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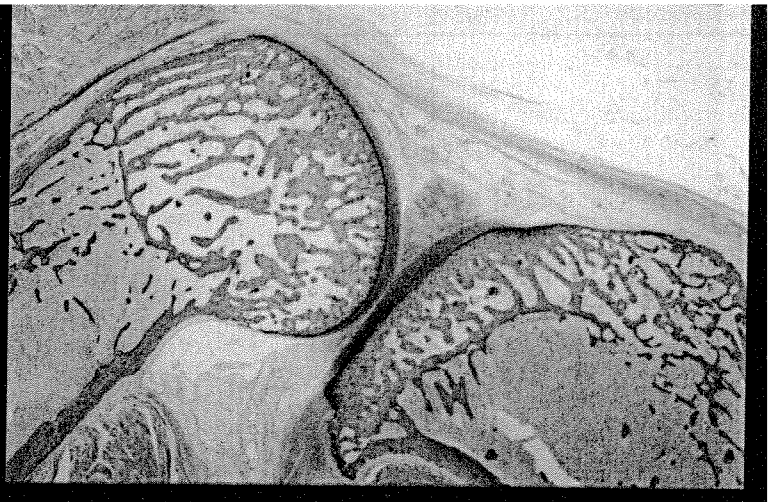

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SAFETY AND EFFICACY OF FERMENTATIVE HYALURONAN IN KNEE OSTEOARTHRITIS: A RETROSPECTIVE STUDY

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A retrospective survey was set up to collect safety, tolerability and efficacy data on Ostenil®, a non-chemically modified (NCM) hyaluronan (HA) of fermentative origin. 23 Swiss centres known to regularly use intra-articular (i.a.) HA to treat knee osteoarthritis (OA) were recruited. This survey was monitored by an independent CRO. Investigators were provided case report forms (CRFs) and asked to record all available data on knee OA patients treated with i.a. HA within the last 15 months. No selection was made regarding tolerability, efficacy and joints treated. A separate CRF was completed for each treatment cycle. Some patients' records also contained data on other HA formulations which were collected for comparison. Data on 467 patients were obtained of which 436 had symptomatic OA and received one or more i.a. injections of HA into one or both knees. Synvisc®, a chemically modified (CM), cross-linked HA of avian origin, and Ostenil were the main products used. A total of 2022 i.a injections were made: 1753 with Ostenil (86.7%) and 264 with Synvisc (13.1%). Other formulations were used in 0.2% of the cases, but were not included in the evaluation.
Investigators rated global efficacy as "good" to "moderate" in 92.3% of the Ostenil cases and 79% of the Synvisc cases, and "poor" or "insufficient" in 7.7% and 21% of the cases respectively. The incidence of adverse device events (ADE) and events classified as at least probably related to study treatment (adverse device reactions - ADR) were significantly greater with Synvisc than with Ostenil [Synvisc: ADE 7.7%, ADR 5.1%; Ostenil ADE 2.1%, ADR 0.7% of all injections ($p<0.0001$ for both ADEs and ADRs)]. ADRs such as inflammatory reactions were more frequent with Synvisc (swelling 6.5%; inflammation 8.7%) than with Ostenil (swelling 1.1%; inflammation 0.2%). The incidence of ADRs increased after the first injection of Synvisc: 4.3%, 5.7% and 6.3% after the 1st , 2nd and 3rd injections respectively compared to 0.6%, 1.1%, 0.7% for Ostenil injections. ADRs were found in 2.8% of Ostenil versus 20.8% of Synvisc patients ($p<0.0001$) and their severity was greater with Synvisc ($p=0.03$). This retrospective study indicates that Ostenil® is a safe and effective therapy for knee OA and supports previously published data indicating that i.a. injection of chemically modified cross-linked hyaluronan of avian origin (Synvisc®) is associated with a higher incidence of adverse device reactions.