

Adhesion and acceptability of novel oral patches in human volunteers

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Introduction

Oral lesions such as Oral lichen planus (OLP) or Aphthous Ulcers are often characterised by painful or erosive oral lesions. These lesions are often treated with steroid-containing mouthwashes or creams but these preparations can be ineffective due to low drug contact times. We have created an oral adhesive patch using electrospinning technology that is able to firmly adhere to porcine and tissue-engineered oral mucosa for prolonged periods and so may be able to deliver drugs directly to a lesion. In this study we examine the adherence of drug-free oral patches in human volunteers to determine their longevity and acceptability in humans.

Study Protocol

- Volunteers (n =37) who met the inclusion and exclusion criteria (Table 1) were recruited to the study with written informed consent.
- All volunteers were asked to refrain from eating and drinking for at least one hour before the study.
- Oral patches (25.4 x 12.7 mm) were placed on the buccal mucosa, lateral tongue (Figure 1) for 5 seconds.
- Patches were monitored every 10 minutes for up to 2 hours and residence time (the length of time the patch remained attached to the oral tissue) recorded.
- Volunteer demographics (age, sex and smoking status) was collected.
- At the end of the study the volunteer were asked to complete an acceptability questionnaire on how the patch felt and behaved in the mouth.

Table 1: Inclusion and exclusion criteria for the study.

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> • All volunteers will be over 18 years of age • Both males and females will be included 	<ul style="list-style-type: none"> • A volunteer that has been diagnosed as having an oral disease (e.g. xerostomia, ulcers, OLP, periodontitis, gingivitis, dysplasia or oral cancer) • A volunteer wearing dental braces • A volunteer with an ongoing infection or inflammation of the throat

Results and Discussion

Table 2: Volunteer demographics

Number of volunteers recruited	37
Average age	35.2
Age range	21-59
Smoking status	100% non-smokers
Male: Female	48.65:51.35

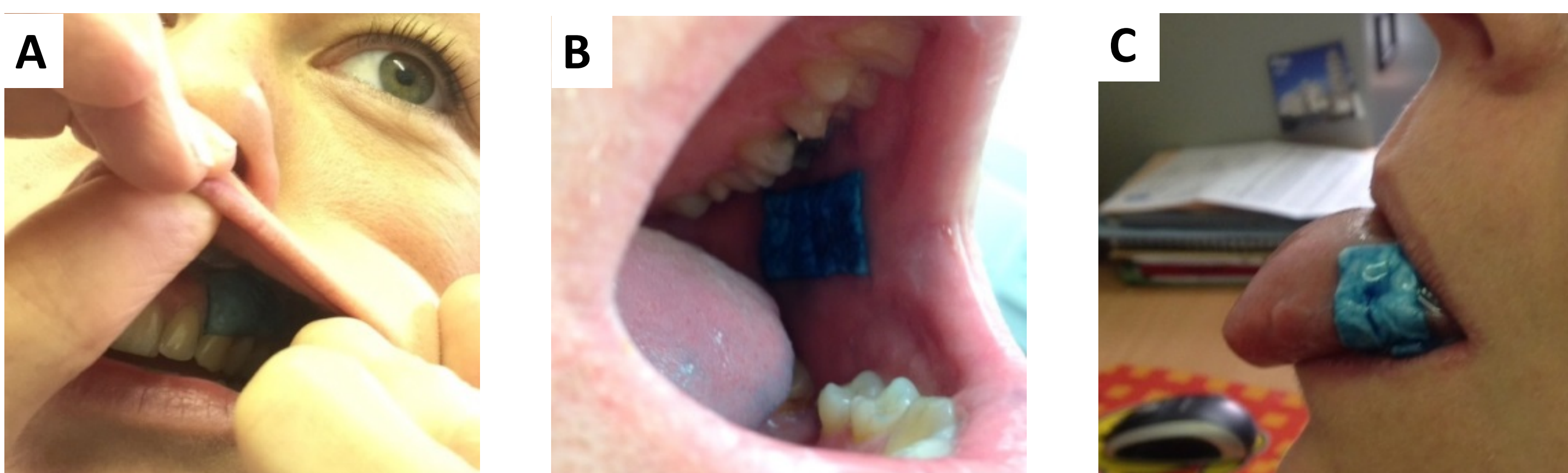


Figure 1: *In vivo* mucoadhesive performance. Bioadhesive patches were placed on the gingiva (a), buccal mucosa (b) or lateral tongue (c) of healthy human volunteers for 5 seconds with applied pressure and residence time measured every 10 minutes for up to 2 hours (n=37).

Oral patches were highly adherent to the human oral mucosal tissues with 100%, 89% and 86% of patches remaining adherent to the gingiva, tongue or buccal mucosa, respectively for 2 hours (Figure 2).



Figure 2: Residence time of oral patches to the gingiva, tongue and buccal mucosa.

At the end of the study when asked, 94% of volunteers felt the patches provided good/excellent adherence (Figure 3) and over 97% of volunteers stated that they would be willing to wear the patch twice-a-day to treat an oral lesion if required (Figure 4).

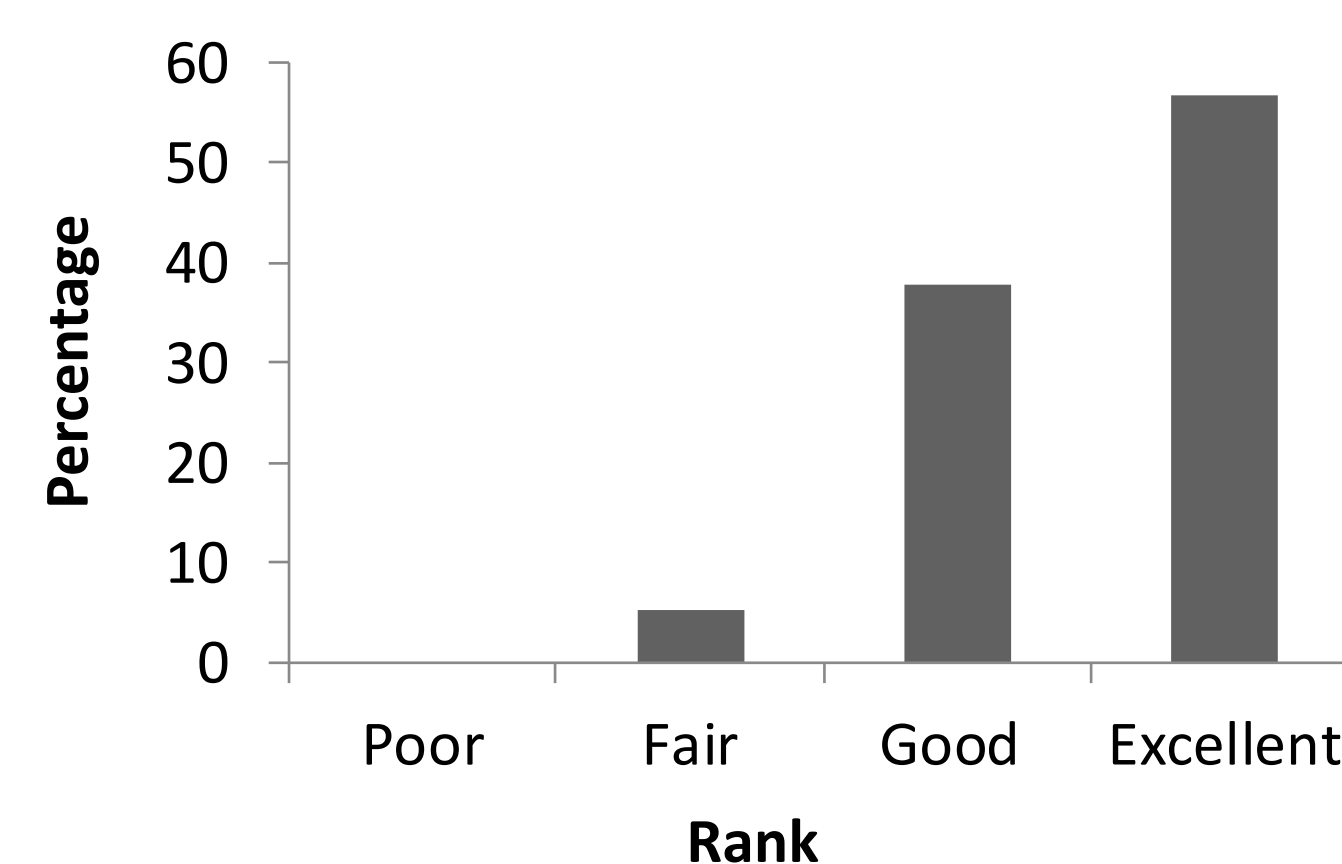


Figure 3: Responses to the question "how did you rate the overall adherence to the lining of the mouth".

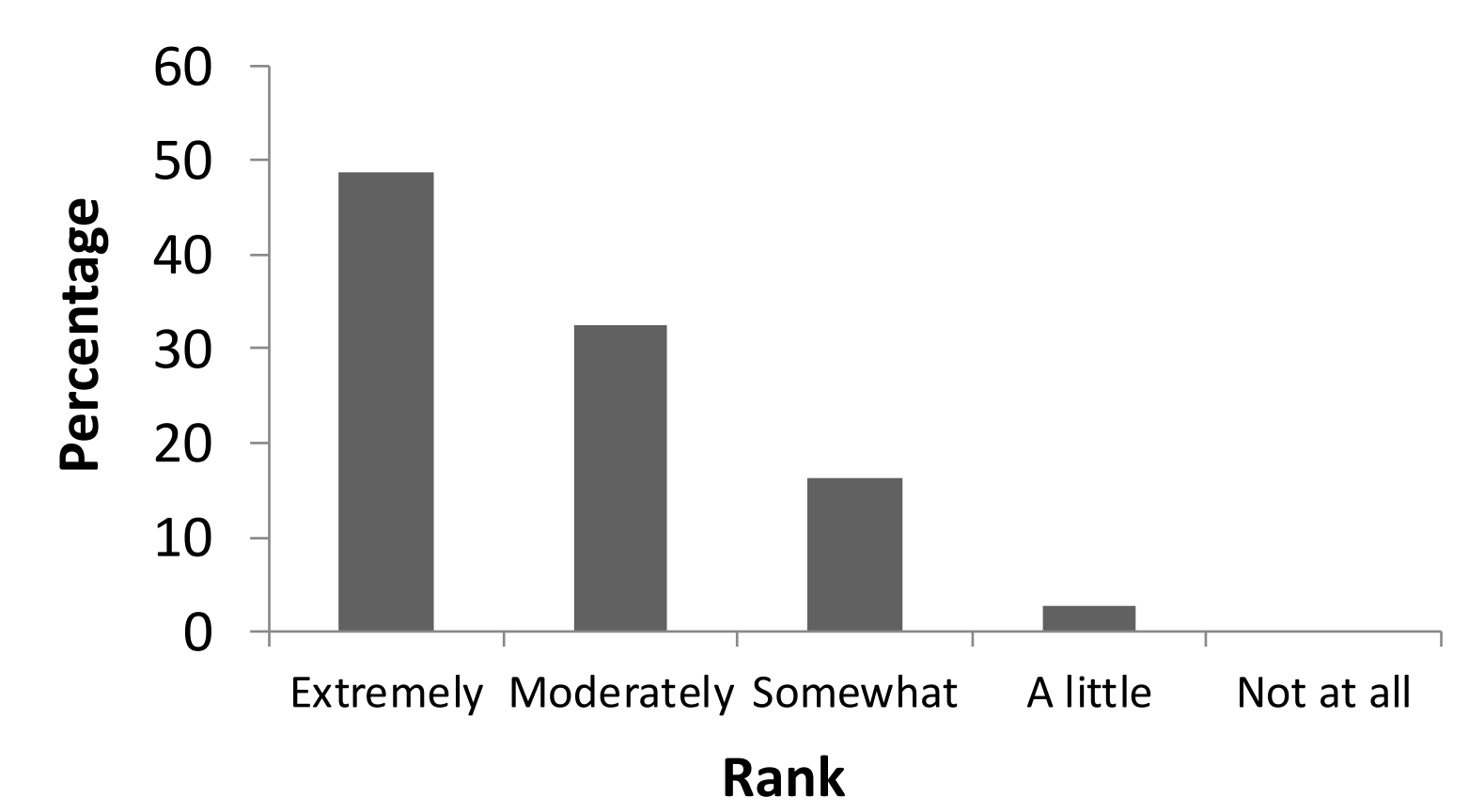


Figure 4: Responses to the question "how willing would they be to wearing the patches".

70% of volunteers felt no irritation whilst wearing the patches (Figure 5) with the majority of volunteers (>70%) stating that the patches were comfortable to wear (Figure 6) and although 16% reported moderate interference with speech (Figure 7) over 55% stated there were no affects on swallowing (Figure 8).

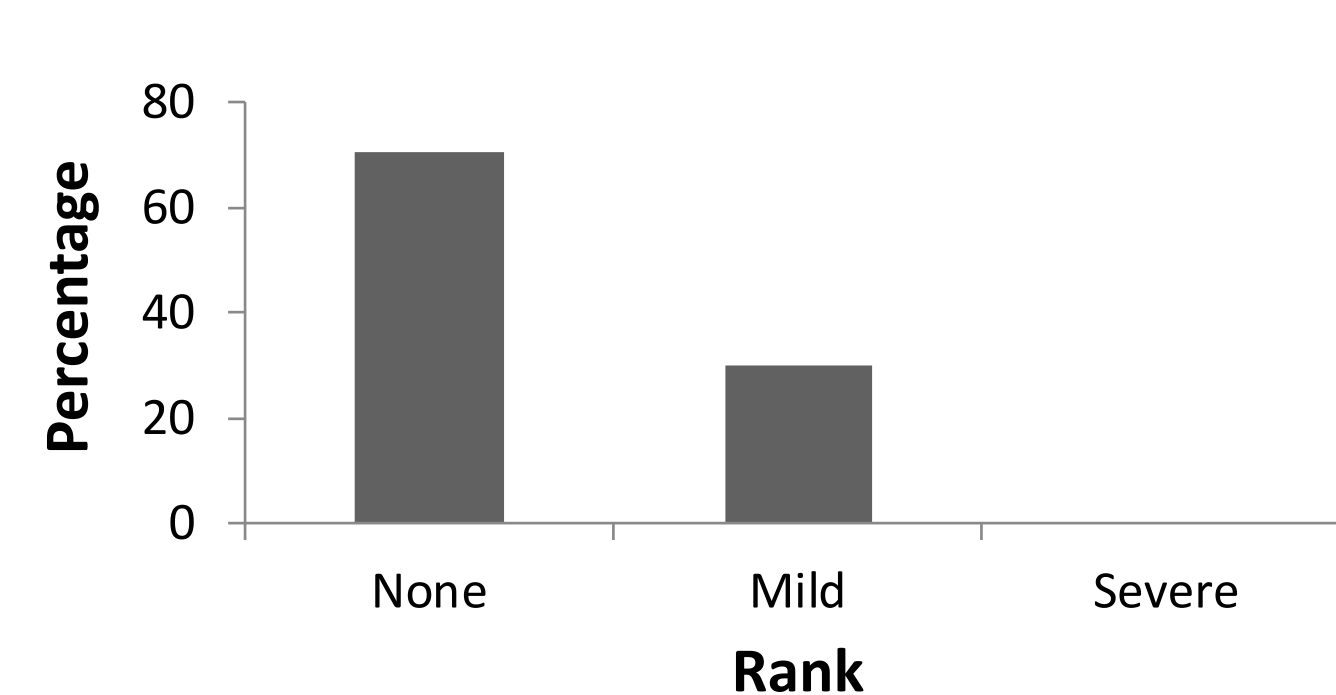


Figure 5: Responses to the question "did you feel any irritation?".

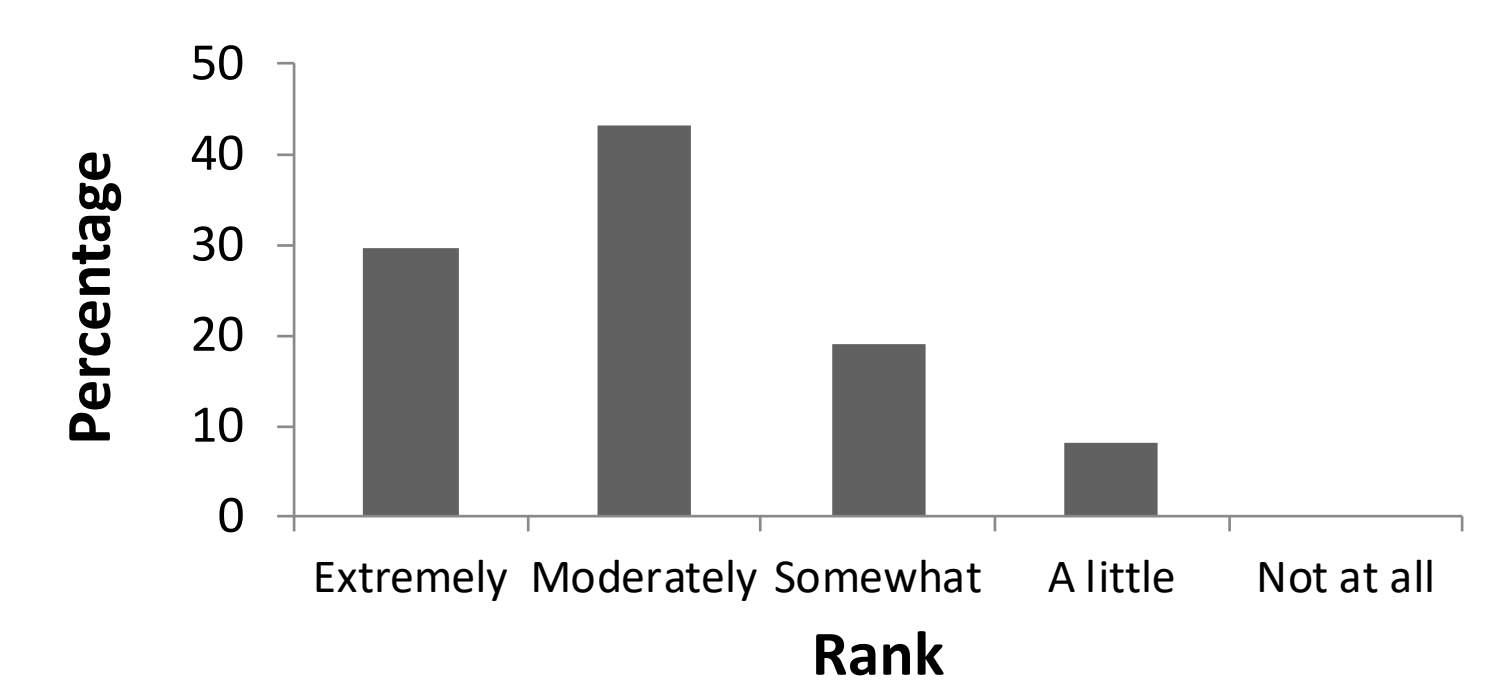


Figure 6: Responses to the question "how comfortable were the patches to wear?".

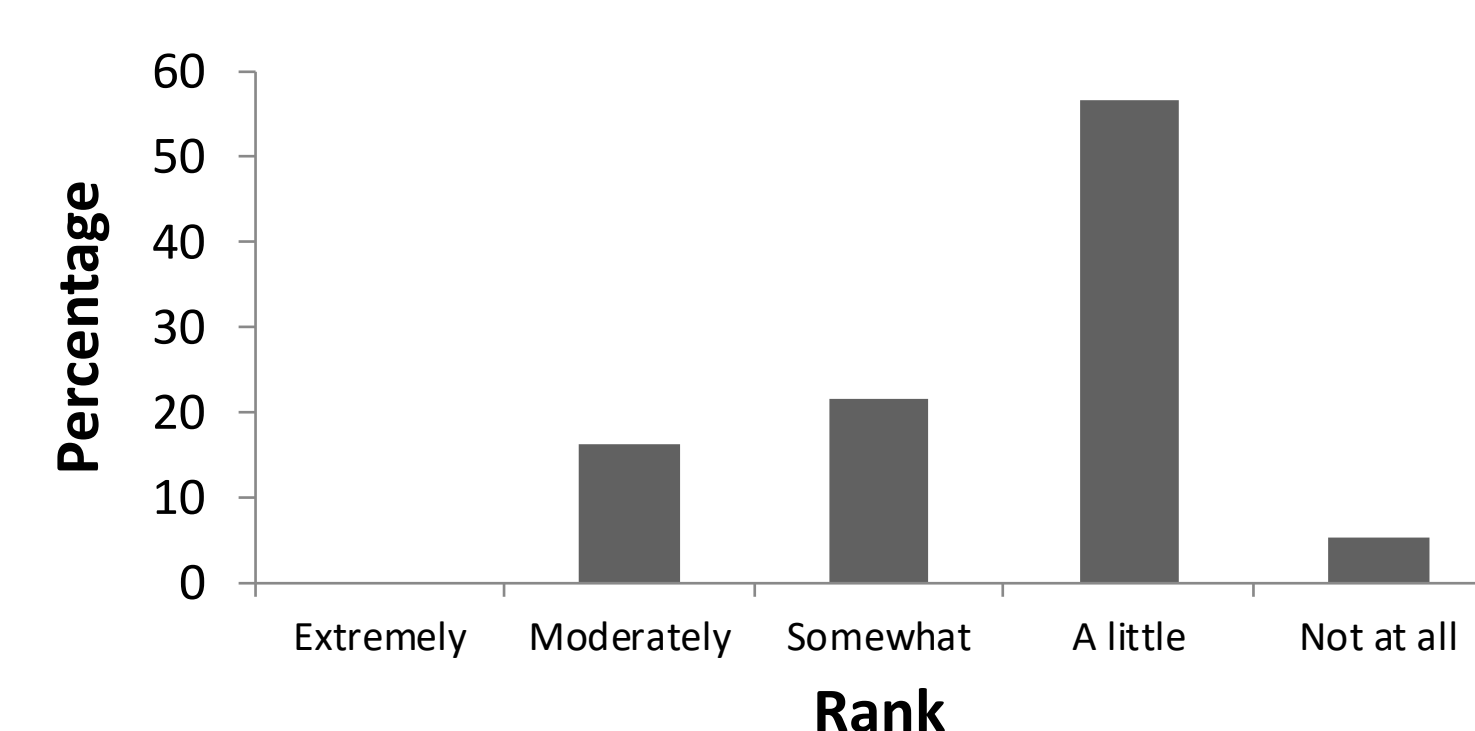


Figure 7: Responses to the question "Did the patches interfere with your speech?".

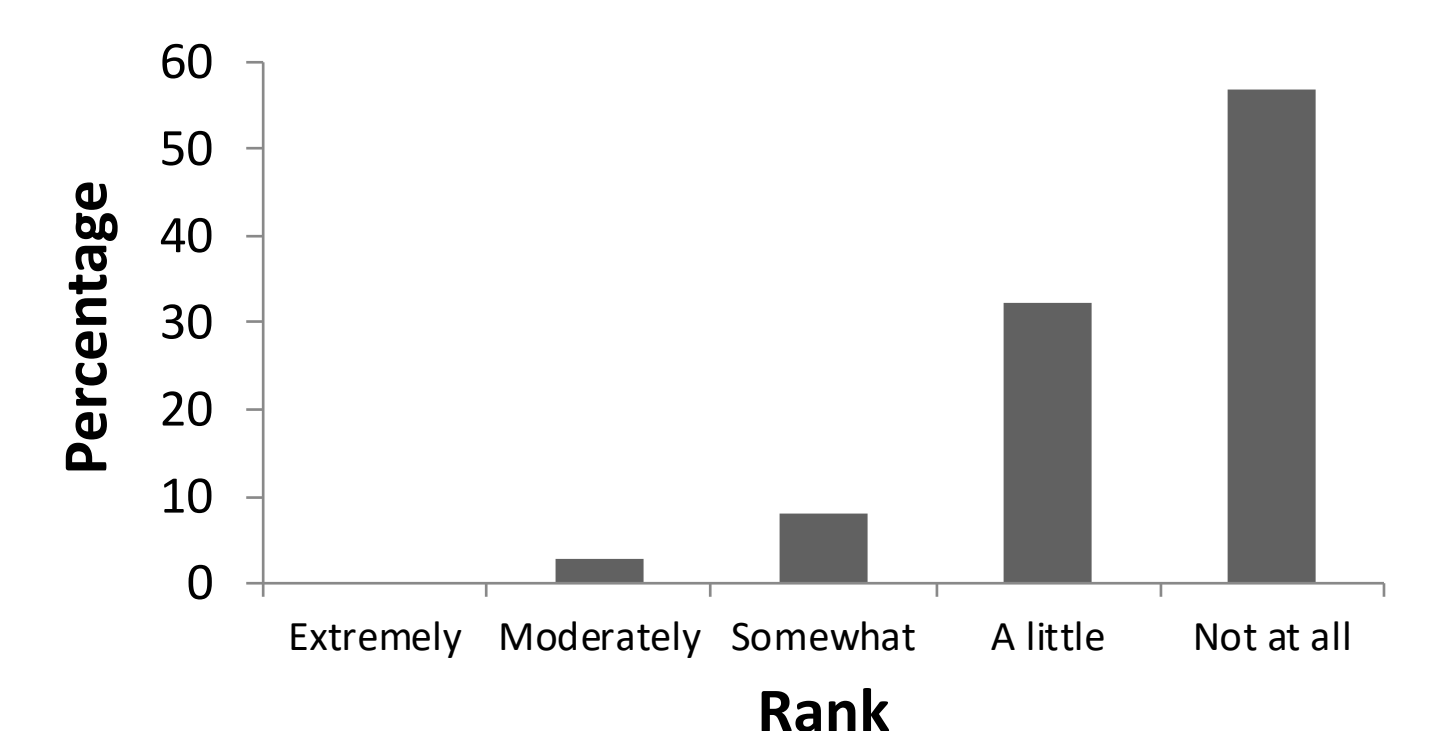


Figure 8: Responses to the question "Did the patches interfere with swallowing?".

In conclusion, electrospun oral patches were strongly adherent to different sites of the oral mucosal for prolonged periods and, overall, were well tolerated. These patches have great potential to deliver drugs directly to oral lesions.