Characterising Capsule Puncture of Different Capsule Types following Patient Actuation of a Dry Powder Inhaler
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Purpose
Gelatin capsules have been used in dry powder inhalers (DPI) since 1971. More recently hypromellose capsules have also been used. Laboratory studies have compared the puncture properties of these two capsules. No work has been published on their in-use performance. This study aimed to characterise the puncturing of gelatin and hypromellose capsules in DPI operated by members of the public.

Methods
Approval was obtained from the Research Ethics Committee of the School. Participants were provided with a brief questionnaire to determine demographic characteristics. Thirty-six participants were recruited and following informed consent were provided with a Plastiape® Monodose 2-pin inhaler and instruction sheet. The patients, in random sequence, were provided with 5 size 3 capsules of hypromellose and gelatin, which had been conditioned in desiccators over saturated solution of calcium chloride (RH 33%). After actuation of DPI and penetration, each capsule was returned to the researcher. Punctured capsules were imaged using a light microscope and the puncture areas were visually inspected and measured, as a percentage of the cap or body cross-sectional area, using Image J® software.

Results
The puncture areas in hypromellose capsule had a body mean of 1.58 ± 0.80% and cap mean 1.72 ± 0.79% and were generally smaller and less variable than those in gelatin capsules that had a body mean of 3.21 ± 1.98% and cap mean 2.89 ± 1.34%. Notably, a cap and a body from two different gelatin capsules shattered during the puncture process. Age, gender and previous experience of using an inhaler device did not significantly effect the puncture area. The flap, created in the capsule wall upon puncture, remained in place for all hypromellose capsules, both cap and body, but for gelatin capsules were only present in 77% of bodies and 73% of caps.

Conclusion
Both the size and shape of punctures created in a capsule when people used a two-pin DPI were more reproducible for hypromellose than for gelatin capsules. Patient factors such as age, gender and previous experiences with an inhaler appear to have little influence on the puncture characteristics of capsules.