Table I. Risk of vitiligo in organ transplant recipients compared to matched controls

				Univariate analysis		Multivariate analysis	
	Population	Vitiligo	3-year risk of vitiligo	Crude OR (95% CI)	*P* value	Adjusted OR (95% CI)*	*P* value
Matched controls	44,136	88	0.20%	Reference		Reference	
Organ transplant recipients	14,712	8	0.05%	0.272 (0.132-0.562)	.0004	0.305 (0.148-0.630)	.0013

CI, Confidence interval; *OR*, odds ratio.
*Adjusted by age, sex, and insurance type.

Table II. Risk of vitiligo in organ transplant recipients according to the transplanted organ and the use of immunosuppressants

				Immunosuppressant*					
	Population	Vitiligo	3-year risk of vitiligo	Tacrolimus	Mycophenolate mofetil	Cyclosporine	Mycophenolate sodium	Azathioprine	Sirolimus
Matched controls	44,136	88	0.20%						
Organ transplant recipients	14,712	8	0.05%	60.36%	53.81%	42.44%	28.02%	5.93%	2.89%
Kidney	10,223	6	0.06%	50.08%	53.14%	53.49%	38.90%	8.10%	4.05%
Liver	4474	2	0.04%	85.19%	54.49%	15.62%	3.31%	0.67%	0.25%
Heart and/or lung	214	0	0.00%	49.53%	77.10%	62.15%	19.16%	10.28%	0.93%

*Immunosuppressants taken for >180 days in organ transplant recipients.

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Activation of melanocytes in idiopathic guttate hypomelanosis after 5-fluorouracil infusion using a tattoo machine: Preliminary analysis of a randomized, split-body, single blinded, placebo controlled clinical trial

To the Editor: This letter presents a preliminary analysis of the first 8 patients who have completed a randomized clinical trial for idiopathic guttate hypomelanosis (IGH) treatment that was approved by the respective ethics committee and registered in the ClinicalTrials.gov database under identifier NCT02904564. The rationale for this study was the preliminary histologic analysis of IGH spots in which we observed varying degrees of papillary dermis fibrosis.[1] Fulton et al[2] described the repigmentation of hypopigmented scars arising from different etiologies after mechanical removal of dermal fibrosis. The formulated hypothesis was that IGH repigmentation could occur if the underlying dermal fibrosis were removed. Instead of mechanically removing this fibrosis, as described by Fulton et al,[2] we attempted to remove or reduce it by delivering medication with antifibrotic properties. Because of its low cost, injectable 5-fluorouracil (5-FU) was the drug of choice, which has been used for scar treatment since 1990.[3] We named the drug delivery technique used in this clinical trial MMP (the Portuguese acronym for microinfusão de medicamentos na pele [ie, microinfusion of drugs into the skin]).[4] This technique drew inspiration from the ancient art of tattooing. In MMP, the tattoo machine's needles convey the medication contained in the sterile needle cartridge into the skin (Fig 1, *B* and *C*)—ie, the microneedling and injection processes occur simultaneously (Fig 1, *A*). Needling depth is gradually adjusted until mild pinpoint bleeding is achieved (Fig 1, *D*), which is an indication that the dermis has been reached.

The intervention was done using a Cheyenne tattoo machine by MT.DERM (Berlin, Germany), the only equipment of the sort approved by the Brazilian Health Agency (ANVISA) for medical use. Two dermatologists, blinded to the randomization, determined the limb present the best therapeutic outcome by clinical analysis (Fig 2, *A-D*). Statistical analysis was performed using Antera 3D[5] (Miravex, Dublin,

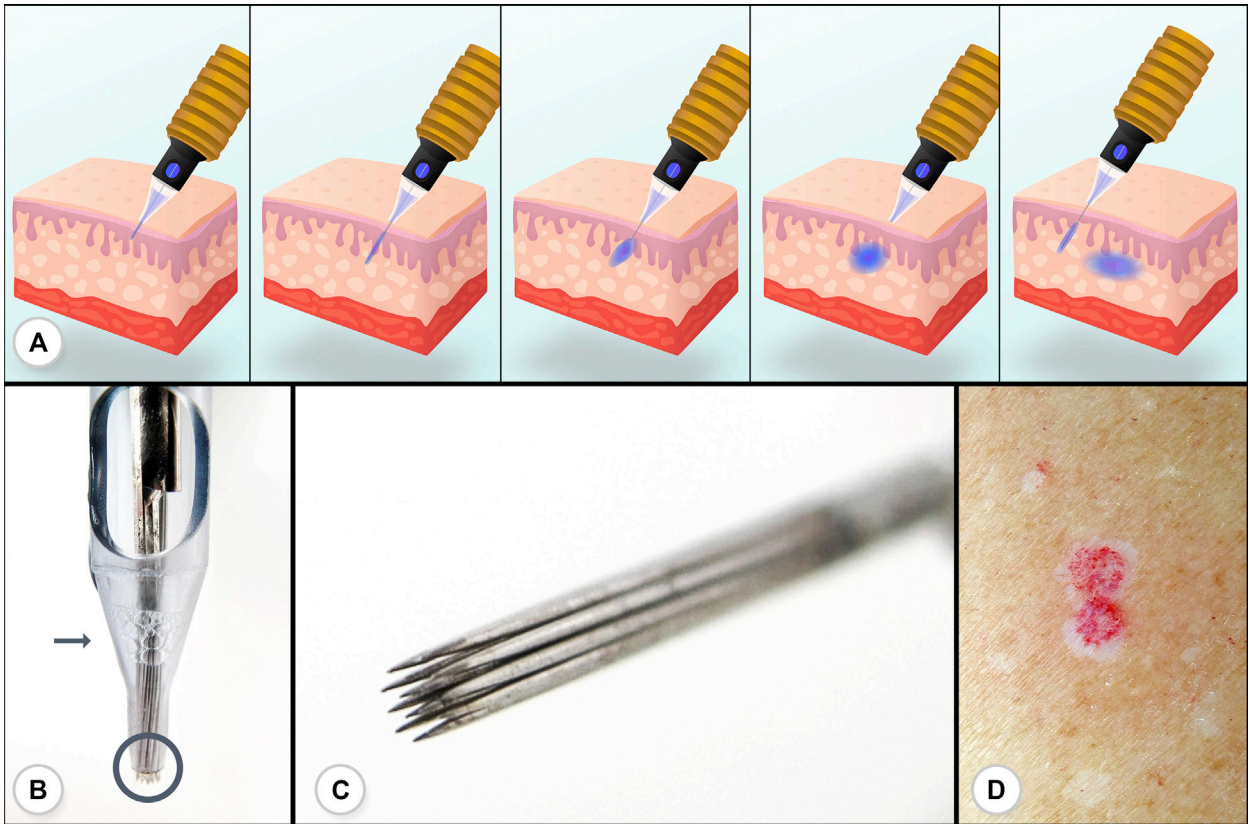

Fig 1. Details of the microinfusão de medicamentos na pele (MMP; microinfusion of drugs into the skin) procedure. **A**, Sequence of illustrations detailing how the drug is inserted into the dermis. The device used for MMP contains a set of needles in a sterile cartridge. The physician loads the cartridge with the desired drug and starts the microneedling process. During each microneedling cycle, the needles are soaked with the drug, and the skin is then perforated deeply enough to reach the dermis, with simultaneous delivery of the drug. **B**, Close view of the cartridge itself. The arrow indicates the level of 5-fluorouracil, also visible because of the bubbles. The circle indicates the tips of the set of needles. **C**, Enlarged image of the set of needles. **D**, Appearance of 2 idiopathic guttate hypomelanosis lesions partially subjected to drug delivery. The procedure was initially performed only in the central regions of these lesions and was subsequently used to treat the entirety of these spots.

Ireland; Fig 2, *E* and *F*), a device with image analytics software capable of quantifying melanin in each IGH macule (Fig 2, *G*). Fig 2, *H* presents the repigmentation percentages of both limbs for all patients. The data show that IGH repigmentation after 5-FU MMP treatment was statistically higher when compared with placebo MMP (75.3% 5-FU repigmentation vs. 33.8% placebo, $P < .001$). Two patients submitted to biopsy 40 days after the procedure presented numerous melanocytes in the 5-FU–treated areas, thereby eliminating the possibility of postinflammatory hyperpigmentation. One patient with Fitzpatrick skin phototype III developed hyperpigmentation areas on both treated limbs 30 days after the intervention, which spontaneously reversed within 2 months.

Partial repigmentation of placebo-treated lesions may have been caused by collagen remodeling induced by simple microneedling of the papillary dermis. We believe that 5-FU MMP treatment may be beneficial in treating IGH. Even though no adverse effects were observed in MMP-treated patients, the safety and efficacy of this 5-FU drug delivery method needs to be proven by means of additional studies.

Tattooing is an ancient technique under public domain done mainly by tattoo artists, we have chosen to copyright the acronym MMP in Brazil and the United States and grant free use exclusively to dermatologists who are members of the Brazilian Society of Dermatology and equivalent entities around the world. Dr Arbache's commercial involvement in this investigation was required in order to obtain approval of the equipment for medical use

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