



Home modeling after penile prosthesis implantation in the management of residual curvature in Peyronie's disease

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Abstract

The aim of this study was to study the clinical effectiveness of a structured home modeling (HM) protocol in Peyronie's disease (PD) patients who have residual curvature up to 45° after inflatable penile prosthesis (PP) placement. A total of 92 patients with PD and coexistent refractory erectile dysfunction received inflatable PP. If residual curvature after manual modeling (MM) was more than 45°, incision-grafting was performed. If curvature was <45° after MM, patients were instructed to perform HM daily for 6 months, after 4 weeks from PP implantation. The mean preoperative penile curvature was 39.4 ± 5.7° (30–60). Sixteen (17.4%) patients required incision-grafting and the remaining 76 (82.6%) patients followed HM protocol. The mean postoperative residual curvature after MM was 29.7 ± 3.2° (5–50). Sixty-five (85.5%) patients who underwent HM had 10° or less residual curvature after 3 months and 72 (94.7%) patients had 10° or less residual curvature after 6 months. Seventy (92.1%) patients responded as satisfied or very satisfied on the questionnaire with the outcome after 6 months. HM of the penis over Inflatable PP may straighten the penis without the need for an additional surgical maneuver in vast majority of the PD patients having residual curvature of <45°.

Introduction

Peyronie's disease (PD) is a connective tissue disorder which mainly affects the tunica albuginea of the penis, which may lead to penile curvature and/or erectile dysfunction (ED) [1]. The etiopathogenesis of PD is still less understood and lot more research is still needed in understanding the disease [2].

Acute phase of PD primarily involves conservative management, although few studies report success with collagenase clostridium histolyticum (CCH) injection [3]

and/or penile traction therapy (PTT) [4] in acute phase, but the evidence is weak on the same. Chronic phase of PD is the right opportunity for surgical intervention when the penile curvature stabilizes [5].

Penile prosthesis (PP) becomes the mainstay of management in patients with PD with coexistent ED [6]. Residual curvature poses a significant hurdle after PP implantation [7]. In spite of Wilson's intraoperative manual modeling (MM) [8] over a PP, significant penile curvature may persist when the preoperative curvature is beyond 60° [9]. Additional surgical interventions like grafting may add to the peri-operative morbidity including increased infection rates and higher costs [10, 11]. Nevertheless, in many series, as many as up to 40% of patients need surgical correction of the curvature in addition to PP [12].

After intralesional CCH injection, home modeling (HM) forms an integral aspect of penile rehabilitation program to improve the results [13]. Applying a similar concept [13], Moncada's HM protocol after inflatable penile prosthesis (IPP) implantation helps improve penile curvature thereby reducing the additional surgical maneuvers.

The primary aim of the study was to assess the residual penile curvature postoperatively after 6 months of HM.

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Materials and methods

A retrospective review of prospectively collected data was performed of all patients diagnosed with PD who underwent IPP implantation between 2008 and 2017. Institutional review board approval was obtained. All patients received AMS 700-CX IPP (Boston Scientific Corp, Marlborough, MA, USA) through a standard peno-scrotal approach. After implantation, the IPP was inflated to maximum and penile curvature was measured using goniometer. All patients underwent subsequent Wilson's MM [8] in the operating room.

If the residual curvature was more than 45°, circumcision and incision-grafting were performed. Rest of the patients with <45° residual curvature after MM were instructed to perform HM after 4 weeks from implantation.

The HM protocol consisted of (1) full inflation of the IPP and gently bending (modeling) the penis in the opposite direction of the curvature, (2) each cycle consisted of holding the penis in this stretched position for 30 s, and then subsequently deflating the IPP, (3) such multiple cycles were done in each episode lasting for 20 min, and (4) such three episodes were done every day for 6 months. The HM was first instructed in office by the urologist after 4 weeks of surgery and subsequently done by the patient himself at home.

Demographic and surgical data were collected from the patient medical records. Improvement in penile curvature and patient satisfaction was assessed postoperatively using a non-validated questionnaire (Supplementary Fig. 1). The main outcome measure was the residual curvature at 6 months postoperatively.

Results

The mean age of the study group was 62.8 ± 2.7 years (52–79) (Table 1). A total of 92 patients with PD and coexistent ED received IPP. The mean preoperative penile curvature was 39.4 ± 5.7° (30–60). Sixteen (17.4%) patients required incision-grafting and the remaining 76 (82.6%) patients followed HM protocol. The mean postoperative residual curvature after MM was 29.7 ± 3.2° (5–50). Sixty-five (85.5%) patients who underwent HM had 10° or less residual curvature after 3 months and 72 (94.7%) patients had 10° or less residual curvature after 6 months (Table 2). Seventy (92.1%) patients responded as satisfied or very satisfied on the questionnaire with the outcome after 6 months. The following complications were noted after IPP: hematoma not requiring surgery (six patients), pain lasting <6 weeks (four), pump revision for malfunction (one), mechanical failure—tubing leakage (one), and

Table 1 Patient's characteristics.

Number of patients	92
Diabetes	18
Hypertension	26
Cardiovascular disease	12
Age (years)	62.8 ± 2.7

Table 2 Results.

Penile curvature	Preoperative	After manual modeling
	39.4 ± 5.7° (30–60)	29.7 ± 3.2° (5–50)
Number of patients	Incision-grafting	Home modeling
	16 (17.4%)	76 (82.6%)
Number of patients with residual penile curvature <10°	At 3 months	At 6 months
	65 (85.5%)	72 (94.7%)

impending erosion (one). No revision surgery was needed in the first 3 months postoperatively.

Discussion

The two important goals of surgery in PD are restoration of erectile function and penile curvature correction for a satisfactory sexual intercourse [14]. PP becomes the mainstay of management in patients with PD with coexistent ED [6]. Simultaneously, procedures like plication or incision-grafting are usually done if residual curvature persists beyond 30° even after MM [5].

The additional surgical maneuvers needed after IPP implantation in PD ranges between 19 and 42% and may be associated with complications [7, 12, 15–17]. Terrier et al. pointed out that the penile sensory changes range from 2 to 21% after incision-grafting and it may take up to 1 year for the resolution of complete loss of sensation [18]. Graft herniation, penile sensory changes, glans edema, recurrence of curvature due to graft contraction, and graft infection rates vary significantly depending on the type of graft used [15–17].

American Urological Association guidelines on PD recommend the use of only IPP and not malleable PP in PD; however, this is only an “Expert Opinion” [19]. Our study included the use of IPP only. Although MM can be done over a malleable PP, IPP is still the most preferred option for MM. Garaffa et al. reported that a three-piece IPP provides better strength than the malleable for MM. In his study group of 209 patients, adequate straightening was

128 achieved in 89.6% of cases with a three-piece IPP and
129 53.8% with a malleable PP [12].

130 There are few studies [20–22] highlighting the role of
131 IPP acting as a tissue expander by stretching the corpora
132 over few months and all these studies have different post-
133 operative IPP cycling protocols stating improvements in
134 penile length. None of these studies [20–22] commented on
135 improvements in penile curvature with cycling of IPP,
136 probably due to the correction of curvature by additional
137 surgical maneuvers.

138 Wilson et al. [20] proposed a protocol which achieved
139 girth and length enhancement by 2–4 cm in patients with
140 previous infection, but only girth enhancement in patients
141 with prior priapism. The protocol involved inflating the
142 IPP for up to 3 h daily over a period of 8–12 months. In 40
143 patients, Henry et al. [21] followed a protocol which
144 involved daily inflation of the IPP from 6 weeks to 1 year
145 with a compulsory inflation of 1–2 h in last 6 months.
146 With this, they noted improvements in penile length,
147 penile circumference, girth and satisfaction rates at
148 12 months. Penile length increased by 1.14, 0.99, and
149 1.04 cm for erect, flaccid, and stretched penis, respec-
150 tively, at 12 months. Chung et al. [22] accessed the
151 American Medical Systems and Coloplast Patient Infor-
152 mation Form databases of 2749 patients and reported that
153 60% of patients increased >0.5 cm and 40% increased
154 ≥ 1 cm in IPP cylinder length at ≥ 2 years. The authors
155 highlighted the possible role of IPP as a tissue expander to
156 increase internal penile length.

157 PTT has gained popularity in recent years, it being a
158 nonsurgical modality to treat PD. The clinical studies
159 reporting the efficacy of PTT have small study groups and
160 lack randomization and patient compliance [23, 24]. The
161 European Association of Urology 2019 guidelines confer a
162 “weak” recommendation for the use of PTT to reduce penile
163 deformity and increase the penile length [25]. Mechan-
164 otransduction is a process that converts mechanical stimuli
165 to cellular biochemical responses.

166 With the use of mechanical traction and tissue expansion
167 therapy, alteration of connective tissue by cellular pro-
168 liferation and expansion of the extracellular matrix have
169 been demonstrated [26]. Having borrowed the concept of
170 mechanotransduction from bone remodeling [27] and
171 Dupuytren’s contracture studies [28], Chung et al. [29]
172 performed the first in vitro experimental analysis to study
173 the efficacy of tissue traction therapy in PD. Chung et al.
174 documented significant alterations in the ultrastructure of
175 connective tissue with increased collagenase activity and
176 decreased collagen–elastin staining. We assume that IPP
177 does the role of PTT as the postoperative IPP cycling causes
178 repeated stretching of tunica albuginea which results in
179 mild-moderate correction of penile curvature, thereby
180 avoiding additional surgical maneuvers. The strong build

181 quality of the IPP cylinders can withstand the pressures
182 during HM and MM. The cylinder tubings are clamped
183 during intraoperative MM, which of course is not done
184 during HM.

185 The IMPRESS trial [13] mentioned about the penile
186 plaque modeling done by the physician during the first visit
187 after two CCH injections and subsequent HM was done by
188 the patient himself. Ziegelmann et al. [30] slightly modified
189 this protocol and instructed his patients to perform the HM
190 themselves (rather than the physician) beginning on the first
191 day of the CCH injection [21]. Like in IMPRESS trial [13],
192 in our study, the first modeling session was done by the
193 physician in the clinic when the patient came for the first
194 postoperative visit at 4 weeks and subsequent ones were
195 done by the patient himself at home. We noted that no cases
196 of tunical rupture due to HM, and it was well accepted by
197 majority of patients.

198 HM after IPP has not been documented in the literature
199 for residual curvature correction, although studies [20–22]
200 have reported on penile length and girth increment after
201 IPP. This would be the first study to highlight the impor-
202 tance of HM after IPP for residual curvature correction even
203 up to 45°. Limitations of this study include: (a) use of a non-
204 validated questionnaire to assess satisfaction, (b) recall bias
205 as 6 months is a longer time for recall period in a
206 questionnaire-based assessment, (c) lack of power analysis,
207 and (d) lack of a control group.

208 Conclusion

209 This is a pilot study reporting the effectiveness of HM and
210 is a viable option in preventing adjunctive surgical man-
211 euvers after IPP implantation even up to residual curvature
212 of 45°. The HM protocol described in our study is patient
213 friendly, easily reproducible, and not cumbersome. Six
214 months of HM gives satisfactory results with no adverse
215 effects.

216 **Author contributions** All authors have: conceived and/or designed
217 the work that led to the submission, acquired data, and/or played an
218 important role in interpreting the results; drafted or revised the
219 paper; approved the final version; agreed to be accountable for all
220 aspects of the work in ensuring that questions related to the accuracy
221 or integrity of any part of the work are appropriately investigated
222 and resolved.

223 Compliance with ethical standards

224 **Conflict of interest** The authors declare that they have no conflict of
225 interest.

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