

ORIGINAL ARTICLE

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Auditing the usage of therapeutic footwear in diabetic foot patients through Amit Jain's extended 'SCC' classification for therapeutic footwear

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Abstract

An audit was conducted from 2 centres' to analyze and study the therapeutic footwear used in diabetic foot patients through the new Amit Jain's classification for therapeutic footwear. Twenty seven new patients who were on therapeutic foot wear were studied. The majority were males. Most of the patients had diabetes duration of more than 20 years (48.7%). Most of the patients were on diabetic sandals (81.5%) followed by modified molded (Custom) footwear (7.4%). Majority of the Footwear used were type 1 diabetic footwear (81.5%). There was a significance difference seen with type of footwear and duration of footwear usage with age wherein type 1 therapeutic footwear were used commonly in patients with age less than and also in patients with more than 60 years whereas type 3 foot wear was used only by patients of less than 60 years. Further, patients above 60 years duration were using therapeutic footwear for more than 2 years without changing them. Amit Jain's classification for therapeutic footwear is a new, simple, practical, easy to remember classification for diabetic foot wear wherein all footwear's can easily be categorized in any one of the 3 categorizes and it helps in our understanding of diabetic footwear usage.

Keywords: Diabetes, foot, Amit Jain, classification, footwear, sandals

Introduction

Diabetic foot is just not patient's problem but also to the family involved in patients care and it is now a major health concern worldwide [1]. Usage of appropriate footwear is one of the common interventions in any diabetic foot care program [2, 3]. In fact, therapeutic footwear has been used from past many years to prevent ulceration and re-ulceration in diabetic foot and also other complications [3, 4].

In spite of knowing the role and benefits of diabetic foot wear (Therapeutic footwear), the usage of them by patients is poor and even prescription and advice by healthcare professional has shown to be dismal. In a recent study by Jain et al on footwear practice in established diabetic foot patients [5], it was seen that only 5.3% of patients were on therapeutic footwear and 84.2% of diabetic foot patients never received any footwear advice from the healthcare professionals in developing country like India wherein the prevalence of diabetes and diabetic foot is quite high.

We conducted this audit to know the usage of therapeutic footwear in diabetic foot patients and analyze them through Amit Jain's classification for therapeutic footwear [Figure 1], which is an extended 'SCC' classification of the author [6], that classifies diabetic footwear into 3 simple types [Table 1].

Table 1. Showing Amit Jain's extended 'SCC' classification for Therapeutic/ Diabetic footwear

Type of Therapeutic Footwear	Description	Characteristics	Examples
Type 1 Diabetic footwear	Simple Footwear	Regular MCR/ MCP diabetic sandals	Diabetes patient with peripheral neuropathy
Type 2 Diabetic footwear	Complex Footwear	Wedge Footwears, Half Footwear, etc	Recurrent trophic ulcers, Transmetatarsal amputation , etc
Type 3 Diabetic footwear	Complicated Footwear	Custom made molded footwears	Charcot foot

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AMIT JAIN'S CLASSIFICATION FOR THERAPEUTIC FOOTWEAR

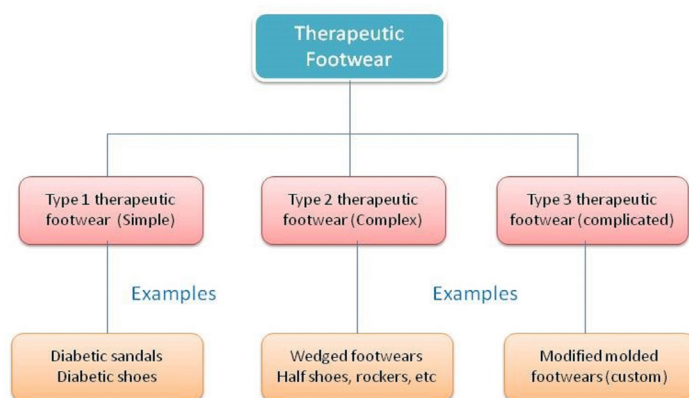


Figure 1. Showing Amit Jain's classification for Diabetic footwear

Materials and Methods

We conducted an audit at two centres where the primary author works namely Amit Jain's Institute of Diabetic Foot and Wound Care at Brindhavvan Areion Hospital and in Surgical Unit 8 in Department of Surgery at Rajarajeswari medical college, Bengaluru, India. The study period was from July 2018 to June 2019. All the new patients who consulted for diabetic foot problems and were on therapeutic footwear were included in the study. All the diabetic foot patients who were on ordinary foot wear or those whom we prescribed new therapeutic footwear were excluded.

Data Analysis [7-9]

Data was analyzed using statistical software SPSS 22.0 and R environment ver.3.2.2. Microsoft word and excel were used to generate graphs and tables. Both descriptive and inferential statistics were carried out in the study. Results on continuous measurements were presented on Mean $\pm$ SD (Min-Max) and results on categorical measurements were presented in number (%). Significance was assessed at 5% level of significance.

The following assumption on data is made

- Dependent variables should be normally distributed,
- Samples drawn from the population should be random
- Cases of the samples should be independent

Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Leven's test for homogeneity of variance has been performed to assess the homogeneity of variance. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, Non-parametric setting for Qualitative data analysis. Fisher exact test was used when samples were very small.

Significant Figures

+ Suggestive significance (P value: $0.05 < P < 0.10$)

* Moderately significant (P value: $0.01 < P < 0.05$)

** Strongly significant (P value: $P \leq 0.01$).

Results

A total of 27 new diabetic foot patients who consulted us and who were already on therapeutic footwear were studied. 77.8% of them were males [Figure 2].

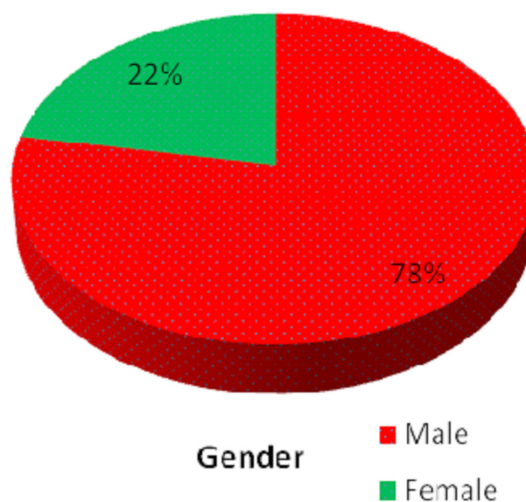


Figure 2. Showing gender distribution

Most of the patients (44.4%) were between 61 to 70 years followed by 33.3% who were between 51 to 60 years. 14.8% of them were above 70 years and 7.4% were less than 50 years of age who were on diabetic footwear (Figure 3).

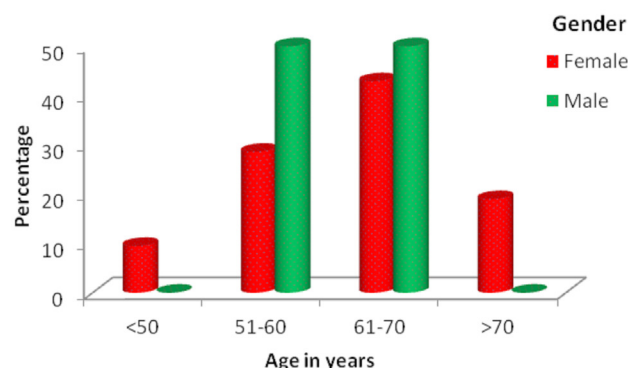


Figure 3. Showing age distribution of patients studied.

Majority of the patients (48.1%) had diabetes of more than 20 years [Table 2].

Table 2. Showing duration of diabetes mellitus (DM) distribution of patients studied.

Duration of DM	Gender		Total	p Value
	Female	Male		
Less than 10 years	3(14.3%)	2(33.3%)	5(18.5%)	P=0.607
11 to 20 years	7(33.3%)	2(33.3%)	9(33.3%)	
More than 20 years	11(52.4%)	2(33.3%)	13(48.1%)	
Total	21(100%)	6(100%)	27(100%)	

70.4% of the patients had hypertension, 74.1% had peripheral neuropathy, 44.4% had some form of plantar wound and 45.1% had history of past amputation. Most patients (81.5%) were on diabetic sandals (Figure 4), 7.4% were on modified molded footwear (Custom), 3.7% were on diabetic shoes, anterior

orthowedge footwear (Figure 5) and half footwear each. Hence on classifying them according to Amit Jain's 'SCC' classification, 81.5% were on type 1 diabetic foot wear followed by 7.4% being in type 3 diabetic footwear (Figure 6). There was no difference in type of footwear worn among both genders. Most therapeutic footwear (48.1%) were worn by patients for less than 1 year of duration with 22.2% of the patients using the therapeutic footwear for more than 2 years continuously without changing them [Table 3].



Figure 4. showing diabetic foot sandals with EVA insoles. This is type 1 diabetic foot wear as per Amit Jain's classification



Figure 5 showing anterior orthowedge footwear. This is type 2 diabetic foot wear as per Amit Jain's classification

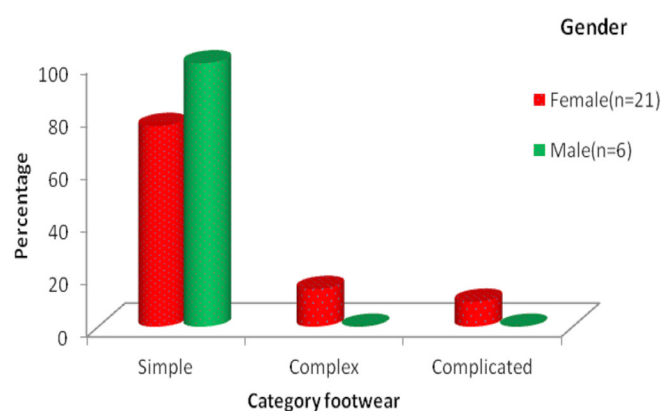


Figure 6. Showing the distribution of diabetic footwear through Amit Jain's classification among both genders

Table 3. Showing different variables of patients studied in relation to gender studied

Variables	Gender		Total	p Value
	Female	Male		
Peripheral Neuropathy				
• Yes	15(71.4%)	5(83.3%)	20(74.1%)	1.000
• No	6(28.6%)	1(16.7%)	7(25.9%)	
Plantar wound				
• Yes	10(47.6%)	2(33.3%)	12(44.4%)	0.662
• No	11(52.4%)	4(66.7%)	15(55.6%)	
Previous Amputation				
• Yes	9(42.9%)	4(66.7%)	13(48.1%)	0.385
• No	12(57.1%)	2(33.3%)	14(51.9%)	
Different Diabetic footwear's				
• Sandals	16(76.2%)	6(100%)	22(81.5%)	1.000
• Shoes	1(4.8%)	0(0%)	1(3.7%)	
• Anterior Ortho wedge	1(4.8%)	0(0%)	1(3.7%)	
• Modified moulded footwear	2(9.5%)	0(0%)	2(7.4%)	
• Half footwear	1(4.8%)	0(0%)	1(3.7%)	
Amit Jain's 'SCC' classification for categorizing diabetic footwear				
• Type 1 (Simple)	16(76.2%)	6(100%)	22(81.5%)	0.733
• Type 2 (Complex)	3(14.3%)	0(0%)	3(11.1%)	
• Type 3 (Complicated)	2(9.5%)	0(0%)	2(7.4%)	
Duration of Use Footwear				
• Less than 1 year	11(52.4%)	2(33.3%)	13(48.1%)	0.606
• 1- 2years	6(28.6%)	2(33.3%)	8(29.6%)	
• More than 2 years	4(19%)	2(33.3%)	6(22.2%)	
Chi-Square/Fisher Exact Test				

Chi-Square/Fisher Exact Test

Significance was seen category of diabetic footwear and duration of usage of therapeutic footwear with age [Table 4]. Although type 1 diabetic footwear were used commonly in patients with less than and also above 60 years age (Figure 7), the type 3 diabetic footwear (Complicated) was used only in patients with less than 60 years (P-0.095+, significant). Also, patients of more than 60 years were using the same therapeutic footwear for more than 2 years without changing it (P-0.039*, significant).

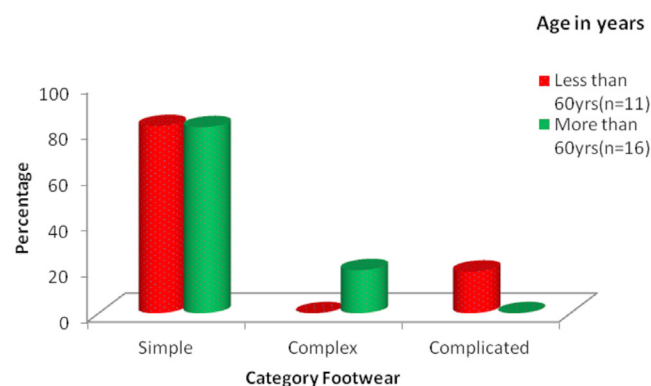


Figure 7. showing distribution of Category of diabetic footwear in relation to age

Table 4. Showing variables of patients studied in relation to age

Variables	Age in years		Total (n=27)	p Value
	Less than 60yrs (n=11)	More than 60yrs (n=16)		
Peripheral Neuropathy				
• Yes	9(81.8%)	11(68.8%)	20(74.1%)	0.662
• No	2(18.2%)	5(31.3%)	7(25.9%)	
Plantar wound				
• Yes	6(54.5%)	6(37.5%)	12(44.4%)	0.452
• No	5(45.5%)	10(62.5%)	15(55.6%)	
Previous Amputation				
• Yes	4(36.4%)	9(56.3%)	13(48.1%)	0.310
• No	7(63.6%)	7(43.8%)	14(51.9%)	
Different diabetic footwear worn				
• Sandals	9(81.8%)	13(81.3%)	22(81.5%)	0.322
• Shoes	0(0%)	1(6.3%)	1(3.7%)	
• Anterior Ortho wedge	0(0%)	1(6.3%)	1(3.7%)	
• Modified molded footwear	2(18.2%)	0(0%)	2(7.4%)	
• Half footwear	0(0%)	1(6.3%)	1(3.7%)	
Amit Jain's Classification for categorizing diabetic footwear				
• Type 1 (Simple)	9(81.8%)	13(81.3%)	22(81.5%)	0.095+
• Type 2 (Complex)	0(0%)	3(18.8%)	3(11.1%)	
• Type 3 (Complicated)	2(18.2%)	0(0%)	2(7.4%)	
Duration of Use				
• Less than 1 year	8(72.7%)	5(31.3%)	13(48.1%)	0.039*
• 1- 2years	3(27.3%)	5(31.3%)	8(29.6%)	
• More than 2 years	0(0%)	6(37.5%)	6(22.2%)	
Chi-Square/Fisher Exact Test				

There was no correlation of different diabetic footwear worn, category of the footwear or duration of use of footwear with plantar wound [Table 5].

There was also no correlation between different diabetic footwear's worn, category of footwear, plantar wound, peripheral neuropathy and duration of use of footwear with previous amputation [Table 6].

There was no association between category of the diabetic foot and its duration of use with peripheral neuropathy [Table 7].

It was seen that diabetic foot sandals (Figure 8) were the most commonly worn footwear in type 1 therapeutic footwear [Table 8] and modified molded footwear were the most commonly used type 3 therapeutic footwear (P-0.001**, significant)

Table 5. Showing variables of patients studied in relation to Plantar wound

Variables	Plantar wound		Total (n=27)	p Value
	Yes (n=12)	No (n=15)		
Different diabetic footwear worn				
• Sandals	9(75%)	13(86.7%)	22(81.5%)	0.179
• Shoes	0(0%)	1(6.7%)	1(3.7%)	
• Anterior Ortho wedge	1(8.3%)	0(0%)	1(3.7%)	
• Modified molded footwear	2(16.7%)	0(0%)	2(7.4%)	
• Half footwear	0(0%)	1(6.7%)	1(3.7%)	
Amit Jain’s classification for Categorizing Footwear				
• Type 1 (Simple)	9(75%)	13(86.7%)	22(81.5%)	0.372
• Type 2 (Complex)	1(8.3%)	2(13.3%)	3(11.1%)	
• Type 3 (Complicated)	2(16.7%)	0(0%)	2(7.4%)	
Duration of Use				
• Less than 1 year	6(50%)	7(46.7%)	13(48.1%)	0.889
• 1- 2years	4(33.3%)	4(26.7%)	8(29.6%)	
• More than 2 years	2(16.7%)	4(26.7%)	6(22.2%)	
Chi-Square/Fisher Exact Test				

Table 6. Showing variables of patients studied in relation to previous amputation

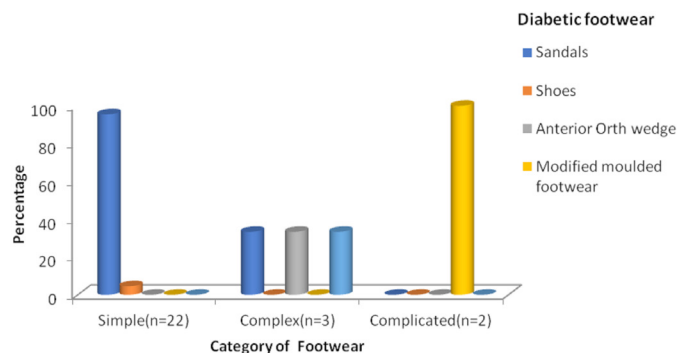
Variables	Plantar wound		Total (n=27)	p Value
	Yes (n=13)	No (n=14)		
Peripheral Neuropathy				
• Yes	10(76.9%)	10(71.4%)	20(74.1%)	1.000
• No	3(23.1%)	4(28.6%)	7(25.9%)	
Different diabetic footwear worn				
• Sandals	10(76.9%)	12(85.7%)	22(81.5%)	0.341
• Shoes	1(7.7%)	0(0%)	1(3.7%)	
• Anterior Ortho wedge	1(7.7%)	0(0%)	1(3.7%)	
• Modified molded footwear	0(0%)	2(14.3%)	2(7.4%)	
• Half footwear	1(7.7%)	0(0%)	1(3.7%)	
Amit Jain’s classification for Categorizing Footwear				
• Type 1 (Simple)	9(75%)	13(86.7%)	22(81.5%)	0.596
• Type 2 (Complex)	1(8.3%)	2(13.3%)	3(11.1%)	
• Type 3 (Complicated)	2(16.7%)	0(0%)	2(7.4%)	
Duration of Use				
• Less than 1 year	6(50%)	7(46.7%)	13(48.1%)	0.784
• 1- 2years	4(33.3%)	4(26.7%)	8(29.6%)	
• More than 2 years	2(16.7%)	4(26.7%)	6(22.2%)	
Planter Wound				
• Yes	5(38.5%)	7(50%)	12(44.4%)	0.547
• No	8(61.5%)	7(50%)	15(55.6%)	
Chi-Square/Fisher Exact Test				

Table 7. Showing category of footwear and its duration of use in relation to peripheral neuropathy

Variables	Plantar wound		Total (n=27)	p Value
	Yes (n=20)	No (n=7)		
Amit Jain’s classification for categorizing diabetic footwear				
• Type 1 (Simple)	16(80%)	6(85.7%)	22(81.5%)	1.000
• Type 2 (Complex)	2(10%)	1(14.3%)	3(11.1%)	
• Type 3 (Complicated)	2(10%)	0(0%)	2(7.4%)	
Duration of use of diabetic footwear				
• Less than 1 year	10(50%)	3(42.9%)	13(48.1%)	0.729
• 1- 2years	5(25%)	3(42.9%)	8(29.6%)	
• More than 2 years	5(25%)	1(14.3%)	6(22.2%)	
Chi-Square/Fisher Exact Test				

Table 8 showing the duration of Use, and different diabetic footwear worn in relation to Category of footwear.**Table 8.** Showing the duration of Use, and different diabetic footwear worn in relation to Category of footwear

Variables	Plantar wound			Total (n=27)	p Value
	Simple (n=22)	Complex (n=3)	Complicated (n=2)		
Duration of Use					
• Less than 1 year	12(54.5%)	0(0%)	1(50%)	13(48.1%)	0.173
• 1- 2years	6(27.3%)	1(33.3%)	1(50%)	8(29.6%)	
• More than 2 years	4(18.2%)	2(66.7%)	0(0%)	6(22.2%)	
Different diabetic footwear worn					
• Sandals	21(95.5%)	1(33.3%)	0(0%)	22(81.5%)	<0.001**
• Shoes	1(4.5%)	0(0%)	0(0%)	1(3.7%)	
• Anterior Ortho wedge	0(0%)	1(33.3%)	0(0%)	1(3.7%)	
• Modified molded footwear	0(0%)	0(0%)	2(100%)	2(7.4%)	
• Half footwear	0(0%)	1(33.3%)	0(0%)	1(3.7%)	
Chi-Square/Fisher Exact Test					

Figure 8 showing different diabetic footwear worn and their categorization as per Amit Jain's classification for therapeutic footwear.**Figure 8.** Showing different diabetic footwear worn and their categorization as per Amit Jain's classification for therapeutic footwear.

Discussion

Diabetic foot is a chronic complication in diabetes and it results in increased morbidity, mortality and cost of treatment [5, 10]. Diabetes patients are prone to develop foot ulcers and other complications due to underlying neuropathy, ischemia, trauma and foot deformity [5, 10, 11].

There are studies that show benefit of diabetic footwear in prevention of foot ulceration and subsequent recurrences [12]. Plantar foot ulcers are caused due to elevated plantar pressures secondary to alteration in foot structure, function and joint mobility [11]. Therapeutic footwear reduces the abnormal foot pressures and also the foot ulcerations due to it [3, 13]. It has been shown that therapeutic footwear can relieve pressure by 30.2% and development by about 50% [11, 14].

Different types of therapeutic footwear are used to serve different purposes. For example, anterior orthowedge footwear's are used to relieve forefoot pressure, posterior orthowedge footwear is used to relieve heel pressure, extra depth therapeutic footwear for toe deformities like hammer toes, half shoes for those who underwent forefoot amputation, custom made molded footwear for Charcot foot, etc [6, 11, 14]. It is essential for high risk diabetic foot patients to wear therapeutic footwear with insoles like polyurethane, ethyl vinyl acetate, microcellular rubber, etc [3, 6].

Amit Jain's classification for therapeutic footwear/diabetic footwear, to the author's knowledge, is the first classification exclusive for diabetic foot wear [6]. This is classification is an extended 'SCC' classification which was first used for diabetic foot ulcers and later was extended to different entities like offloading, callus, Charcot foot, etc [6, 15-17].

In this series, type 1 diabetic foot wear were the commonest therapeutic footwear used in 81.5% of diabetic foot patients. Often these footwear are easily available in most of the established diabetes or diabetic foot centers and in south Asian countries like India, they are usually available as microcellular rubber (MCR) sandals or microcellular polymer (MCP) sandals [2, 6].

The footwear's are often needed to be inspected frequently and few suggest that they should be changed at least once a year as the insoles in them are effective in maintaining the pressure reduction for a year [11]. In this study, it was observed that patients of more

than 60 years duration, who were on therapeutic footwear, did not change their footwear for more than 2 years.

Although, therapeutic footwear are beneficial to diabetic foot patients, it is seen that many times, patients are non-compliant with them, further, many find them expensive, heavy and also slippery [11].

In this study, there are several limitations. First is that it is a simple audit. Second, the sample size was small. Third, we did not aim to study the appropriateness of the footwear prescribed by healthcare professionals whether correct footwear was given for right indication.

Conclusion

Diabetic footwear is an important intervention in diabetic foot management as it serves to protect the patient's feet and prevent re-ulceration. This study shows that type 1 diabetic foot wear are the most type of therapeutic footwear used with diabetic sandals being the commonest variety worn. Elderly patients over 60 years had lesser propensity to change their diabetic foot regularly. Amit Jain's classification for therapeutic foot wear is a new, simple, practical, easy to remember 3 tier classification wherein all the varieties of diabetic footwear used in clinical practice can be categorized comfortably. Further research is needed.

Acknowledgement

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Conflict of interest

There is no financial or personal relationship with other people or organizations that could inappropriately influence (bias) the authors' actions.

Financial Disclosure

All authors declare no financial support.

Ethical approval

This study was approved by Institutional ethics committee (RRMCH-IEC/159/2019-20).

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