AdV positive and negative groups was not observed(cut-off: 2 log10, 2.3 log10 copies/mL), but the overall survival HR was significantly higher in AdV positive group. In the single-arm studies, the mortality was 37.5 % (0 ~ 100 %) and maximum AdV viral load was 5 log10 (< 2.7 log10 ~ 8.6 log10) copies/mL; the AdV-related mortality was 25 % (0 ~ 100 %) and maximum AdV viral load was 7 log10 (3 log10 ~ 10.8 log10) copies/mL. **CONCLUSIONS:** By from current data, since a correlation between the group of high dose(7 log10 copies/mL over) of AdV and high mortality and hazard ratio, the monitoring of the trend of AdV viral load is likely to be useful in checking the patient's health and making clinical decisions. Therefore, AdV qPCR is a valuable technique for the diagnosis and quantitative monitoring of AdV infection in patients with or suspected of AdV infection.

PMD20

COMPARATIVE STUDY OF SPINE ANTERIOR LUMBAR INTERBODY FUSION DEVICES

Corso KA[1], Etter K[2], Lerner J[2], Menzie AM[3], Bhattacharyya SK[1], Pracyk JB[4]
[1]*Johnson & Johnson, New Brunswick, NJ, USA,* [2]*Johnson & Johnson Medical Devices, Raynham, MA, USA,* [3]*DePuy Synthes, Inc., Raynham, MA, USA,* [4]*Johnson & Johnson, Raynham, MA, USA*

OBJECTIVES: Patients may undergo anterior lumbar interbody fusion (ALIF) for treatment of degenerative disc disease, which can include the use of standalone cage devices to promote fusion across the disk space. During ALIFs with standalone devices, the surgeon may choose to additionally perform posterior fixation. To understand surgeon preferences during ALIF procedures, this study compared the rate of patients receiving fixation concurrent with ALIF of standalone cages. **METHODS:** Patients who underwent ALIF of 2-3 vertebrae were identified in the Premier Healthcare Database using ICD-9/10 codes, 2010-2016. The cohort was categorized by cage: SYNFIX® LR System (DePuy Synthes, Raynham, MA) versus a group of comparator cages (non-SYNFIX). Patient, provider, hospital characteristics were collected. Patient outcomes evaluated were percent of fixation concurrent with ALIF, hospital costs, and operation room time (ORT). Logistic regression and generalized estimating equations were used to adjust outcomes. **RESULTS:** Of the 2,238 patients identified, 51.2% received SYNFIX® LR. Patients with SYNFIX® LR were younger (mean (SD), 47.9 (13.1) vs. 50.6 (12.1)), and more often male 47.1% vs. 43.7%; rates of diabetes (10.4% vs. 11.5%) and hypertension (37.3% vs. 42.0%), SYNFIX® LR vs. non-SYNFIX, were comparable. Procedures with SYNFIX® LR occurred more often at teaching hospitals (50.0% vs. 20.2%), but a similar frequency in urban hospitals (89.2% vs. 95.0%). SYNFIX® LR had a statistically significant lower odds of fixation, odds ratio, 0.75 (95% Confidence Interval (CI) 0.567, 0.996; p-value = 0.047). Overall procedure costs and ORT differences were not statistically significant, but mean values were lower for SYNFIX® LR: $31,839 (95% CI: $28,999-$34,957) vs. $33,694 ($30,565-$37,143); ORT 165.7 (157.9-173.9) vs. 176.6 (168.8-184.9) minutes. **CONCLUSIONS:** In patients treated with SYNFIX® LR vs. Non-SYNFIX, there was a statistically significant 25% reduction in fixation at the time of ALIF, with lower trends of overall procedure costs and ORT that were not statistically significant.

PMD21

PRESSURE INJURIES IN PATIENTS WITH URINARY INCONTINENCE: EFFICACY OF REGENERA, A NEW MEDICAL DEVICE TESTED AT THE OSPEDALE MAGGIORE IN NOVARA

Iorio A[1], Arreni A[2], Bottosso S[2], Lanati EP[1]
[1]*MA Provider Srl, Milano, Italy,* [2]*Azienda Ospedaliero-Universitaria Maggiore della Carità di Novara, Novara, Italy*

OBJECTIVES: The aim of this study was to evaluate the efficacy of Regenera, a medicated absorbent pad containing ozonised solution, in patients with urinary incontinence and pressure injuries (superficial lesions, stage 1 and 2). **METHODS:** A randomized, controlled, 1:1 parallel-arms clinical trial was performed enrolling patients with urinary incontinence and superficial pressure injuries (PIs), hospitalized at the Internal Medicine Unit of Ospedale Maggiore in Novara, during the period December 2016-December 2017. The primary endpoint was the recovery rate per treatment group within 10 days from the hospitalization date. A subanalysis for different ranges in the length of hospital stay was also performed. **RESULTS:** 124 patients were enrolled. 63 randomly assigned to the Regenera arm and 61 to the standard protocol arm (mean age 82,2). Patients treated with Regenera showed a higher recovery rate compared to the control arm (55% vs 29% patients respectively). In the subanalysis by range (1-4 days, 5-9 days and > 10 days) of hospital stay, the recovery rate in the Regenera group compared to control arm was 40% vs 0%, 57% vs 34%, 73% vs 42%. Regarding the overall duration of the hospitalisations, no significant differences between the two arms were observed. **CONCLUSIONS:** This study has showed that innovative devices such as Regenera may play an important role in the management of the fragile elderly population, often affected by PIs in case of hospitalization. Further analysis is needed to assess implications for patient in terms of quality of life and potential economic impact from the NHS perspective.

PMD22

THE EFFECTIVENESS OF ELECTRONIC LARYNX FOR SPEECH REHABILITATION OF LARINGECTOMIZED PATIENTS: A REVIEW OF THE LITERATURE

Biz AN[1], Santos M[2], Senna K[1]
[1]*Instituto Nacional de Cardiologia, Rio de Janeiro, Brazil,* [2]*Brazilian Ministry Of Health, Rio de Janeiro, Brazil*

OBJECTIVES: The objective of this study was to evaluate the scientific evidence currently available about the efficacy and safety of the electronic larynx in speech rehabilitation of patients with larynx cancer after total laryngectomy. **METHODS:** Medline and Embase were searched for studies that assessed the use of electronic larynx compared to tracheoesophageal prosthesis, esophageal voice and/or control group, using quality of life and/or auditory-perceptual outcomes. Search strategies combined descriptors and free terms for the technology and disease under analysis. References obtained were evaluated in two stages, by titles and abstracts and in full text. Articles published in English, Spanish or Portuguese were included. No restrictions were made on the type of study. Evidence and recommendations were classified according to the GRADE recommendation. **RESULTS:** After elimination of duplicates, 1,232 references were obtained, 142 were selected for evaluation in full text, and 14 studies for data extraction. Given the number and diversity of methodologies and outcomes used by those studies, only outcomes related to quality of life (V-RQOL, VHI, QLQ-C30) and perceptual (speech intelligibility and acceptability) were selected, resulting in 6 articles being included in the final analysis. In general, the results did not point to a better quality of life perceived by the group of patients using electronic larynx in relation to the other groups, nor to its better performance in perceptive terms. The quality of the evidence was classified as of very low quality. **CONCLUSIONS:** Almost all the studies included in the analysis were cross-sectional and had a very small sample, which makes impracticable to infer decisive conclusions regarding the better performance of one of the technologies to the detriment of others, whether in quality of life, voice intelligibility or acceptability.

PMD23

EASYPOD™ CONNECT OBSERVATIONAL STUDY (ECOS) – FRENCH CASE HISTORIES AND GROWTH OUTCOMES

Nicolino M[1], Coutant R[2], Tauber M[3], Ribault V[4], Lopez Y[5], Besserve A[5], van Hille B[6]
[1]*Hôpital Femme-Mère-Enfant, Bron cedex, France,* [2]*University Hospital of Angers, ANGERS, France,* [3]*Hôpital d'enfants, TOULOUSE, France,* [4]*Centre Hospitalier Universitaire, CAEN, France,* [5]*Merck, LYON, France,* [6]*Merck s.a.s., LYON, France*

OBJECTIVES: ECOS (a 5-year, open-label, observational study in 24 countries, started in 2010) assessed 'real-world' adherence and effects on growth outcomes of children treated for growth disorders with Saizenâ recombinant human growth hormone (r-hGH, somatropin) administered by the easypod™ electronic auto-injector device. We report an interim analysis of the final results from ECOS in France (NCT01291394). **METHODS:** Data from 202 children (mean [SD] age 9.56 [3.65] years; 54% male) were available for analysis (111 GHD, 71 SGA, 18 Turner syndrome and 2 with chronic renal failure). The majority (180 [90%]) were r-hGH naïve at baseline **RESULTS:** In the global study, the majority of patients maintained ≥80% adherence over 3 years. In France, mean treatment adherence was 81% (95% CI 79-84 [81% GHD and SGA, 83.6% TS]). Adherence was ≥80% for 180 patients (89%) at 3 months, 175 (86%) at 6 months, 145 (72%) at 1 year, 93 (46%) at 2 years and 38 (19%) at 3 years. After 1 year, r-hGH-naïve children had a median (Q1:Q3) change in height SDS of +0.45 (0.24:0.69), height velocity of 7.98 cm/year (6.80:9.13) and change in height velocity SDS of 1.89 (0.38:3.79). The Spearman's product-moment correlation for adherence rate and change in height SDS was 0.035. Median adherence rate was ≥90% and was similar in all subgroups (e.g. age, gender, pubertal stage, self/non-self-injection and regimen). Median adherence was also >90% for patients with injections 6 days/week vs. with 7 days/week. **CONCLUSIONS:** This study in France confirms the high, sustained adherence rates with the easypod™ device noted in other results from the ECOS global study. Study cases were solicited to evaluate the impact in monitoring and these show the benefits of patient monitoring using the easypod™ device to alert the physician to potential red flags (e.g. puberty and poor family support) for on-going compliance.

PMD24

ASSOCIATION BETWEEN IOL DESIGN AND INCIDENCE OF PCO AND ND:YAG CAPSULOTOMY: A RETROSPECTIVE REAL WORLD EVIDENCE STUDY IN THE UK

Dhariwal M[1], O'Boyle D[2], Bouchet C[1], Khan J[3], Venerus A[3], Muthutantri A[3]
[1]*Alcon Laboratories, Inc, Fort Worth, TX, USA,* [2]*Novartis Ireland Limited, Dublin, Ireland,* [3]*IQVIA, London, UK*

OBJECTIVES: Patients post-cataract surgery may experience abnormal proliferation of lens epithelial cells on the posterior capsule (posterior capsule opacification, PCO). Neodymium-doped yttrium aluminium garnet (Nd:YAG) laser capsulotomy is considered a safe surgical treatment for PCO, but could occasionally lead to further complications. Existing studies have reported numerous factors influencing PCO incidence including IOL material and design. In this study, real-world incidence of both PCO and Nd:YAG in the 5 years post-cataract surgery were assessed in a large UK population, including their association with IOL material. **METHODS:** Patients (≥65 years) undergoing cataract surgery with 'in-the-bag' placement of acrylic monofocal single-piece IOLs between 2010-2013 were included. Data were collected from Electronic Medical records (EMR) from 7 UK NHS Ophthalmic clinics; only IOL models used in at least 500 procedures were included. The analysis focused on the association between the IOL model and the risk of PCO and Nd:YAG. Incidence proportion of PCO and Nd:YAG at 5 years from cataract surgery was calculated for each IOL model. Pairwise comparisons were conducted between AcrySof IOLs and other IOLs using Bonferroni adjustment for multiplicity. Multivariate analyses were also conducted adjusting for known confounders. **RESULTS:** Incidence proportion of Nd:YAG at 5 years post-cataract surgery was 5.8% for AcrySof (CI 5.2%-6.4%, n=5,342); this was significantly lower than Tecnis (8.5%, CI 7.8%-9.2%, n=5,609), B&L (15.2%, CI 14.3%-16.0%, n=6,847) and Lenstec (19.3%, CI 17.9%-20.8%, n=2,964) (all P values <0.001). AcrySof IOLs also had significantly lower incidence proportion of PCO compared with the other IOLs. **CONCLUSIONS:** This real world evidence study demonstrated that hydrophobic single-piece AcrySof IOLs are associated with a significantly lower incidence of Nd:YAG capsulotomy and PCO post cataract surgery, at a long-term follow-up of five years.