Medical report on IPP

A specialist recently told us the moving story a patient with IPP who refused to undergo surgery. The angle of lateral deviation of his penis was extreme at approx. 90°. The curvature made sexual intercourse impossible.

The specialist decided to try a treatment with PHALLOSAN® forte. Only 3 months after the start of treatment involving traction (pull) on the penis in the opposite direction, a significant decrease in deviation was observed (angle of deviation 60°). After 6 months the deviation had reduced to 30°, so that the patient was once again able to engage in pain-free sexual intercourse. The case has been documented with photographs, treatment is still underway. The specialist in attendance intends to publish a case study of the therapy in a medical journal.

We are well aware that these plaques will not be removed by the use of PHALLOSAN® forte. The above-named patient, however, delivered proof that if the penis is subjected to constant traction in the direction opposite to the curvature, the latter can be considerably reduced over a period of a few months, or at least the process can be inhibited. Admittedly, long-term results are not yet available. We are unable to confirm whether and from which point in time a permanent remission can be assumed. It is possible, that with these chronic symptoms, a treatment at shorter intervals will remain necessary, as a maintenance therapy. Still, this result encourages us to recommend a treatment with PHALLOSAN® forte in certain cases, especially before resorting to operative measures. It is recommended as it does not interfere with other treatment options.
Presentation of a new form of therapy (PHALLOSAN® forte) for non-invasive treatment of induratio penis plastica (IPP)

Introduction:

As a disease of the penis, induratio penis plastica is difficult to treat. With increasing severity it makes sexual intercourse painful or even prevents it. To date, the exact pathogenesis of IPP has not been fully explained. Histopathological studies show that a major cause is a disruption of collagen metabolism. Increased synthesis of type III collagen was determined [1] (this may be responsible for plaque formation).

Surgical treatment of IPP does not achieve the desired result in all patients. As an alternative, several non-surgical forms of therapy were developed over the past few years. In a clinical study involving a total of 130 patients, 21 patients were treated with ultrasonic waves, 73 patients with Verapamil injections and 36 patients with ultrasonic waves in combination with Verapamil injections [2]. In 11 of 21 patients the plaques were reduced by the ultrasonic wave treatment. Although the authors recommend the treatment with ultrasound and Verapamil, the results of the combination therapy are not convincing.

Another study was able to show that the injection of betamethasone or placebo reduced the volume of plaque in 40% of the patients examined [3]. In this study it was thus only possible to identify the mechanical effect of the injection volume as the actual effective mechanism. This study encouraged us to investigate a completely non-invasive procedure for the treatment of IPP that is described in the following case.

Casuistic:
A 61 year old patient has been treated for IPP since the end of 1999 without positive results. Due to a colitis ulcerosa and constant micro hemorrhaging, the patient was under regular care of an internist. From the internist's point of view, the colitis ulcerosa was in remission and kidney function normal. Since the patient did not want to have an operation to treat the IPP, he was offered a new, non-invasive therapy, which showed impressive results after just a few months. The patient was keen on having his successful treatment published and gave his written consent for the publication.

The patient was instructed how to use a (PHALLOSAN® forte). The principal of the sleeve depends on a continuous and gentle pull on the penis (image 1). Due to a sideways deviation, a variable pull can be excreted on the penis (image 2). For more detailed information, please see the user manual. All known aspects concerning wear and application of the product are shown here. Important hygiene measures are described, as well.

Summary and outlook:
The heavy-duty bell sleeve (PHALLOSAN®) enables a new and completely non-invasive treatment of IPP. A straightening and normalization of the sexual function can be achieved by exerting tension on the penis for several hours a day in the direction opposite the curvature. Further studies with a larger number of cases will be necessary to determine whether the heavy-duty bell sleeve is also capable of remedying other types of erectile dysfunction. Reports by diabetics with erectile dysfunction and paraplegic patients are so far very encouraging.

Literature:

**Author:**
The author is known to Orbisan Ltd. and will be named upon specific request.

**Use of Penile Extender Device in the Treatment of Penile Curvature as a Result of Peyronie's Disease. Results of a Phase II Prospective Study - Abstract**

("Klinische Studie als Nachweis zur erfolgreichen Behandlung zur Begradigung von Penisverkrümmungen ohne OP.")

Pilot experiences have suggested that tension forces exerted by a penile extender may reduce penile curvature as a result of Peyronie's disease.

To test this hypothesis in a Phase II study using a commonly marketed brand of penile extender. Methods. Peyronie's disease patients with a curvature not exceeding 50 degrees with mild or no erectile dysfunction (ED) were eligible. Fifteen patients were required to test the efficacy of the device assuming an effect size of >0.8, consistent with an "important" reduction in penile curvature. Changes in penile length over baseline and erectile function (EF) domain scores of the International Index of Erectile Function (IIEF) constituted secondary end points.

Patients were counselled on the use of the penile extender for at least 5 hours per day for 6 months. Photographic pictures of the erect penis and measurements were carried out at baseline, at 1, 3, 6, and 12 months (end of study). The IIEF-EF domain scores were administered at baseline and at the end of study. Treatment satisfaction was assessed at end of study using a nonvalidated institutional 5-item questionnaire.

Penile curvature decreased from an average of 31 degrees to 27 degrees at 6 months without reaching the effect size ($P = 0.056$). Mean stretched and flaccid penile length increased by 1.3 and 0.83 cm, respectively at 6 months. Results were maintained at 12 months. Overall treatment results were subjectively scored as acceptable in spite of curvature improvements, which varied from "no change" to "mild improvement."

In our study, the use of a penile extender device provided only minimal improvements in penile curvature but a reasonable level of patient satisfaction, probably attributable to increased penile length. The selection of patients with a stabilized disease, a penile curvature not exceeding 50 degrees, and no severe ED may have led to outcomes underestimating the potential efficacy of the treatment.

**Written by:**

**Reference:**

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