

Silicon Irregular Hexagon Pessary Versus Polyvinyl Chloride Ring Pessary For Pelvic Organ Prolapse: A Randomized Controlled Trial

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Introduction

Pelvic organ prolapse (POP) is common and troublesome problem many women experience worldwide. Pessaries are the mainstay of non-surgical management. An intrinsic problem with pessaries is their inability to fit all patients. Pessaries such as the Gelhorn and cube are associated with discomfort, offensive vaginal discharge, pain, ulceration, bleeding, sexual dysfunction and expulsion. Whilst various shaped vaginal pessaries exist, it is standard clinical practice to use a polyvinyl chloride (PVC) ring pessary. Prior hysterectomy, short vaginal length (<6cm), widened genital hiatus, and advanced POP are known risk factors for vaginal pessary discontinuation (5). Our group developed a mouldable silicone irregular hexagonal (SIH) pessary based on the results of a prior vaginal cast study and the recognition that traditional PVC pessaries do not have discrete folding points. We believe these discrete folding points aid in pessary retention and self-care as we hypothesize better vaginal moulding occurs. These points were incorporated into our SIH pessary design (Figure 1).

Aims

The aim of this study was to compare the success of a novel silicone irregular hexagonal (SIH) pessary to the conventional polyvinyl chloride (PVC) ring pessary for the treatment of symptomatic pelvic organ prolapse (POP).

Methodology

This IRB approved prospective non-blinded, randomized controlled trial was conducted between July 2017 to August 2019. Eligible women were enrolled after consent. Women were randomised and fitted with pessaries. They were reviewed 1 week, and 6 and 12 months after initial pessary fitting. All participants completed relevant validated questionnaires. The primary outcome measure compared the treatment success between the two studied pessaries. Treatment success was defined as pessary retention of the allocated pessary type at 6 months follow-up. Secondary outcome measures included participants' ability to perform self-care during pessary use, women's satisfaction with pessary treatment and complications of pessary use. Appropriate statistical tests were performed with statistical significance defined as an alpha of ≤ 0.05 with a power of 80%.

Results

A total of 104 subjects were randomised. Primary outcome data was available for 90 women (43 - SIH, 47-PVC). There were no baseline differences between the SIH and PVC groups with the exception of POP-Q stage. The women were mostly Caucasian with a mean age of 58.2 years old, were parous and largely postmenopausal (67.8%). The majority of the cohort (69.2%) had POP stage II. Compartmental prolapse was noted as follows, anterior 37.6%, apical 8.9%, posterior 34.4%, and combined anterior and posterior prolapse was 18.9%.

Successful pessary retention at 6 months was not statistically different between both groups (68.1% PVC, 65.1% SIH, $p= 0.76$). SIH women were more likely to perform pessary self-care. No differences in satisfaction was noted. Quality of life scores and recorded complications improved with pessary use but no differences between groups was seen.

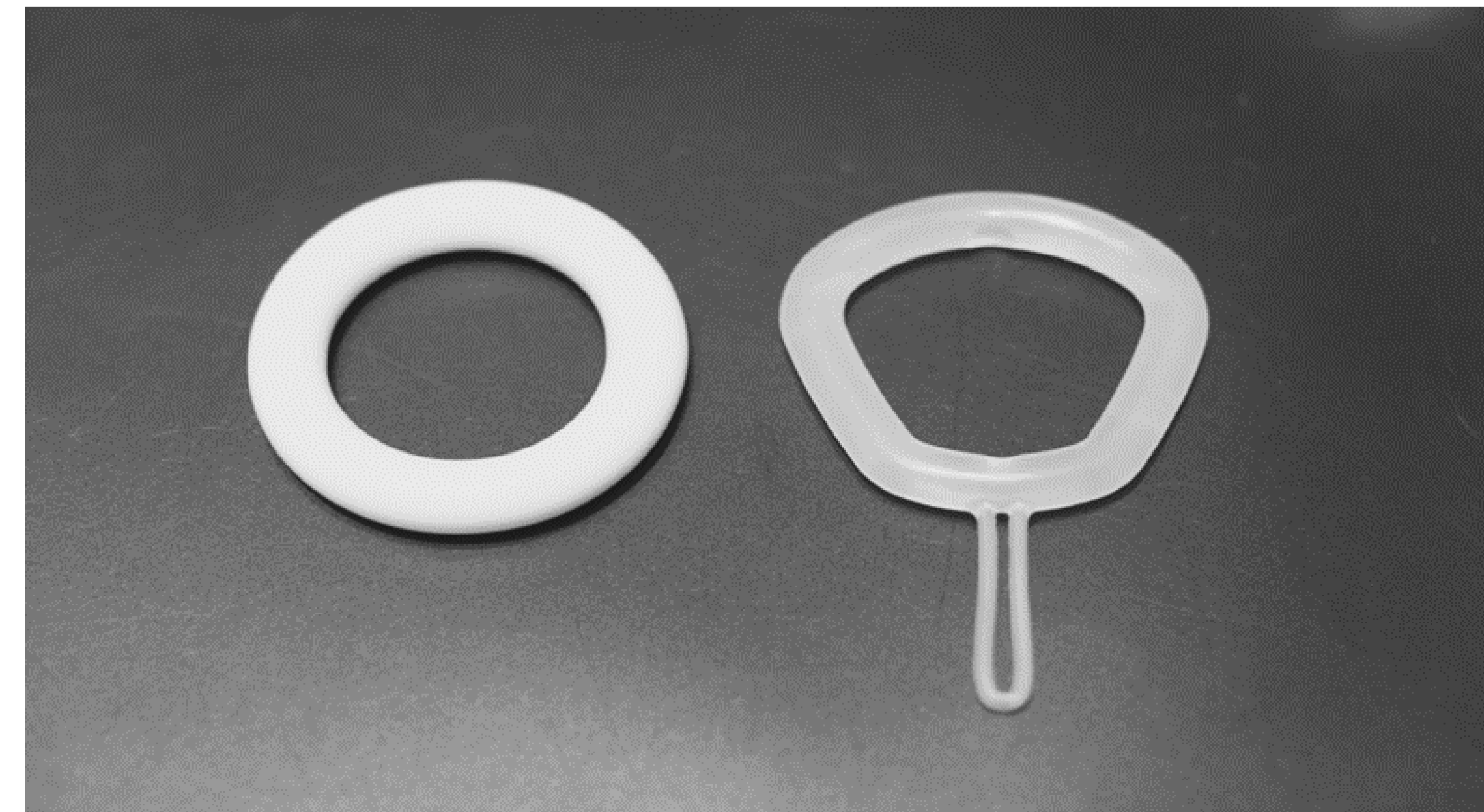


Figure 1:
Conventional PVC
Ring Pessary
(left), Silicon
Irregular Hexagon
Pessary with loop
attached (right)

Conclusions

There were no significant differences in the pessary retention rate between SIH and PVC pessary. Subjects with SIH were more likely to self-manage but no significant differences were observed in quality of life or complications. Women in the SIH group had significantly more advanced POP than in the PVC group.