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### Novel fit for purpose single use tourniquet: best of both worlds

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# Novel fit for purpose single use tourniquet: best of both worlds

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*Introduction:* Healthcare associated infections (HAI), such as Meticillin resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* (C. Diff) are estimated to cost the NHS £1 billion and contribute to 5000 deaths/year in the UK. To date the main emphasis to reduce HAIs has been on hand hygiene. However environmental microbial load and compliance limits the efficacy of hand washing alone. Cultures from tourniquets have demonstrated contamination by pathogens including MRSA. Consequently, many UK trusts are introducing disposable tourniquets as policy. The use of most disposable tourniquets is still limited, as few are able to maintain patient comfort, ease of use and cost effectiveness.

This study compares patient and phlebotomist experiences of the single-use tourniquet, Tournistrip™, with currently available disposable and re-usable alternatives.

*Methods:* The trial was performed in on patients attending two West London teaching hospital outpatient phlebotomy departments, over a four week period. After Tournistrip™ use, the patients were invited to fill in an anonymous questionnaire, covering comfort and appearance. A separate questionnaire was filled in by the phlebotomists.

*Results:* Ninety five percent of patients found the Tournistrip™ professional looking, with 54% preferring it to the current re-usable alternatives. One hundred and seventy eight of the 227 patients found Tournistrip™ comfortable. Overall, 85% of patients found Tournistrip™ at least as good, if not better than re-usable tourniquets.

All of the phlebotomists found the Tournistrip™ professional looking, and none preferred previously used disposable alternatives. Ninety-five percent found it as easy to use as a re-usable and none found previous disposables better to use.

*Discussion:* The Tournistrip™ was designed to match the comfort and ease of use of the re-usable tourniquet, whilst maintaining cost efficacy. This clinical trial shows the Tournistrip™ is viewed as a superior tourniquet to the current generation of disposables and a viable replacement to the re-usable tourniquet in the continuing challenge to reduce HAIs.

*Keywords:* Single-use; Venepuncture; Tourniquet; Cannulation; Disposable

## 1. Introduction

Within the UK, healthcare associated infections (HAI) such as Meticillin resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* (C. diff) are estimated to cost the NHS an additional £1 billion/year. The cost of treating each

patient infected with a HAI is £3000 more than the average hospital inpatient, due in part to additional treatment and prolonged length of stay. Aside from the financial implications associated with HAIs, these are reckoned to contribute to 5000 deaths per year in hospital [1].

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The main emphasis for tackling HAIs is focused on hand hygiene, which has been shown to reduce the incidence of HAI [2]. Poor hand washing compliance and environmental microbial load limit the efficacy of hand washing alone [3]. Numerous hospital items have been the subject of studies such as stethoscopes [4], keyboards [5] and tourniquets [6,7], which have all been shown to act as vector for hospital pathogens. Therefore, in order to reduce environment bacterial load, multiple strategies are required.

Studies that have cultured re-usable tourniquets have demonstrated that they can be contaminated by MRSA and other pathogens in clinical environments [8]. This is particularly of note as reusable tourniquets are in contact with multiple patients throughout the clinical day for venepuncture and cannulation. This is significant as the clinical life of a reusable tourniquet may be up to 104 weeks [7]. Increasing numbers of NHS trusts are enforcing infection control policies, which include the use of disposable tourniquets for all venepuncture and venous cannulation procedures.

Single-use tourniquets are available in hospitals, with the most common type based on a rubber strip that is stretched around the limb and tied to maintain pressure. Their degree of use within the clinical environment is known to vary in different settings; however, in the author's experience this is influenced by three predominant factors: (1) patient comfort; (2) ease of use for healthcare professionals; and (3) cost. Whilst some current disposable tourniquets are cost effective, their use is restricted by their limitations of the first two factors, and others that address the first two factors are limited by price. It is noteworthy that many healthcare professionals use rubber gloves as a tourniquet device when other suitable alternatives are not available.

Due to the potential infection risk posed by reusable tourniquets, and the identified shortcomings of current disposables, the author has designed a novel single use tourniquet, which takes into consideration patient comfort, usability and cost.

This study compares patient and phlebotomist experiences of the author's single use tourniquet (Tournistrip™) with current available options within a phlebotomy outpatient setting in two major West London teaching hospitals. To date there are no previous studies evaluating usability and patient perception of a single-use tourniquet compared to the current re-usable tourniquets.

## 2. Method

The trial was performed in two West London teaching hospital phlebotomy outpatient departments, over a four-week period in November 2006. All eligible patients attending the phlebotomy service were verbally consented

for use of Tournistrip™ during venepuncture. After the procedure, they were invited to answer an anonymized questionnaire aimed at gaining feedback on comfort and appearance compared to their personal experiences of alternatives and rubber gloves for venepuncture. The questions were answered using a Likert Scale, either numbered 0 to 6 (even integers only) or progressive statements of agreement.

The phlebotomists who used Tournistrip™ filled in a questionnaire at the end of the day giving their opinion on its ease of use compared to alternatives, its appearance and their overall rating, again using a Likert Scale. Additionally, they recorded any concerns and problems on a per patient basis, if required, to help ensure accurate data collection and to minimize recall bias.

Fisher Exact Tests were performed on the data with results being deemed significant if the  $p$  value was  $<0.05$ . Local Riverside Ethics Committee approval was granted and CE marking was obtained for the trial and product. Patients were excluded during the trial if:

- they were under the age of 18;
- they were unable to consent to Tournistrip™ use;
- there were open skin lesions at the site of tourniquet use;
- the patient had frail/thin skin, e.g. with long term steroid use; or
- peripheral vascular disease was present.

## 3. Results

### 3.1. Patient data

Table 1. Responses to patient question 1: 'does the Tournistrip look professional?'

Answer	Frequency
No	12
Acceptable	69
Professional	79
Very professional	69
Total	229

Table 2. Responses to patient question 2: 'does the Tournistrip look as professional as a standard re-usable tourniquet?'

Answer	Frequency
Prefer re-usable	46
No difference	57
Prefer Tournistrip	88
Tournistrip much more professional	36
Total	227

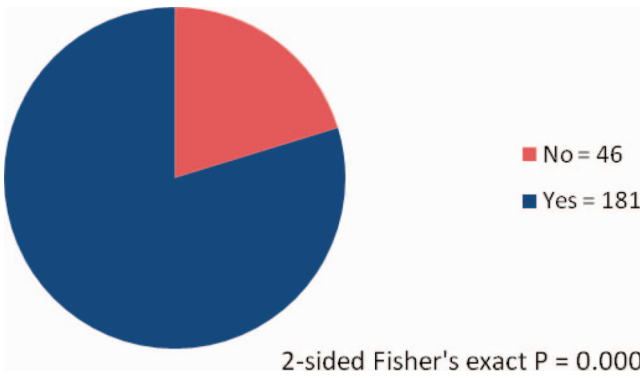


Figure 1. Responses to patient question 2: 'does the Tournistrip look as professional as a standard re-usable tourniquet?'

Table 3. Responses to patient question 3: 'how does the Tournistrip compare to a rubber glove for use in venepuncture?'

Answer	Frequency
Prefer rubber glove	5
Similar	38
Prefer Tournistrip	102
Much prefer Tournistrip	63
Total	208

Table 4. Responses to patient question 4: 'was the Tournistrip comfortable?' (Range 0-6, where 6 = very comfortable).

Answer	Frequency
0	15
2	33
3	1
4	64
6	114
Total	227

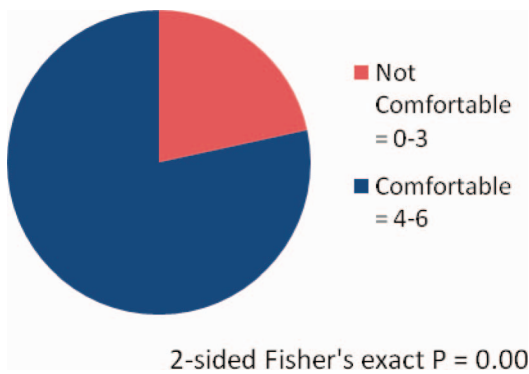


Figure 2. Responses to patient question 4: 'was the Tournistrip comfortable?'

Table 5. Responses to patient question 5: 'did the use of the Tournistrip cause any pinching of your skin?' (Range 0-6, where 6 = significant pinch).

Answer	Frequency
0	185
2	22
3	1
4	10
6	12
Total	230

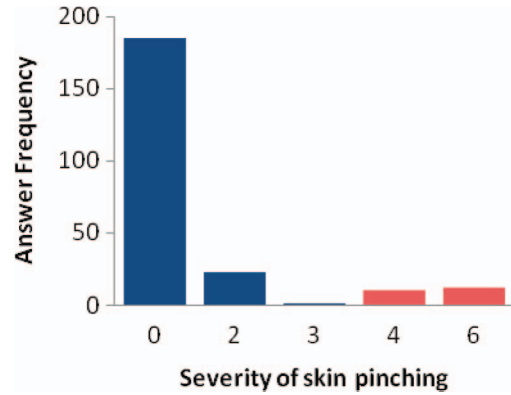


Figure 3. Responses to patient question 5: 'did the use of the Tournistrip cause any pinching of your skin?'

Table 6. Responses to patient question 6: 'overall how would you rate Tournistrip compared to standard re-usable tourniquets?'

Answer	Frequency
Prefer re-usable	35
On par	57
Prefer Tournistrip	72
Much prefer Tournistrip	62
Total	226

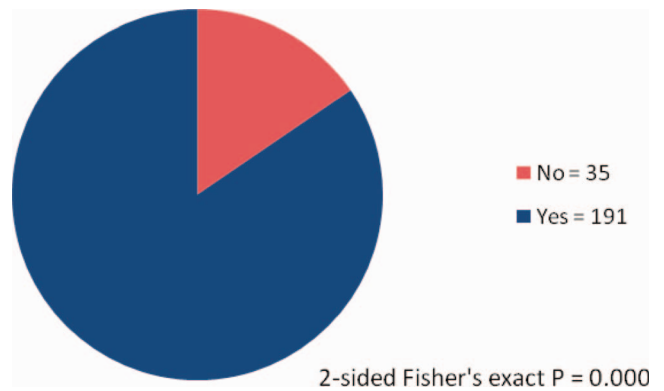


Figure 4. Responses to patient question 6: 'overall was Tournistrip at least as good as the current re-usable tourniquets?'

### 3.2. Phlebotomist data

Table 7. Responses to phlebotomist question 1: 'how professional does Tournistrip look compared to current alternatives?'

Answer	Frequency
Not at all	0
Acceptable	9
Professional	9
Very professional	2
Total	20

Table 8. Responses to phlebotomist question 2: 'how professional does Tournistrip look compared to standard re-usable tourniquets?'

Answer	Frequency
Prefer re-usable	3
Similar	3
Prefer Tournistrip	9
Much prefer Tournistrip	4
Total	19

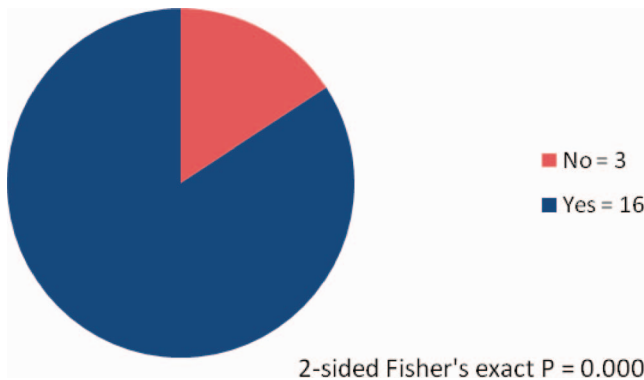


Figure 5. Responses to phlebotomist question 2: 'does the Tournistrip look at least as professional as the current re-usable Tourniquets?'

Table 9. Responses to phlebotomist question 3: 'how professional does Tournistrip look compared to current disposable tourniquets?'

Answer	Frequency
Prefer current disposable	0
Similar	7
Prefer Tournistrip	6
Much prefer Tournistrip	2
Total	15

Fisher Exact Test noted required as comparing against '0'.

Table 10. Responses to phlebotomist question 4: 'how easy is Tournistrip to use compared to current re-usable tourniquets?'

Answer	Frequency
Prefer current re-usables	1
Similar	6
Prefer Tournistrip	8
Much prefer Tournistrip	4
Total	19

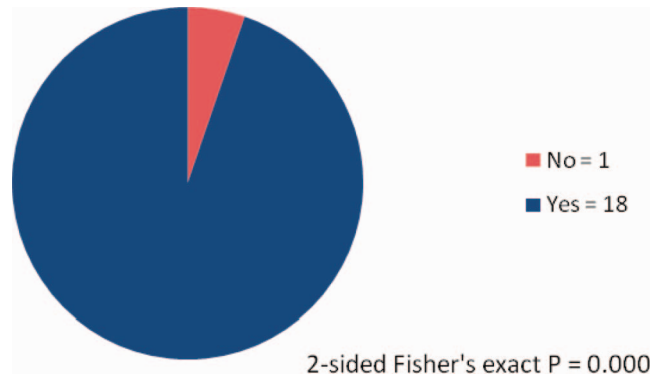


Figure 6. Responses to phlebotomist question 4: 'is Tournistrip as easy to use as current re-usable tourniquets?'

Table 11. Responses to phlebotomist question 5: 'how easy is Tournistrip to use compared to current disposable tourniquets?'

Answer	Frequency
Prefer current disposables	0
Similar	4
Prefer Tournistrip	9
Much prefer Tournistrip	5
Total	18

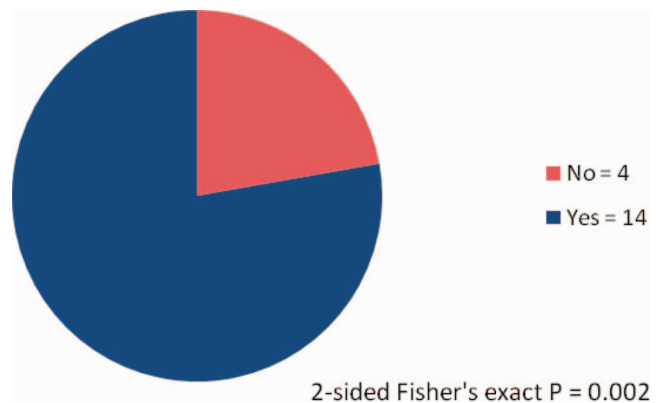


Figure 7. Responses to phlebotomist question 5: 'is the Tournistrip easier to use than current disposable tourniquets?'

## 4. Discussion

The aim of the study was to compare the Tournistrip against both the current re-usable tourniquets (RT) and the disposable (DT) alternatives. The current gold standard is the elastic and clip re-usable tourniquet, which is widely used within the clinical setting because of ease of use and patient comfort. Therefore any new device for venepuncture must be at least as capable as this. For that reason analysis between Tournistrip and RT is always 'prefers re-usable' versus 'similar' or better. On the other hand comparisons between Tournistrip and existing DT is always 'prefers Tournistrip' versus 'similar' or 'prefers disposables', as a new product into a market must be better than the current alternatives.

### 4.1. Patient data

The tools used by healthcare professionals can impact on patient opinion and anxiety. Of the patient cohort 95% felt Tournistrip looked professional when used in venepuncture. Against the current RT, 79.7% stated the Tournistrip was at least as professional looking as the RT ( $p < 0.001$ ), with over half preferring the professionalism of Tournistrip.

At present the main DT in use is a rubber strip, which is tied around the patient's limb. This can cause discomfort and pinching. Any new fit-for-purpose device should consider the patient comfort. Of the participants 72% ( $p < 0.001$ ) found the Tournistrip was comfortable during use with 94.5% ( $p < 0.001$ ) reporting no considerable pinching.

Overall 191 of the 226 responders (84.5%,  $p < 0.001$ ) felt the Tournistrip was as good as or better than the current gold standard tourniquet, with 59% preferring Tournistrip for venepuncture.

Within clinical practice, rubber gloves are often used as a substitute for a tourniquet. From the authors' experience these are often uncomfortable and do not look fit for purpose. 79.3% of responders stating that Tournistrip appears more professional ( $p < 0.001$ ).

### 4.2. Phlebotomist data

The healthcare professional must consider a medical device fit-for-purpose and easy to use in order for it to become part of their clinical practice. All of the phlebotomists within the study considered the Tournistrip a professional device in blood taking, with 84.2% stating it looked at least as a professional as the RT ( $p < 0.001$ ). None of the phlebotomists preferred the current DT to the Tournistrip. Of the 19 phlebotomists 18 reported that the Tournistrip was at least as easy to use as the RT, with 77.7% preferring Tournistrip to the DT for ease of use ( $p < 0.001$ ).

### 4.3. Study limitations

The major limitation of this study is the lack of a control arm for direct comparison. All patients were outpatients having blood taken. This only requires one venepuncture episode per patient. Therefore we could not directly compare two tourniquets for each patient. As nearly all patients would have had a previous blood test, their experience of alternative tourniquets at that time was taken into consideration.

The study is also limited by not being blinded; however, as the questionnaire directly asks for opinions of the new tourniquet it would not be possible to blind either phlebotomist or patient to the purpose of the study.

Finally for two of the numbered Likert Scale questions the same patient responded with 3, which was not a printed option. The author decided to include this answer into the results as it was within the range set, and describes a participant's perception.

## 5. Conclusion

There is currently huge political and public pressure to reduce hospital acquired infections due to the avoidable morbidity and mortality it can cause. One of the strategies implemented is the use of single use clinical items. The introduction of disposable clinical tools potentially adds an additional financial burden to the NHS and other healthcare providers. This must be offset against the economic and personal costs of HAIs when developing national and local strategies in dealing with the problem.

Some of the new medical devices are designed with cost in mind and are not always fit-for purpose. Alternatively healthcare professionals use existing items for purposes other than they were designed, such as rubber gloves for venepuncture.

The Tournistrip was designed to match the comfort and ease of use the RT, but maintain cost efficiency. This clinical trial shows the Tournistrip is viewed as a superior tourniquet to the current generation of disposable tourniquets and a viable replacement to the re-usable tourniquet in the continuing challenge to reduce hospital acquired infections.

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