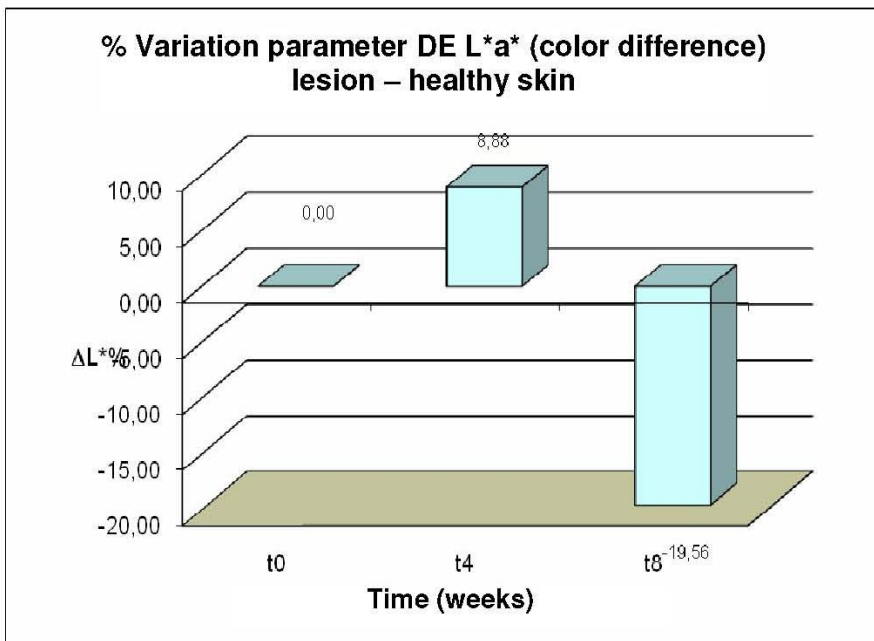
Graphic 3a

t_0	9,3
t_4	10,1
t_8	7,5



Graphic 4b

t_0	9,3	t_0	0,00
t_4	10,1	t_4	8,88
t_8	7,5	t_8	-19,56

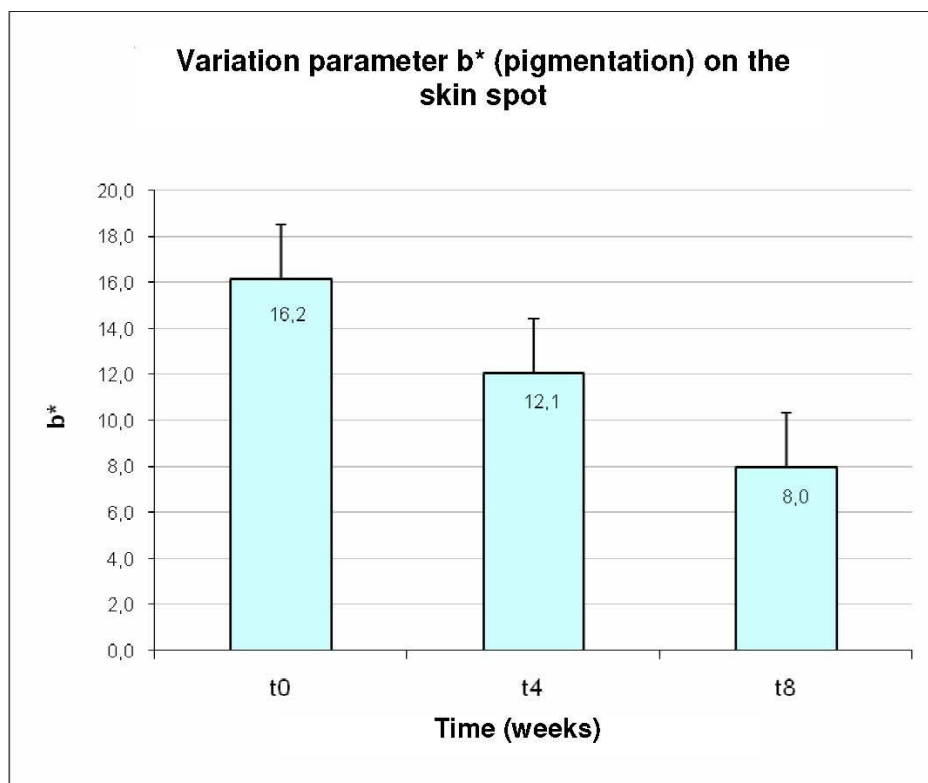


b* (pigmentation) parameter.

Graphic 4a shows trend over time of average value parameter **b* (pigmentation)**, obtained at the beginning of the test (T₀:16,2) and in following evaluation times (T₄:12,1 - T₈:8,0), has highlighted a significant statistical variation at the end of the study period (T₄:p=0,007 - T₈: p=0,0003).

Graphic 4a

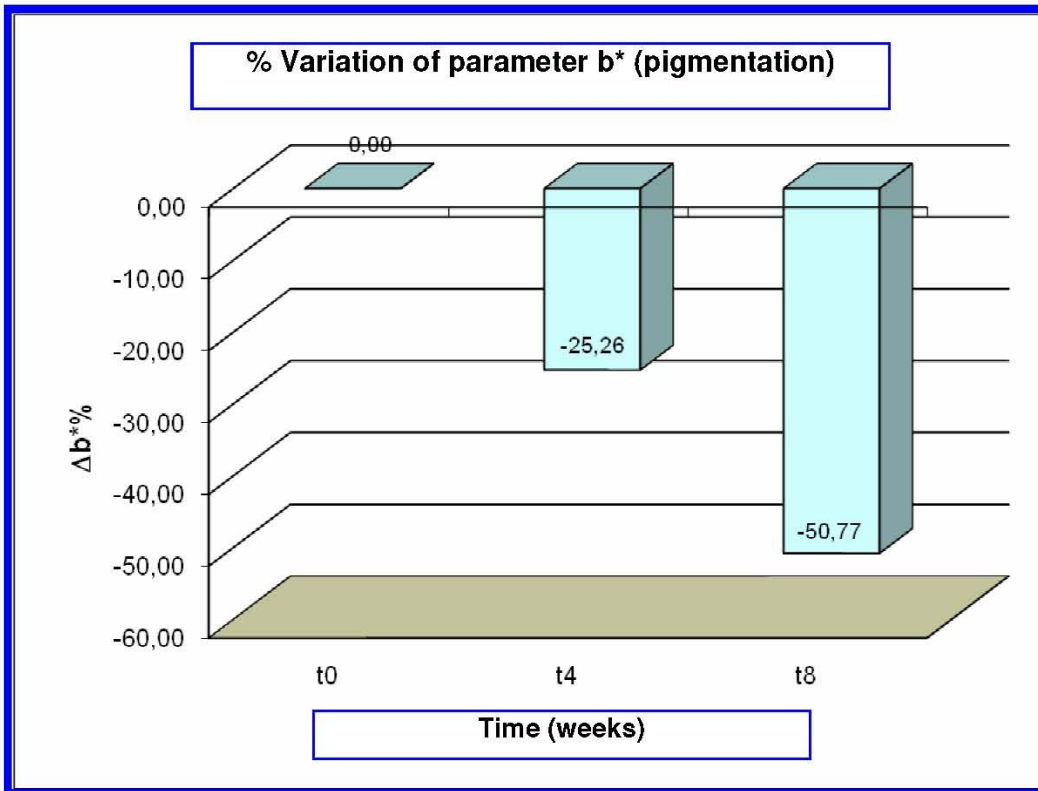
t ₀	16,2
t ₄	12,1
t ₈	8,0



Graphic 4b shows percentage variation over the time of parameter b* (T₄: -25,258% - T₈: -50,773%).

Graphic 4b

t ₀	16,2	t ₀	0,00
t ₄	12,1	t ₄	-25,26
t ₈	8,0	t ₈	-50,77



Below photos showing 2 treated spots at time T_0 beginning, T_4 after 4 weeks and T_8 after 8 weeks. It can be seen a progressive lightening and brightening of the spots treated and also the overall area around them.



T_0



T_4



T_8



T_0



T_4



T_8

None of the volunteers expressed phenomenon of intolerance to the treatment.



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CONCLUSIONS

INSTRUMENTAL EVALUATIONS REGARDING THE EFFICACY OF THE DEVICE:

42 WHITENIG BODYWAVE

QUADRAMEDICAL SRL

USED THE DEVICE LIKE REPORTED ON THE PROTOCOL FOR 8 WEEKS, HAVE HELPED TO HIGHLIGHT A SIGNIFICANT EFFECTIVENESS IN INCREASING SKIN BRIGHTNESS, DECREASING THE EVIDENCE OF SKIN HYPER-MELANOSIS AFTER 8 WEEKS OF USE.

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UNIVERSITÀ
DEGLI STUDI
DI FERRARA

A brief history of Ferrara University

The University of Ferrara is one of the oldest in Italy. It was founded in 1391 by Alberto V, Marquis of Este, and granted by Pope Boniface IX.

The origins : The earliest courses were in the arts, theology and law and from the very beginning it attracted well-known teachers. These included Bartolomeo of Saliceto, "Prince of the jurists", and Guarino of Verona, who had Enea Silvio Piccolomini (the future Pope Pious II) among his pupils.

The 15th and 16th centuries : During the 15th and 16th centuries, the University witnessed the splendour of the city, as it developed into one of the most important cultural centres of the Italian Renaissance. In this period, the fame of the Este University was enriched by the presence of many great intellectuals. Among them were the Portuguese botanist Amato Lusitano; Copernicus' teacher, Domenico Maria Novara; and Celio Calcagnini, the mathematician, man of letters, poet, philosopher and jurist.

In 1598, Ferrara came under the control of the Papal States and the University underwent the reforms and changes required by the Papacy. Alternating periods of crisis and difficulty followed, due to a gradual decline in student numbers. It was only in 1771 that reformatory measures established a financial endowment and a permanent administrative structure for the University.

After the French Revolution: When the French Revolution occurred, the University gained importance and the professors were called up by the city authorities. The University of Ferrara took an active part in the Cispadana Republic and in 1797 it became the first European university with a course in constitutional law. In 1803, the University was changed into a secondary school due to the extremely low number of students. It had to wait until after the Restoration to resume its university status. At this time there were three faculties: Law, Mathematics and Medicine, and three schools: Notary, Pharmacy and Obstetrics.

The 20th century: At the beginning of the 20th century, the University of Ferrara had over 500 students, marking it as the most popular of the independent Italian universities. During the Fascist period, in 1934, the school of Pharmacy was upgraded to a Faculty. This added to the three existing faculties of Law, Medicine and Surgery, and Science.



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