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Title: A comparative study between the two patch test systems Finn Chambers® and Finn Chambers® AQUA.

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Abstract

BACKGROUND: Finn Chambers AQUA® (FCA) is a development of the Finn Chambers (FC) test system where the test chambers are mounted on a moisture-resistant adhesive patch. FCA have pre-fixed filter papers. Since the use of FCA does not require any extra taping or use of separate filter papers, a change from FC to FCA chambers may be beneficial for both patients and patch test technicians.

OBJECTIVES: To investigate whether there are any differences regarding detection of contact allergy when simultaneous patch testing is performed with FC and FCA.

MATERIALS AND METHODS: Results from 434 dermatitis patients; simultaneously tested with 10 allergens in both FC and FCA were evaluated.

RESULTS: There were no significant differences regarding detection of positive reactions between the two test systems. There were significantly more doubtful reactions to methylisothiazolinone, fragrance mix I and hydroperoxides of linalool when testing with FCA. We only observed significantly more doubtful reactions in FC regarding nickel(II)sulfate. Irritant reactions to formaldehyde were also significantly more common when using FCA.

CONCLUSION: The FC and FCA had good agreement in detection of positive reactions. However, the results including doubtful and irritant reactions justify further research regarding optimization of the dose.

Introduction

Patch testing is the gold standard procedure used to diagnose contact allergy. The patch test is performed by applying patch test substances under occlusion to the skin and the outcome is dependent upon a number of factors such as patch test concentration of known substances, vehicle, occlusion time and the applied dose per unit area. Over the years much effort has been made to standardize the method with regard to these factors as well as to the readings of the patch test reactions. Another factor that might influence the patch test outcome is the test system that is used. Several different test systems are used for patch testing. To our knowledge, the few and small studies that have been done until today are scarce when it comes to comparing test system's advantages/disadvantages. The choice of patch test system in a clinic is often based on experience, tradition and economy. The patch system, Finn Chambers® (FC)(SmartPractice, Phoenix, Arizona, USA)(1) has been the system used for routine patch testing at the Department of Occupational and Environmental Dermatology in Malmö, Sweden since 40 years. The system consists of 10 aluminium chambers mounted on a panel made from non-occlusive tape with a hypoallergenic acrylic-based adhesive (Table 1). A disadvantage with this system is that the test personnel often must perform additional taping on top and around the test panels to ensure that test panel adhere well to the skin and do not move (Figure 1). A new patch test system, developed from FC, has been introduced. This system is called Finn Chambers® AQUA (FCA) (2) and according to the manufacturer, SmartPractice, additional taping is not necessary due to the strong adhesive tape and the system is moisture resistant which allows the patients to moderately exercise and/or take a light shower, while the test panels still remain on the patient's back (Figure 1)(Table 1). FCA also involves aluminium chambers, mounted on panels, however, contrary to FC the filter papers are, pre-fixed in the chambers. The aim of this study was to see if there

is any difference in the results regarding detecting contact allergy by direct comparing the two patch systems FA and FCA. The initiative for this study arose when the test personnel were starting to get work-related musculoskeletal backaches because of the repetitive, one-sided and strenuous taping of the test panels to FC.

Method

During the period from October 2016 till October 2017, 435 (268 females, 167 males, mean age 45 years, range 16-87 years) dermatitis patients, both general and occupational dermatology patients were tested simultaneously with 10 patch test preparations in both FC and FCA. During this period, approximately 700 patients were tested with the baseline series and the reason why only 435 patients were tested with FCA was mainly because there was not enough time for additional testing in all patients. The 10 substances represented the most common allergens as well as some allergens known to give many weak reactions that may be difficult to interpret when reading (Table 2). Both aqueous solutions and petrolatum preparations were tested as well as Amerchol L101 as petrolatum, i.e. 100%. After approximately 6 months textile dye mix (291 patients) was replaced by methylisothiazolinone + methylchloroisothiazolinone (MI/MCI), because we wanted to evaluate another aqueous preparation and also reduce the number of test panels to one panel, i.e. 10 test chambers. The reason for this replacement was the fact that methylisothiazolinone on its own had given a ring reaction in many patients, interpreted as irritant, and we wanted to see whether this would also be seen with MI/MCI (117 patients). All test preparations were bought from Chemotechnique Diagnostics, Vellinge, Sweden and the chambers from SmartPractice. The patch testing was done according to the recommendations of the European Society of Contact Dermatitis guidelines (ESCD) and the International Contact Dermatitis Research Group (ICDRG) (3)(4) and the patch test results were read by experienced dermatologists. The occlusion time was 48 hours and after that the test panels were removed by the

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patients themselves and discarded. Test reactions were read on day 3 or 4 and on day 7. When using FC, the appropriate amount of a patch test preparation in petrolatum has been determined to be 20 mg petrolatum (5) and for liquids 15 µl using a micropipette (6). SmartPractice's recommendation when using FCA is 20 µg for petrolatum preparations and 20 µl for liquids(2). Initially the aim was to compensate for the increased area in FCA by increasing the dose but since this, to our knowledge, has not been investigated scientifically and to minimize the risk of irritation we used the same amount for FCA as in FC. Fragrance allergens were applied to the test chambers immediately before application of the test panels to the patients' backs to avoid evaporation (7). One dermatitis patient (well controlled dermatitis at patch testing) was excluded since the patient reacted with strong reactions (++) to all patch tests in the FCA and only to three in the FC (nickel(II)sulfate, balsam of peru and fragrance mix I). When retested on the arm with FCA the patient was negative to all substances. Reactions to FCA chambers caused by the presence of modified colophony in the adhesive used to fix the filter papers to the test chambers has been reported, and the adhesive has since been replaced by the manufacturer (8). However, the excluded patient tested negative to colophony. There was no general flare at the patch test reading. We could not find any explanation to the reaction pattern and therefore the patient was excluded.

Statistics

McNemar's two-sided test was used to compare the number of patients reacting to the allergens tested in FC and FCA. Fisher's exact test (2-sided) was used to compare the total number of positive and doubtful reactions in FC and FCA. Differences were considered significant at $p < 0.05$. In the statistical calculations the strongest reaction on either day 3 or 4 or day 7 was used (Table 2).

Ethics

Patient data are registered and used with ethical approval by the Ethical Review Board, Stockholm, Sweden Dnr 2020-02190.

Results

The results from the simultaneous patch testing are presented in Table 2, Table 4 and Figure 2, 3, and 4.

There were no significant differences regarding detecting a positive reaction when comparing the two test systems, FC and FCA (Table 2 and Figure 2). Neither when comparing the total number of positive reactions nor when comparing each individual test preparation.

When we compared the strength of the reactions we noticed significant differences between the 2 test systems for 2 allergens. Significantly more patients had a stronger reaction to cobalt(II)chloride with FC than with FCA ($p = 0.039$). The other way around was seen for hydroperoxides of linalool ($p = 0.023$) (Table 2 and Figure 3).

There were significantly more doubtful reactions to methylisothiazolinone, fragrance mix I and hydroperoxides of linalool when testing with FCA. For nickel(II)sulfate we observed significantly more doubtful reactions when testing with FC (Table 2 and Figure 4).

There were in total 90 doubtful reactions in FCA for methylisothiazolinone, fragrance mix I and hydroperoxides of linalool without simultaneously doubtful reactions in FC. With the exception of 3 positive reactions, all other reactions to these 3 test preparations (above) in FC were negative. Among the 34 patients with doubtful reactions to nickel(II)sulfate in FC (without a concurrent doubtful reaction in FCA), 11 positive reactions were noticed in FCA.

Total numbers of irritant reactions were 10 for FC (5 preparations) and 13 for FCA (7 preparations). 5 of 10 in FC were noted cobalt(II)chloride while only 1 was noted in FCA. 6 of 13 were noted for formaldehyde in FCA while 0 was noted in FC, which is significantly more irritant reactions in FCA ($p = 0.041$).

Discussion

In our experience the FC is not optimal regarding its adhesive properties and without additional taping the occlusion of the allergens may be affected and therefore alter the test results. Another drawback is that the FC does not have pre-fixed filter papers in the chambers which may affect the result of the test if this loose filter paper is displaced from its initial placement, i.e. directly under the aluminium chamber. The test personnel need to do additional taping on top and around the test panels to secure fixation on the skin and do extra manual preparations when handling the loose filter papers. Both aspects are time requiring and they also contribute to a strenuous posture which may result in backache. With this in mind it is important to try other and possibly better test systems.

A few studies have compared different patch-testing systems, for example FC to IQ Ultra™ (9) and FC to T.R.U.E TEST® (10) and there is no evidence indicating that one test system is significantly better than the other. To our knowledge such comparison has not been done between FC and FCA.

Generally, many factors can influence the patch test result such as individual factors and different technical aspects within patch testing (patch system, occlusion time, test dose/concentration, reading time and the stability of different substances (7)(11)(12)). In our study, when comparing the two patch systems, two major differences became apparent. FCA come in pre-fixed filter paper that extends over the edges which makes the occlusive surface 3 mm larger in diameter and the improved adhesive tape. Theoretically these two differences will result in a better occlusion of the test preparation and in the end affect the test result.

In this study, all the patch test outcomes were read by dermatologists at the department, having arranged and taken part in courses for standardization and following the ICDRG/ESCD criteria. The patch test readings were done on day 3 or 4 and on day 7. Svedman et al showed how important standardized patch test readings are and how it could affect the interpretation of the results when reading without the ICDRG/ESCD reading criteria, especially for one plus-, doubtful - and irritant reactions (13).

Another factor of importance for elicitation of a positive reaction is the dose per unit area (14). For FC the appropriate amount is 15 µl for solutions (6) and 20 mg petrolatum preparations (5). The test area of the petrolatum preparations should be the same for both FC and FCA assuming that the petrolatum preparation does not migrate within the paper outwards towards the rim of the FCA chamber. When using a liquid as vehicle, the test preparation area is not equal for both systems because the filter paper in FCA extends over the edges and covers the whole occlusive test preparation area (11 mm). The filter paper for FC is 7 mm in diameter while the whole diameter for the chamber is measured to 8 mm. In some cases, reactions were only localized where the rim of the FCA chambers touches the skin. The morphology of these reactions could vary but in some cases could resemble the morphology of a contact allergy with erythema, infiltration, papules and vesicles. In total, we noticed 42 rim reactions (RR) in 20 patients when testing with FCA. 22 of these reactions had aqua as vehicle, 16 had petrolatum

as vehicle and 4 RR were observed for Amerchol L101 (as is). 35 of the 42 reactions were concurrent negative in FC while 3 test preparations, MI/MCI (aq), MI (aq) and hydroperoxides of linalool (pet) were one plus positive. The last 4 were doubtful reactions in FC for peru balsam (pet), textile dye mix I (pet), hydroperoxides of linalool (pet) and formaldehyde (aq). To note is that these reactions were not systematically monitored and/or written down by every doctor but in several cases the doctors did make notes regarding RR reactions. These reactions are difficult to interpret because this may stand for a doubtful or irritant reaction. A likely explanation is that the test substances accumulate in the periphery after application to the chambers and cause an irritant reaction when testing with FCA.

There were no significant differences regarding positive reactions for aqua or petrolatum preparations. When testing aqueous solutions we did not find any significant differences in our study between the two tests systems although the dose/cm² is almost twice as high in FC compared to FCA. For instance, formaldehyde was tested with the dose 0.60 mg/cm² in FC and 0.32 mg/cm² in FCA, and still the results were practically the same. This is in contrast to the study by Hauksson et al (15), where it was demonstrated that when patch testing formaldehyde at 2 % (0.60 mg/cm²) significantly more positive reactions were detected compared to testing with 1 % (0.30 mg/cm²). A possible explanation might be a better occlusion when testing with FCA. This may also explain why FCA had significantly more irritant reactions for formaldehyde even though the dose/cm² was half the amount. Another example is MI/MCI for which it has been demonstrated that testing with 200 ppm (0.006mg/cm²) detects significantly more positive reactions than 100 ppm (0.003mg/cm²). However this was not seen in our case when comparing FC to FCA (16) even though there is a 2 fold higher dose/cm² in FC compared to FCA and again the explanation might be the better occlusion. We did not see any differences when comparing petrolatum

preparations but theoretically if the petrolatum preparation is drawn in to the filter paper when using FCA this might alter the availability of the test substances.

Conclusion

There were no significant differences with regard to detection of positive reactions when comparing the two test systems, FC to FCA. In the study, we were using the same test dose as in the ordinary FC and we saw a significantly higher number of doubtful reactions to methylisothiazolinone, fragrance mix I and hydroperoxides of linalool and a higher number of irritant reactions to formaldehyde when using FCA. When patch testing the aim is to minimize the number of irritant reactions and maximize the number of positive reactions without giving rise to active sensitization. The better occlusive effect might explain the fact that although the dose was not equivalent we did not find significantly different amounts of positive contact allergic reactions. These results and the number of irritant/doubtful reactions do indicate the need to optimize the dose for the FCA test system since this may result in higher pick up rates for allergic reactions and possibly decreasing the amount of irritant/doubtful reactions. If we were to use SmartPractice's recommendation, a higher dose for FCA when using liquids (2) it would probably result in higher pick up rate for allergic reactions but also more irritant/doubtful reactions and possibly even active sensitization. Therefore further studies should be done with respect to dose to find the optimal one because an adjustment of the dose may be needed. FCA chambers were introduced to the market as being more patient and test personnel friendly. In our study, the impression from the test personnel was that this system was easy to work with when the additional taping and the extra manual preparations regarding the loose filter paper were not necessary. The tested patients experienced the better fixation as favourable when test panels were well adhered to their back (Table 3.). If these results were analysed with an epidemiologic perspective, a change in the preferred test chamber, could in our study, with a much larger study population lead

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to an alteration of prevalence for some allergens. For decades FC has been the choice at the Department of Occupational and Environmental Dermatology in Malmö, Sweden and the previous published data were based on studies that used FC as test chamber. For instance if FCA was the standard test chamber, our data could imply that the pick up rate for nickel(II)sulfate allergies could increase and decrease for Amerchol L101 which leads to an alteration of the prevalence of type IV allergies for these 2 allergens (Table 2).

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Table 1. Characteristics	Finn Chambers® (FC) (1)	Finn Chambers® AQUA (FCA) (2)
Chambers and thickness	Aluminium 0.28 mm	Aluminium 0.23 mm (0.42 mm with filter paper)
Pre-fixed filter paper	-	Yes, covers the whole chamber surface
Thickness of the filter paper	0.34 mm	0.19 mm
Diameter of the chamber	8 mm	8 mm
Occlusive surface of the test preparation when solution is applied on filter paper	7 mm	11 mm (>7 mm because the filter paper extends over the edges)
Tape	Scanpor tape, hypoallergenic surgical tape made of rayon and polyester fibres with a non-latex adhesive	The tape is a clear polyurethane film coated on one side with a medical grade acrylic adhesive

Table 3. Pros and Cons	Test personnel	Test results	Patients
FCA, pros	Adhere well without extra taping. Moisture resistant. No need for loose filter paper.		Better fixation on the patients back. Can be active and the test do not limit movement. Moisture resistant and the patient can take a shower.
FCA, cons	Difficult to adhere to patients back when testing with only one cut out chamber (the adhesive collapses). Needs extra tape.	Rim Reactions	
FC, pros	Well known chamber. Many years of experience using FC.	Well known chamber. Many years of experience, Dermatologist are used to interpret reactions when using FC	
FC, cons	Need extra taping. Need loose filter paper.		No activity and sometimes “Sick-leave” if the patients work requires physical activity. Limiting movement. The adhesive loses attachment easily. No showers or bath.

Table 4. Comparison of reactivity in patients simultaneously patch tested with Finn chamber (FC) and Finn Chamber Aqua (FCA). Irritant reactions were considered negative reactions.

Allergens / Concentration (%) / Vehicle	Total positive reactions					
	FC \ FCA	-	(+) ?	+	++	+++
Nickel(II)sulfate hexahydrate 5.0 pet	-	312	11	3	2	0
	(+) ?	23	5	7	3	1
	+	4	0	5	3	1
	++	3	1	7	12	7
	+++	0	0	0	1	23
Cobalt(II)chloride hexahydrate 0.5 pet	-	399	6	1	0	0
	(+) ?	7	3	0	0	0
	+	1	0	1	1	0
	++	1	0	3	2	0
	+++	0	0	0	3	6
Amerchol 101 100	-	375	13	1	0	0
	(+) ?	26	3	0	0	0
	+	7	0	6	1	0
	++	0	0	0	2	0
	+++	0	0	0	0	0
Caine Mix II 10.0 pet	-	394	13	0	0	0
	(+) ?	11	6	1	0	0
	+	2	1	1	2	0
	++	0	0	1	1	0
	+++	0	0	0	1	0
Peru balsam 25.0 pet	-	348	27	1	0	0
	(+) ?	16	6	4	0	0
	+	6	4	10	2	0
	++	0	0	3	7	0
	+++	0	0	0	0	0
Hydroperoxides of Linalool 1.0 pet	-	315	43	7	0	1
	(+) ?	19	16	4	0	0
	+	4	2	12	5	0
	++	0	0	0	5	1
	+++	0	0	0	0	0
Fragrance mix I 8.0 pet	-	362	23	6	1	1
	(+) ?	8	5	0	2	0
	+	2	1	9	0	0
	++	2	0	1	8	0
	+++	0	0	0	0	3
Textile dye mix 6.6 pet	-	261	10	0	2	0
	(+) ?	11	3	1	0	0
	+	0	0	0	1	0
	++	0	0	0	0	1
	+++	0	0	0	0	1
Methylisothiazolinone 0.2 aq	-	383	21	2	0	0
	(+) ?	6	1	1	0	0
	+	3	0	3	2	0
	++	0	0	0	4	0
	+++	1	0	0	2	5
Formaldehyde 2.0 aq	-	384	20	3	1	0
	(+) ?	9	1	0	0	1
	+	0	0	4	2	0
	++	2	1	0	2	0
	+++	1	0	0	1	2
Methylisothiazolinone / Methylchlorisothiazolinone 0.02 aq	-	106	2	1	0	0
	(+) ?	2	0	0	0	0
	+	2	0	1	0	0
	++	0	1	0	0	0
	+++	0	0	0	0	2



Figure 1.

The two chambers demonstrated on a patient's back, Finn Chambers® AQUA (left side) and Finn Chambers® (right side with additional taping).

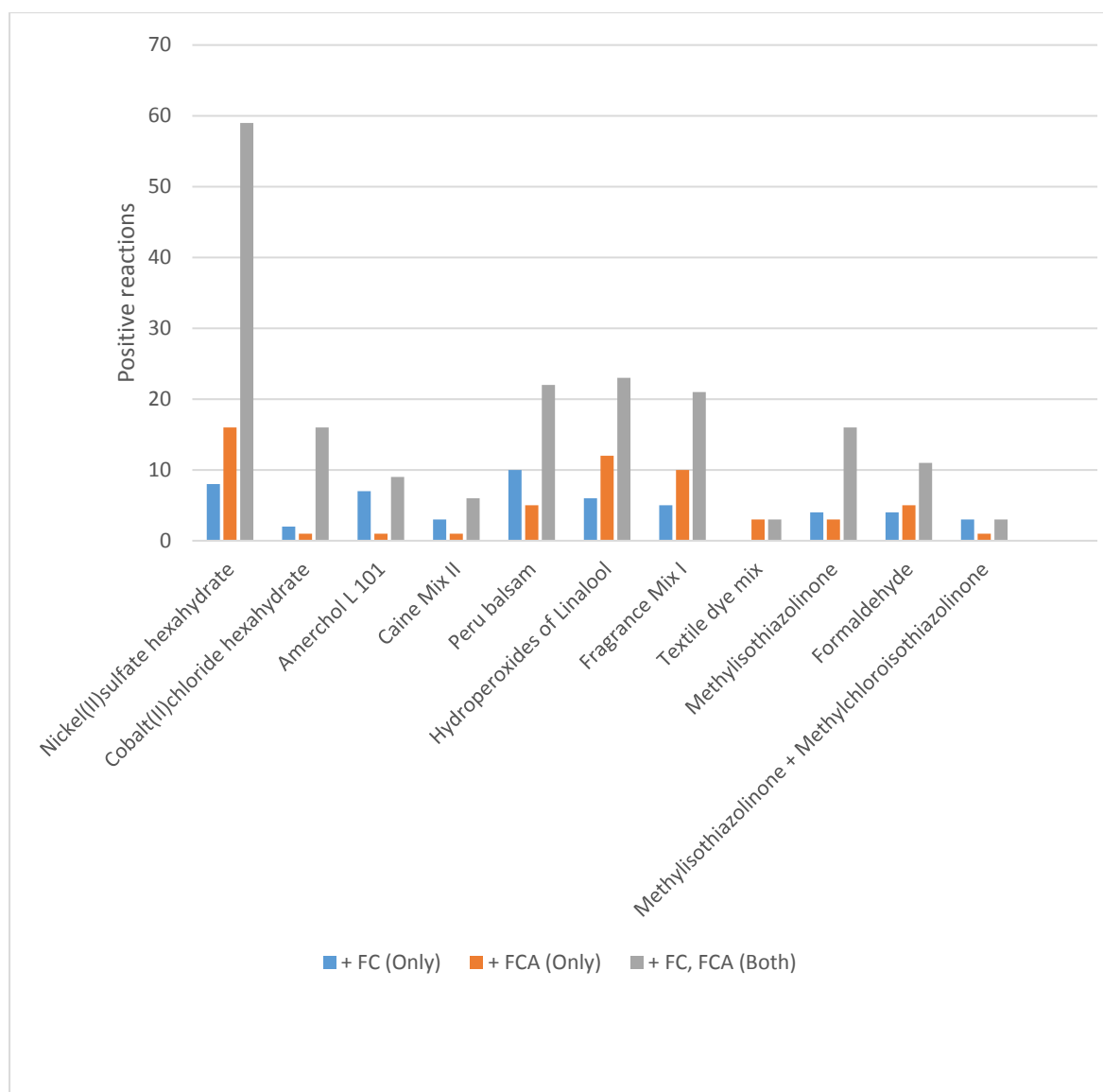


Figure 2.

Number of positive reactions to allergens simultaneously patch tested in Finn Chambers® (FC) and Finn Chamber® AQUA (FCA). Any positive reaction on day 3/4 or day 7 is presented.

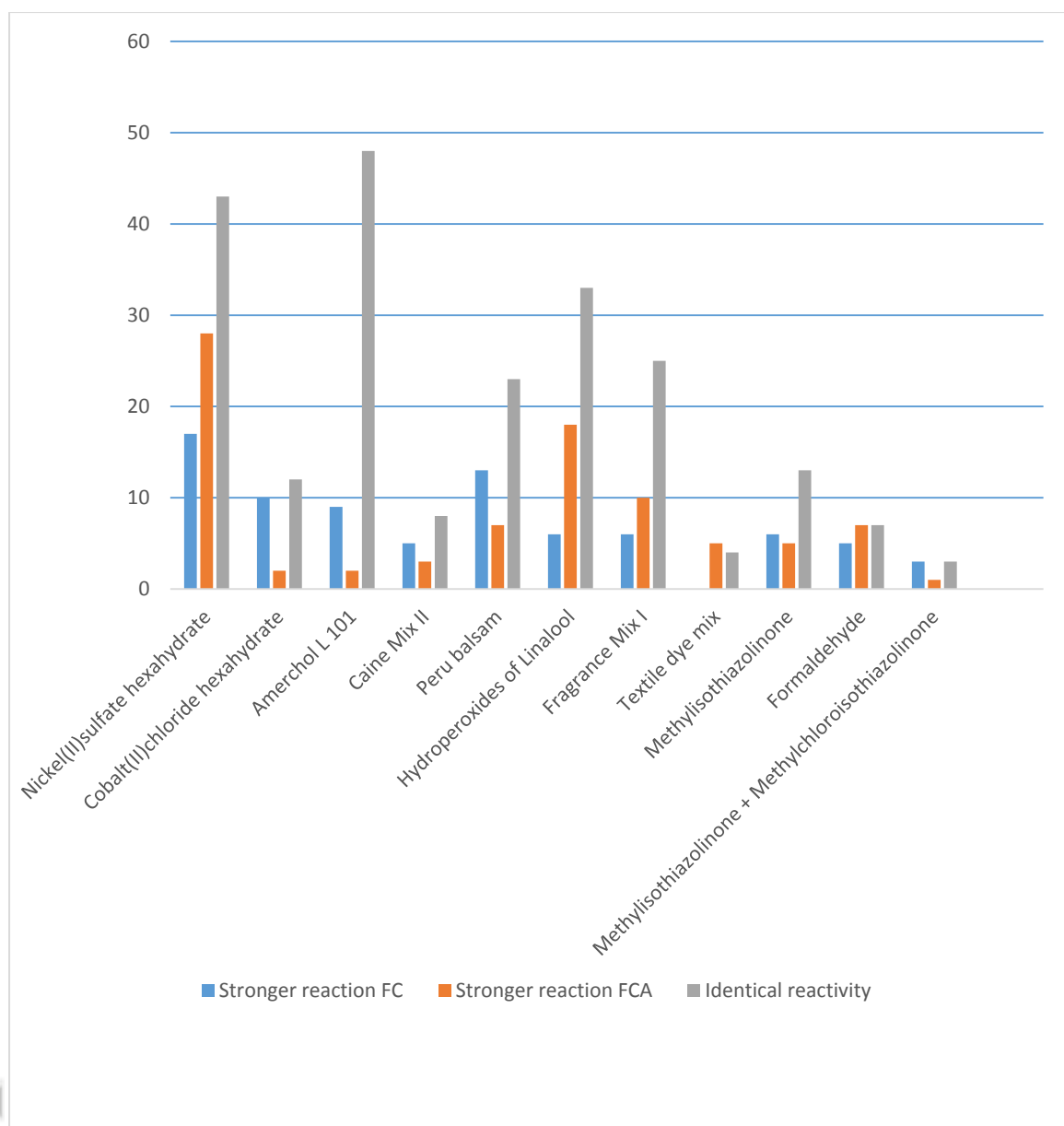


Figure 3.

Comparison of patients that were patch tested simultaneously with both Finn Chambers® (FC) and Finn Chamber® AQUA (FCA). This table shows either identical reactivity (excluding the negative reactions) or a stronger reaction in one of the patch systems.

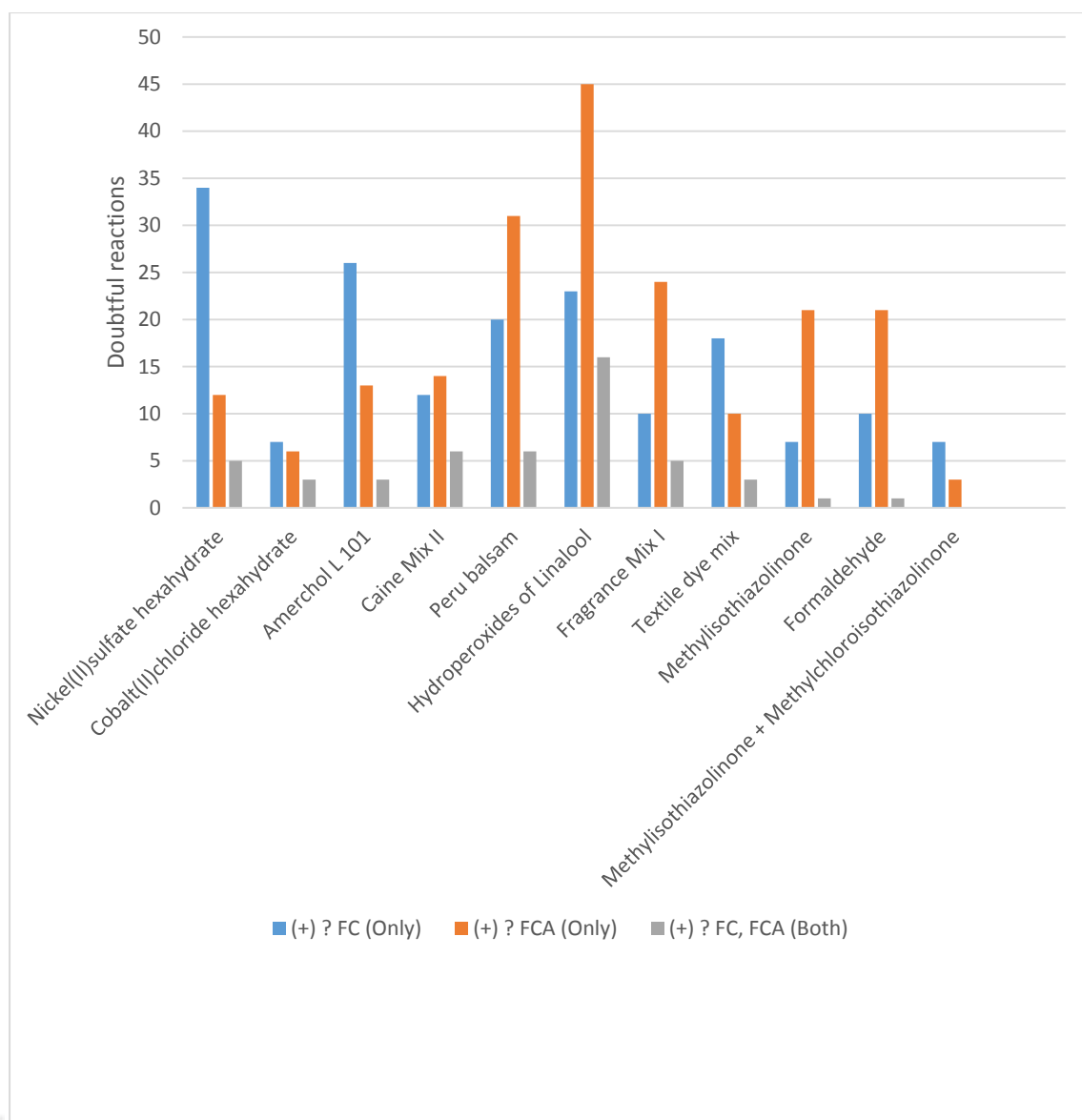


Figure 4.

Number of doubtful reactions to allergens simultaneously patch tested in Finn Chambers® (FC) and Finn Chamber® AQUA (FCA). Doubtful reactions are presented when noted either on reading day 3/4 and/or day 7. Patients with doubtful reactions on one reading and positive on the other reading are not included.